Update September 2022 - change of address for sending mail to the CRPPP Secretariat

HEALTH CARE SERVICES DEPARTMENT PHARMACEUTICAL POLICY

Practical instructions for the *adjustment of product lists* in the appendix to the Royal Decree of 23 November 2021 establishing the procedures, deadlines and conditions under which the compulsory health care and benefits insurance contributes to the cost of the pharmaceutical benefits referred to in Article 34, paragraph 1, 5° a), 19°, 20° and 20bis of the Law on compulsory health care and benefits insurance, coordinated on 14 July 1994

Version 2.0

Table of Contents

1. General

Address of our offices:
INAMI-RIZIV
Secretariat of the Commission for Reimbursement of Pharmaceutical Products and Benefits
Avenue Galilée 5/01
B-1210 Brussels

Our office hours:
INAMI-RIZIV is open Monday to Friday, 9am to 12pm and 1pm to 4pm.

Closed:
- Saturdays and Sundays
- Statutory holidays
- 2 November
- 11 November
- 15 November
- from 25 December to 2 January

Christmas and New Year break:
To ensure that deadlines are met and that the quality of the Commission's discussions and decisions is maintained, the following instructions are issued by the CRPPP's Secretariat:

Please avoid submitting new files between the 2nd Friday in December and 2 January inclusive. In other words, we would ask you to submit your files no later than the 2nd Thursday in December in order to ensure that the admissibility of your file is sent within the legal deadlines.

2. Practical instructions for creating a file

All mailings/files/notifications/communications must be sent by registered mail with acknowledgement of receipt via Bpost to the following address:

INAMI
Secrétariat de la Commission de remboursement des produits et prestations pharmaceutiques
Avenue Galilée 5 bte 1
1210 Bruxelles
Belgique

If you send by Bpost, please also send an email to the corresponding address (mentioned above), with secr-far-bel@riziv.fgov.be in cc and specifying the file name in the subject and the acknowledgement of receipt number in the body of the email.

Incoming mail via Bpost is scanned and provided to INAMI-RIZIV employees digitally.

No post can be submitted directly to our offices.

Below you will the instructions for submitting a complete and admissible file that meets the requirements of the current regulations.

These instructions relate to:
- applications for admission for reimbursement
- applications to change reimbursement terms
  - change in the reimbursement terms and category
  - change in the basis of reimbursement
    - application for a price increase
    - notification of a voluntary price reduction
    - special provisions for magistral preparations
      - application for admission of a new package

    - notification of the removal of a package, the temporary interruption of the marketing of a package, or changes that may affect the basis of reimbursement
- removal requests
- revisions

Below you will the instructions for submitting a complete and admissible file that meets the requirements of the current regulations in the form of a check list.

In the "mandatory" column, you will find the items that must be in your file in accordance with the RD of 23 November 2021. These elements are detailed to ensure that the information is complete.
In the "optional" column, you will find items that are highly recommended but are not legal requirements.

These instructions do not replace the legal basis.

3. Preliminary note to applicants

A complete individual file must be submitted for each package and/or dosage of a product.

The products concerned fall under the following 3 sectors:

- Products for magistral preparations
- Medical nutrition
- Diagnostic resources and health care equipment (hereinafter "medical devices")

The classification of medical devices can be consulted on the FAMHP website: Medical devices and their accessories | FAMHP

4. Submitting the application

4.1. APPLICATION FOR ADMISSION FOR REIMBURSEMENT

4.1.1. The commitment form

A commitment must be:

- provided for any application for admission for reimbursement
- renewed each time there are the types of changes which means that the applicant who is responsible for a registered product no longer bears this responsibility;

All commitment forms MUST include the following information

ADMINISTRATIVE FILE **SEMI-ADMINISTRATIVE FILE/FILE WITH ADDED VALUE**	
	Explanations/examples
Identification of the applicant;	
Name of the company responsible for submitting the application	= Name of the company responsible for submitting the application for reimbursement = Name of the company signing the commitment
Product identification	
Product category	- Diagnostic resources and health care equipment or - Medical nutrition or - Magistral preparations
Product group	*Diagnostic resources and health care equipment* - bladder irrigation solutions - portable diffusers - cassettes - oxygen concentrators - hypertonic sodium chloride inhalation solution for the treatment of cystic fibrosis - blood pressure monitors - glucose meter - lancet holder - test strips - lancets - self-catheterization catheters - active dressings
	Medical nutrition
	Magistral preparations - Active substance - Excipient - Ready-made medicinal product - Passive dressing

Product name	= Full name of the product = the one that will be published *E.g.*: Melolin
Packaging	Full description of the packaging of the product concerned → will be published next to the product name *E.g.*: 10x(5x5cm)
Name of the company that places the product on the market	= name of the company that will be published next to the product name → may be different from the company that signs the commitment (NB: for raw materials for magistral preparations, the name of the company is not published)
Composition	Complete product composition *E.g.*: Dalibour Water zinc sulfate 25.5 mg/ml copper sulfate 7.65 mg/ml water ad 100mL If the composition is not applicable → complete the "Not applicable" box *E.g.*: OMRON blood pressure monitor
ATC Code	For medical nutrition and diagnostic resources and health care equipment: this is not applicable → complete the "Not applicable" box For products for magistral preparations that do not have an ATC code: this is not applicable → complete "Not applicable" box
EU Classification	To be completed for diagnostic resources and health care equipment as well as passive dressings. For other products: this is not applicable → complete the "Not applicable" box
Commitment	Complete - The surnames and first names of the person responsible for the application - The company address - The "title" of the person responsible for the application
	Tick the following boxes: - He/she declares - He/she agrees - He/she knows (They know)
	Complete the following: Signed at ....., on ..... Surname: ……. First name(s): ..... Address: ……. …….
	Tick the box "Read and approved"
	Sign the commitment

4.1.2. The content of the file

When you submit your application, you must indicate which file type it is:

- "Administrative" type application
- "Semi-administrative" type application
- Application with added value

As a reminder:
"*administrative file*", any application for admission for reimbursement relating to an extension of the range of products/benefits that are already reimbursable without any therapeutic added value and without any budgetary impact: addition of a product identical to those already reimbursable, addition of a new flavour;

"*semi-administrative file*", any application for admission for reimbursement relating to an extension of a product/benefit range that is already reimbursable without any therapeutic added value and without any budgetary impact: other packaging, other pharmaceutical form;

"*added-value file*", any application for reimbursement relating to a product/benefit claiming a demonstrated therapeutic and/or social added value compared to existing alternatives.

ADMINISTRATIVE FILE TYPE				
	Diagnostic resources/ health care equipment - Medical nutrition		**Products for magistral preparations**	
Elements of the file	Mandatory	Optional	Mandatory	Optional
Product identification				
Full product name	X		X	
Synonyms				X
Pharmaceutical form		X	X	
Packaging → the packaging is described using the following elements:				
- quantity	X		X	
- volume/weight + unit or - dimensions + unit or - dosage	X		X	
Product reference number (for self-catheterization catheters only)		X		
Medication status "orphan"		X		X
Product status "imported"		X		X
Reason for the application				
Therapeutic value	X		X	
Consideration in the medical practice according to therapeutic and social needs	X		X	
Reimbursement conditions - Royal Decree of 18 April 2017 setting out the conditions under which the compulsory health care and benefits insurance contributes to the cost of self-catheterization at the beneficiary's home Or - Royal Decree of 23 March 2019 implementing Article 37, § 16bis, paragraph 1, 3°, and paragraph 4, of the Law on Compulsory health care and benefits insurance, coordinated on 14 July 1994, with regard to active dressings Or - Royal Decree of 23 November 2021 establishing the procedures, deadlines and conditions under which the compulsory health care and benefits insurance contributes to the cost of the pharmaceutical benefits referred to in Article 34, paragraph 1, 5° a), 19°, 20° and 20bis of the Law on Compulsory health care and benefits insurance, coordinated on 14 July 1994 - Part X, Title X (where applicable:§), Chapter X (where applicable:§), Section X, Subsection → **specify the "Part/Title/Chapter/Section/Subsection/§" concerned**	X		X	
Ex-factory price, selling price to the pharmacist and retail price, proposed basis of reimbursement and reason				
Ex-factory price	X		X	
Selling price to the pharmacist (ex. VAT) Except for blood pressure monitors - glucose meters - test strips - lancets → Price to the pharmacist (incl. VAT)	X		X	
BEBAT (for blood pressure and blood glucose meters only)	X			
RECUPEL (for blood pressure and blood glucose meters only)	X			

VAT	X		X	
Retail price (inc. VAT)	X			
Basis of reimbursement/flat rate/maximum amount proposed and reason	X		X	
Budgetary impact				
Evidence of zero budgetary impact	X		X	
Estimated quantities sold in Belgium			X	
Attached documents				
Copy of the declaration of compliance with Directive 93/42/EEC or Regulation (EU) 2017/745 for medical devices	X			
Copy of the declaration of compliance with Directive 98/79/EC or Regulation (EU) 2017/746 for in vitro diagnostic medical devices	X			
Copy of the EC certificate for non-class 1 medical devices and for sterile class 1 medical devices	X			
Copy of the notification file to the Directorate General for Animals, Plants and Food of the Federal Public Service Health, Food Chain Safety and Environment **and** acknowledgement of receipt *with the notification number* for food for special medical purposes	X			
If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: copy of the notification for placing on the market to the Federal Agency for Medicines and Health Products **and** acknowledgement of receipt for class 1 medical devices and for in vitro diagnostic medical devices	X			
Reproduction of the labelling/packaging of the product	X			
Dosage	X			
Indications for which the product is used	X			
Patient information leaflet		X		
If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: copy of the notification for placing on the market to the Federal Agency for Medicines and Health Products for passive dressings **and** acknowledgement of receipt			X	
Authorisation for the placing on the market **or** authorisation for the placing on the market of sterile products			X	
Authorisation number (except for flavours)			X	
Quality standards				
Quality standards set by the Minister		X		

SEMI-ADMINISTRATIVE and FILE WITH ADDED VALUE FILE TYPE				
	Diagnostic resources/ health care equipment - Medical nutrition		**Products for magistral preparations**	
Elements of the file	Mandatory	Optional	Mandatory	Optional
Product identification				
Full product name	X		X	
Synonyms				X
Pharmaceutical form		X	X	
Packaging → the packaging is described using the following elements:				
- quantity	X		X	
- volume/weight + unit or - dimensions + unit or - dosage	X		X	
Product reference number (for self-catheterization catheters only)		X		
Medication status "orphan"		X		X
Product status "imported"		X		X
Reason for the application				
Therapeutic value	X		X	
Added value (for files with added value only)	X		X	
Usefulness - safety (adverse effects)	X		X	
Applicability (contraindications) - comfort	X		X	
Consideration in the medical practice according to therapeutic and social needs	X		X	
Epidemiological elements (incidence, prevalence...)		X	X	
Product protected by a patent or not			X	
Budgetary impact				
Target group	X		X	
Estimated number of beneficiaries	X		X	
Presumed duration of treatment	X		X	
Frequency of administration in disorders for which the product can be administered	X		X	
Estimated volume		X		X
Comparison with reimbursable alternatives		X		
Cost of treatment/Budgetary impact on an annual basis	X		X	
Ratio of insurance cost to therapeutic value		X		X
Reasoned proposal of reimbursement conditions based on admission criteria				
Proposed reimbursement conditions - Royal Decree of 18 April 2017 setting out the conditions under which the compulsory health care and benefits insurance contributes to the cost of self-catheterization at the beneficiary's home Or	X		X	

- Royal Decree of 23 March 2019 implementing Article 37, § 16bis, paragraph 1, 3°, and paragraph 4, of the Law on Compulsory health care and benefits insurance, coordinated on 14 July 1994, with regard to active dressings Or - Royal Decree of 23 November 2021 establishing the procedures, deadlines and conditions under which the compulsory health care and benefits insurance contributes to the cost of the pharmaceutical benefits referred to in Article 34, paragraph 1, 5° a), 19°, 20° and 20bis of the Law on Compulsory health care and benefits insurance, coordinated on 14 July 1994 - Part X, Title X (where applicable:§), Chapter X (where applicable:§), Section X, Subsection → **specify the "Part/Title/Chapter/Section/Subsection/§" concerned** **or** → **propose a new "Part/Title/Chapter/Section/ subsection/§"**				
Letter "M" in the "Observations" column		X		
Type of dispensing: public pharmacy/hospital pharmacy/supplier	X		X	
Reimbursement category		X		X
Attached documents				
Copy of the declaration of compliance with Directive 93/42/EEC or Regulation (EU) 2017/745 for medical devices	X			
Copy of the declaration of compliance with Directive 98/79/EC or Regulation (EU) 2017/746 for in vitro diagnostic medical devices	X			
Copy of the EC certificate for non-class 1 medical devices and for sterile class 1 medical devices	X			
Copy of the notification file to the Directorate General for Animals, Plants and Food of the Federal Public Service Health, Food Chain Safety and Environment **and** acknowledgement of receipt *with the notification number* for food for special medical purposes	X			
If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: copy of the notification for placing on the market to the Federal Agency for Medicines and Health Products **and** acknowledgement of receipt for class 1 medical devices and for in vitro diagnostic medical devices	X			
Reproduction of the labelling/packaging of the product	X			
Dosage	X			
Indications for which the product is used	X			
Patient information leaflet		X		
If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: copy of the notification for placing on the market to the Federal Agency for Medicines and Health Products for passive dressings **and** acknowledgement of receipt			X	
Authorisation for the placing on the market **or** authorisation for the placing on the market of sterile products			X	
Authorisation number (except for flavours)			X	
Information on the label, the description of the primary packaging and any secondary packaging			X	

Quality standards				
Quality standards set by the Minister		X		
Ex-factory price, selling price to the pharmacist and retail price, proposed basis of reimbursement and reason				
Ex-factory price	X		X	
Selling price to the pharmacist (ex. VAT) Except for blood pressure monitors - glucose meters - test strips - lancets → Price to the pharmacist (incl. VAT)	X		X	
BEBAT (for blood pressure and blood glucose meters only)	X			
RECUPEL (for blood pressure and blood glucose meters only)	X			
VAT	X		X	
Retail price (inc. VAT)	X			
Basis of reimbursement/flat rate/maximum amount proposed and reason	X		X	
Directions for use	X			
Most recently published clinical studies relating to existing experience with the product	X		X	

4.2. APPLICATION TO CHANGE REIMBURSEMENT TERMS

4.2.1. Reimbursement conditions/reimbursement category

Diagnostic resources/health care equipment - Medical nutrition - Products for magistral preparations		
Elements of the file	Mandatory	Optional
Product identification		
Full product name	X	
Pharmaceutical form		X
Packaging → the packaging is described using the following elements:		
- quantity	X	
- volume/weight + unit or - dimensions + unit or - dosage	X	
Medication status "orphan"		X
Product status "imported"		X
Reasoned proposal of new reimbursement conditions or the new reimbursement category based on admission criteria		
Proposed new reimbursement conditions/new reimbursement category - Royal Decree of 18 April 2017 setting out the conditions under which the compulsory health care and benefits insurance contributes to the cost of self-catheterization at the beneficiary's home → **propose new reimbursement conditions or a new reimbursement category** Or - Royal Decree of 23 March 2019 implementing Article 37, § 16bis, paragraph 1, 3°, and paragraph 4, of the Law on Compulsory health care and benefits insurance, coordinated on 14 July 1994, with regard to active dressings → **propose new reimbursement conditions or a new reimbursement category**	X	

Or - Royal Decree of 23 November 2021 establishing the procedures, deadlines and conditions under which the compulsory health care and benefits insurance contributes to the cost of the pharmaceutical benefits referred to in Article 34, paragraph 1, 5° a), 19°, 20° and 20bis of the Law on Compulsory health care and benefits insurance, coordinated on 14 July 1994 - Part X, Title X (where applicable:§), Chapter X (where applicable:§), Section X, Subsection → **propose new reimbursement conditions or a new reimbursement category**		
Letter "M" in the "Observations" column		X
Type of dispensing: public pharmacy/hospital pharmacy/supplier	X	
Reimbursement category		X
Therapeutic value	X	
Added value		X
Epidemiological elements (incidence, prevalence...)		X
Consideration of the product in the medical practice according to therapeutic and social needs	X	
Budgetary impact		
Target group	X	
Estimated number of beneficiaries	X	
Presumed duration of treatment	X	
Frequency of administration in disorders for which the product can be administered	X	
Estimated volume	X	
Comparison with reimbursable therapeutic alternatives	X	
Cost of treatment/Budgetary impact on an annual basis	X	
Ratio of insurance cost to therapeutic value	X	
Attached documents		
Copy of the declaration of compliance with Directive 93/42/EEC or Regulation (EU) 2017/745 for medical devices	X	
Copy of the declaration of compliance with Directive 98/79/EC or Regulation (EU) 2017/746 for in vitro diagnostic medical devices	X	
Copy of the EC certificate for non-class 1 medical devices and for sterile class 1 medical devices	X	
Copy of the notification file to the Directorate General for Animals, Plants and Food of the Federal Public Service Health, Food Chain Safety and Environment **and** acknowledgement of receipt *with the notification number* for food for special medical purposes	X	
If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: copy of the notification for placing on the market to the Federal Agency for Medicines and Health Products **and** acknowledgement of receipt for class 1 medical devices and for in vitro diagnostic medical devices	X	
Reproduction of labelling/packaging for medical devices and medical nutrition	X	
Information on the label, the description of the primary packaging and any secondary packaging with regards products for magistral preparations	X	
Indications	X	
Dosage	X	
Patient information leaflet		X

If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: copy of the notification for placing on the market to the Federal Agency for Medicines and Health Products **and** acknowledgement of receipt for passive dressings	X	
Authorisation for the placing on the market of products in the context of magistral preparations **or** authorisation of placing on the market of sterile products in the context of magistral preparations	X	
Authorisation number (except for flavours)	X	
Clinical studies		
Most recently published clinical studies relating to existing experience with the product and concerning the proposed change to the reimbursement terms	X	

4.2.2. Basis of reimbursement

4.2.2.1. Price increase for a reimbursable product or one or more package(s) of a reimbursable product

Diagnostic resources/health care equipment - Medical nutrition - Products for magistral preparations		
Elements of the file	Mandatory	Optional
Product identification		
Full product name	X	
Pharmaceutical form		X
Packaging → the packaging is described using the following elements:		
- quantity	X	
- volume/weight + unit or - dimensions + unit or - dosage	X	
Medication status "orphan"		X
New price structure		
Ex-factory price	X	
Selling price to the pharmacist (ex. VAT) Except for blood pressure monitors - glucose meters - test strips - lancets → Price to the pharmacist (incl. VAT)	X	
BEBAT (for blood pressure and blood glucose meters only)	X	
RECUPEL (for blood pressure and blood glucose meters only)	X	
VAT	X	
Retail price (inc. VAT)	X	
Budgetary impact		
Target group	X	
Estimated number of beneficiaries	X	
Presumed duration of treatment	X	
Frequency of administration in disorders for which the product can be administered	X	
Estimated volume	X	
Cost of treatment/Budgetary impact on an annual basis	X	
Reasoned proposal for the new basis of reimbursement		
New basis of reimbursement base/flat rate/maximum amount	X	
Calculation method for the new basis of reimbursement base/flat rate/maximum amount	X	

Opinion of the Price Commission		
Opinion of the Price Commission for raw materials included in the Ministerial Order of 13 June 2014.	X	

4.2.2.2. Voluntary price reduction

Art.53. of the Royal Decree of 23 November 2021: "In the event of a reduction in the price of a reimbursable product or of one or more package(s) of a reimbursable product, the applicant must inform the Secretariat within 24 hours."

In this case, the applicant is therefore required to send a **notification** to the Secretariat of the CRPPP within 24 hours following the voluntary price reduction.

Diagnostic resources/health care equipment - Medical nutrition - Products for magistral preparations		
Elements of the **notification**	Mandatory	Optional
Product identification		
Full product name	X	
Pharmaceutical form		X
Packaging → the packaging is described using the following elements:		
- quantity	X	
- volume/weight + unit or - dimensions + unit or - dosage	X	
New price structure		
Ex-factory price	X	
Selling price to the pharmacist (ex. VAT) Except for blood pressure monitors - glucose meters - test strips - lancets → Price to the pharmacist (incl. VAT)	X	
BEBAT (for blood pressure and blood glucose meters only)	X	
RECUPEL (for blood pressure and blood glucose meters only)	X	
VAT	X	
Retail price (inc. VAT)	X	

4.2.2.3. Special provisions for products for magistral preparations

Art.54. of the Royal Decree of 23 November 2021: "Changes in the basis of reimbursement of a product for magistral preparations may also result from the following initiatives taken by the applicant":

1° the application for admission of a new package in the list
If an applicant wishes to have a new package admitted for a product which is already admitted, the application is submitted in the same way as for the admission of a semi-administrative file (point 4.1.2)
→ new application

2° the application to remove a product or package when the product or package continues to be marketed
If an applicant withdraws the packaging that is used to determine the basis of reimbursement from the market, the applicant shall notify the Secretariat three months in advance and provide the Secretariat with the expiration date of the last batch of that packaging.

→ notification to the Secretariat of the CRPPP

Products for magistral preparations	
Elements of the **notification**	Mandatory
Product identification	
Full product name	X
Pharmaceutical form	X
Packaging → the packaging is described using the following elements:	
- quantity	X
- volume/weight + unit or - dimensions + unit or - dosage	X
Expiry date of the last batch	X

3° the notification to stop temporarily placing on the market one, several or all packages of a product
If an applicant temporarily discontinues the marketing of a package that is used to determine a basis of reimbursement, the applicant shall notify the Secretariat one month in advance and inform it of the expected duration of the interruption in the marketing.

→ notification to the Secretariat of the CRPPP

Products for magistral preparations	
Elements of the **notification**	Mandatory
Product identification	
Full product name	X
Pharmaceutical form	X
Packaging → the packaging is described using the following elements:	
- quantity	X
- volume/weight + unit or - dimensions + units or - dosage	X
Duration of the marketing interruption	X

4.3. APPLICATION TO REMOVE PRODUCTS FROM THE LIST

Diagnostic resources/health care equipment - Medical nutrition - Products for magistral preparations		
Elements of the **notification**	Mandatory	Optional
Product identification		
Full product name	X	
Pharmaceutical form		X
Packaging → the packaging is described using the following elements:		
- quantity	X	
- volume/weight + unit or - dimensions + units or - dosage	X	
Reason for the application		
Reason for the removal request	X	

5. Revisions

- Diagnostic resources/health care equipment
  → the initiative for a revision may be taken by the working group, the Commission or the Minister

- Products for magistral preparations → revision every 5 years

A complete individual file must be submitted for each package/dosage of a product with the following elements:

Diagnostic resources/health care equipment - Medical nutrition - Products for magistral preparations		
Elements of the file	Mandatory	Optional
Product identification		
Full product name	X	
Pharmaceutical form		X
Packaging → the packaging is described using the following elements:		
- quantity	X	
- volume/weight + unit or - dimensions + units or - dosage	X	
Product reference number (for self-catheterization catheters only)		X
Medication status "orphan"		X
Product status "imported"		X
Price structure and volumes sold in Belgium over the last three years		
Ex-factory price	X	
Selling price to the pharmacist (ex. VAT) Except for blood pressure monitors - glucose meters - test strips - lancets → Price to the pharmacist (incl. VAT)	X	

BEBAT (for blood pressure and blood glucose meters only)	X	
RECUPEL (for blood pressure and blood glucose meters only)	X	
VAT	X	
Retail price (inc. VAT)	X	
Volumes sold in Belgium over the last three years	X	
The price structure and reimbursement conditions of the relevant product in European Union countries		
Ex-factory price		X
Selling price to the pharmacist (ex. VAT)		X
BEBAT		X
RECUPEL		X
VAT		X
Retail price (inc. VAT)		X
Reimbursement conditions in the European Union		X
A re-evaluation report to confirm or revise the reimbursement terms, together with the elements that **were agreed upon** at the time of admission onto the list (or the change in the reimbursement terms of the speciality) and the published and unpublished comparative clinical, epidemiological and health economic studies, as well as the scientific reasoning that led to this report		
Elements agreed upon at the time of the admission or change in reimbursement terms, namely:		
Therapeutic value	X	
Usefulness - safety (adverse effects)	X	
Applicability (contraindications) - comfort	X	
Consideration in the medical practice according to therapeutic and social needs	X	
Epidemiological elements (incidence, prevalence...) (in the case of diagnostic resources/health care equipment and medical nutrition)		X
Epidemiological elements (incidence, prevalence...) (in the case of raw materials for magistral preparations)	X	
Comparison with reimbursable alternatives		X
Product protected by a patent or not (only in the case of raw materials for magistral preparations)	X	
Reimbursement conditions with - the reimbursement terms - the reimbursement category - the type of dispensing: public pharmacy/hospital pharmacy/supplier - the presence/or not of the letter "M" in the "Observations" column	X	
Budget impact data with: - the target group - the estimated number of beneficiaries - the presumed duration of treatment - the frequency of administration in disorders for which the product can be administered - the cost of treatment/Budgetary impact on an annual basis - the ratio of insurance cost to therapeutic value	X	
Published and unpublished comparative clinical studies	X	
Published and unpublished comparative epidemiological studies	X	
Published and unpublished comparative health economic studies	X	
Scientific reasoning that led to this report	X	

Attached documents		
Copy of the declaration of compliance with Directive 93/42/EEC or Regulation (EU) 2017/745 for medical devices	X	
Copy of the declaration of compliance with Directive 98/79/EC or Regulation (EU) 2017/746 for in vitro diagnostic medical devices	X	
Copy of the EC certificate for non-class 1 medical devices and for sterile class 1 medical devices	X	
Copy of the notification file to the Directorate General for Animals, Plants and Food of the Federal Public Service Health, Food Chain Safety and Environment **and** the acknowledgement of receipt with *the notification number* for food for special medical purposes	X	
If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: copy of the notification for placing on the market to the Federal Agency for Medicines and Health Products **and** acknowledgement of receipt for class 1 medical devices **and** for in vitro diagnostic medical devices	X	
Reproduction of labelling/packaging for medical devices and medical nutrition	X	
Primary packaging and any secondary packaging with regards products for magistral preparations	X	
Indications	X	
Dosage	X	
Patient information leaflet		X
If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: copy of the notification for placing on the market to the Federal Agency for Medicines and Health Products **and** acknowledgement of receipt for passive dressings	X	
Authorisation for the placing on the market **or** authorisation for the placing on the market of sterile products	X	
Authorisation number (except for flavours)	X	
DDD		
DDD (defined daily dose)		X