Updated on 01.02.2024 : addition of quality standards for blood pressure monitors, glucometers and test strips (diagnostic and healthcare equipment) (M.R. of 09.01.2024 published in the B.M. on 19.01.2024)

# HEALTH CARE SERVICES DEPARTMENT PHARMACEUTICAL POLICY

## USER GUIDE: TR-FPP FRONT-OFFICE

## Procedure for submitting an application to amend the list of products 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

## +

## Active dressings

**Version 5.0**

## Table of Contents


1. General ..... 3
2. Foreword ..... 3
3. General introduction - access procedure ..... 3
4. Contact information ..... 5
   - 4.1. THE COMPANY ..... 5
   - 4.2. CONTACT PERSON(S) ..... 7
5. Creating a file ..... 10
   - 5.1. TYPES OF FILES ..... 10
   - 5.2. LIST OF CURRENT FILES ..... 10
6. Submitting the application ..... 12
   - 6.1. APPLICATION FOR ADMISSION FOR REIMBURSEMENT ..... 14
   - 6.2. APPLICATION TO CHANGE THE REIMBURSEMENT CONDITIONS AND/OR REIMBURSEMENT CATEGORY ..... 46
   - 6.3. APPLICATION FOR A PRICE INCREASE ..... 66
   - 6.4. NOTIFICATION OF A VOLUNTARY PRICE REDUCTION ..... 75
   - 6.5. REMOVAL REQUEST ..... 83
   - 6.6. NOTIFICATION OF REMOVAL OF A PACKAGE FOR A RAW MATERIAL FOR MAGISTRAL PREPARATIONS ..... 88
7. Follow-up on the request ..... 92

## 1. General

**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. Foreword

These user instructions explain how to access the application and submit a file in accordance with the requirements set out in 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.
These instructions also cover changes to the following lists:
- **Active dressings** → Royal Decree of 23 March 2019 implementing Article 37, § 16*bis*, 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

## 3. General introduction - access procedure

The web programme allowing the electronic submission of an application to the secretariat of the Commission for Reimbursement of Pharmaceutical Products and Benefits is available on the RIZIV-INAMI website, via the following link

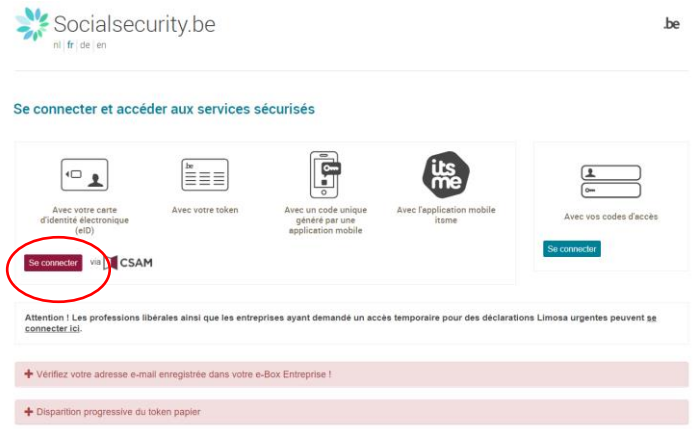
Aperçu des programmes web - INAMI (fgov.be)
→ Moyens diagnostiques, matériel de soin, nutrition médicale, produits pour préparation magistrale : Services en ligne pour l'industrie pharmaceutique

If your company name does not appear in the list of companies or for any questions about the access procedure, please contact the General Secretariat on 02/739.77.41 or send an email to the following address: crppp-ctfpv@riziv-inami.fgov.be, with secr-farbel@riziv.fgov.be in cc.

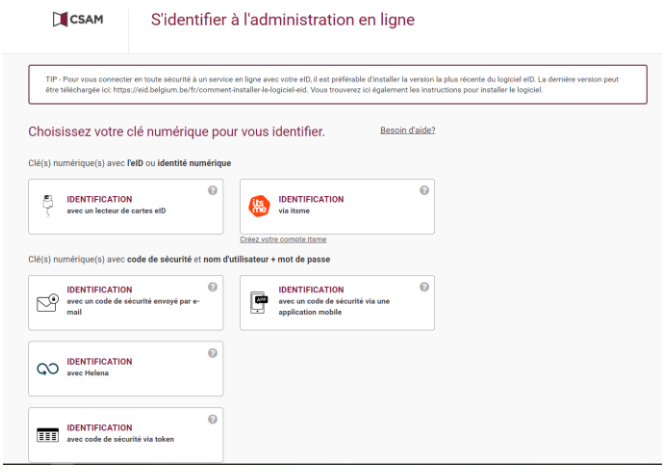
The access procedure is as follows:

1) Click "Company"

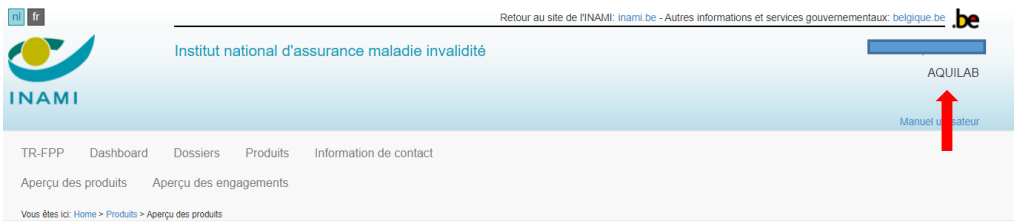
2) Click "Log on"




3) Choose your connection method:




4) The company's home page appears:



## 4. Contact information

The contacts relate to the companies and the contact persons for the files submitted to the Commission for Reimbursement of Pharmaceutical Products and Benefits (CRPPP).

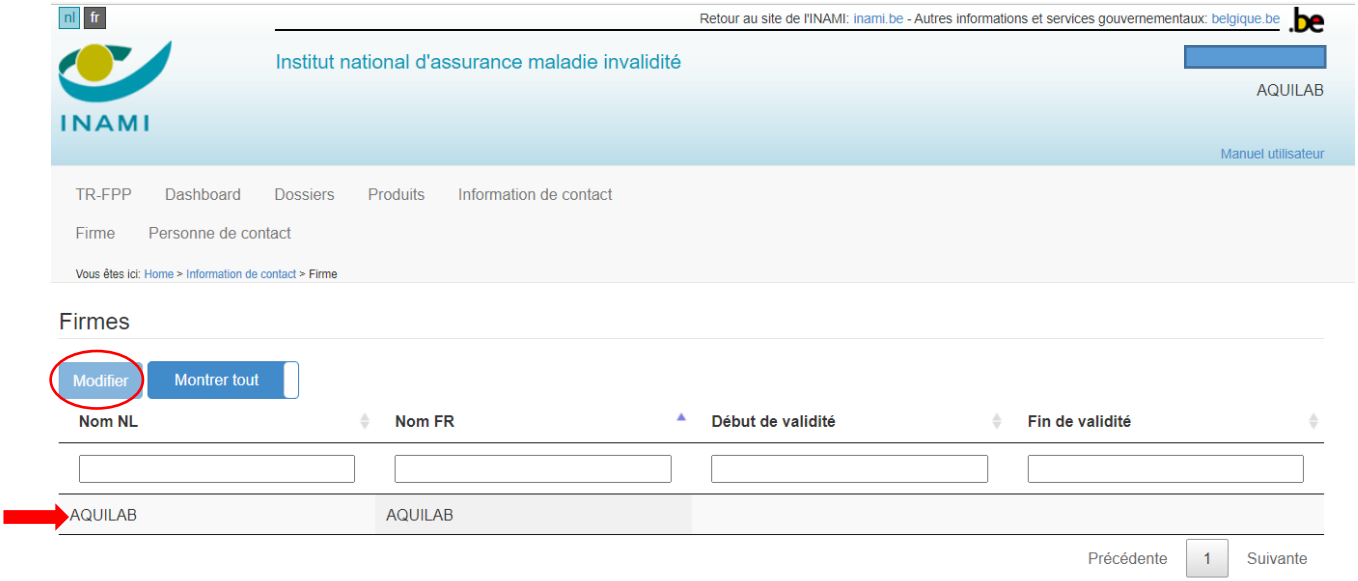
### 4.1. THE COMPANY

Update and complete your data in the system.
!! Please ensure that you complete the postal data (although this is not "mandatory").

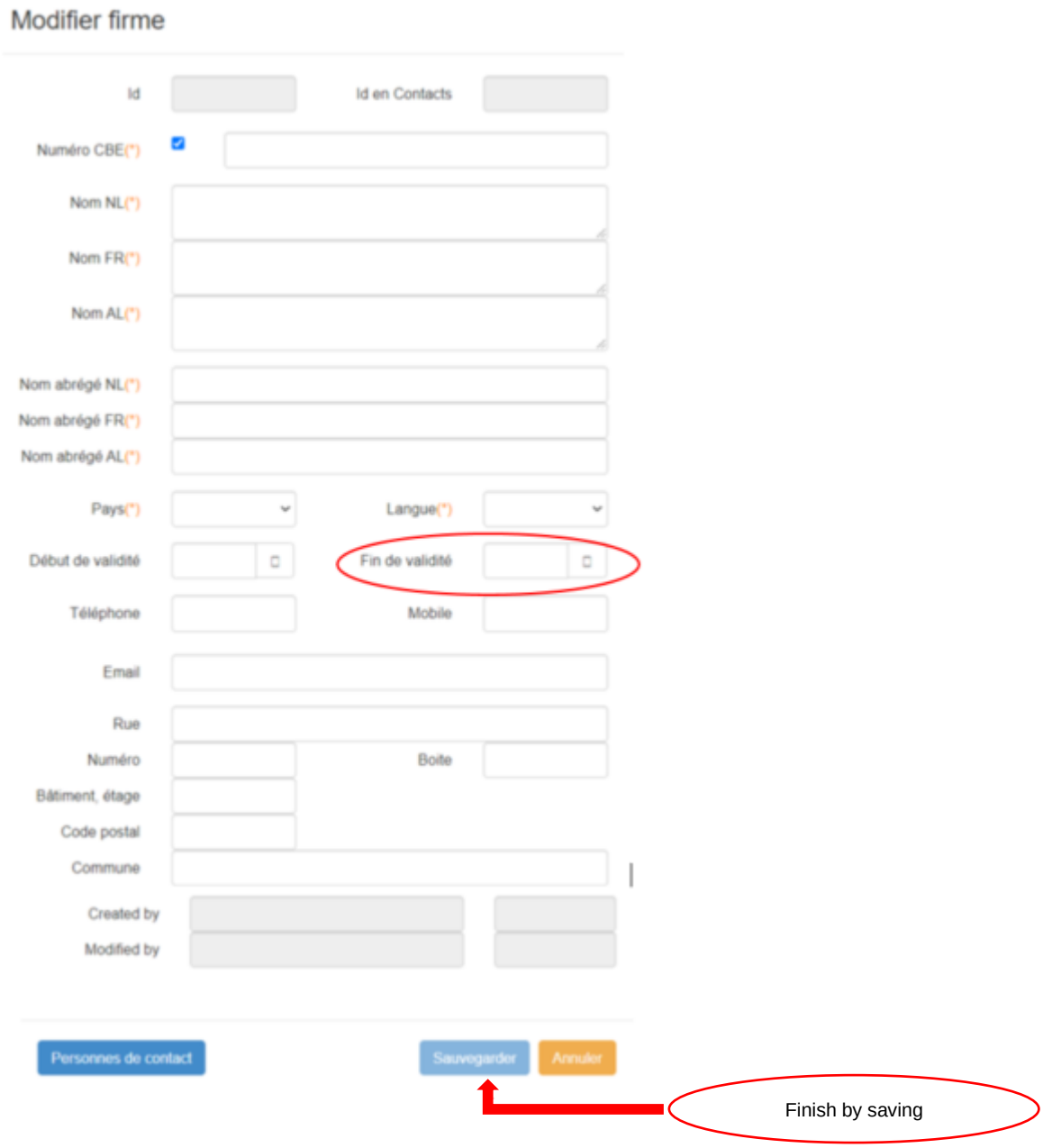
On the home page, select the "Contact information" menu

Once in "Contact Information":

→ 1°. The name of the corresponding company is displayed: click the name
→ 2°. Select the option: "Modify"




This will take you to the next form where you will be asked to add the missing data.
Mandatory data (*) is already entered.




In the same form, if your company ceases its activities, enter the validity end date for the current data using the "End of validity" field and select the appropriate date.
In this case, do not forget to take the necessary steps for the products admitted and the files in progress in accordance with the procedure provided for this purpose.

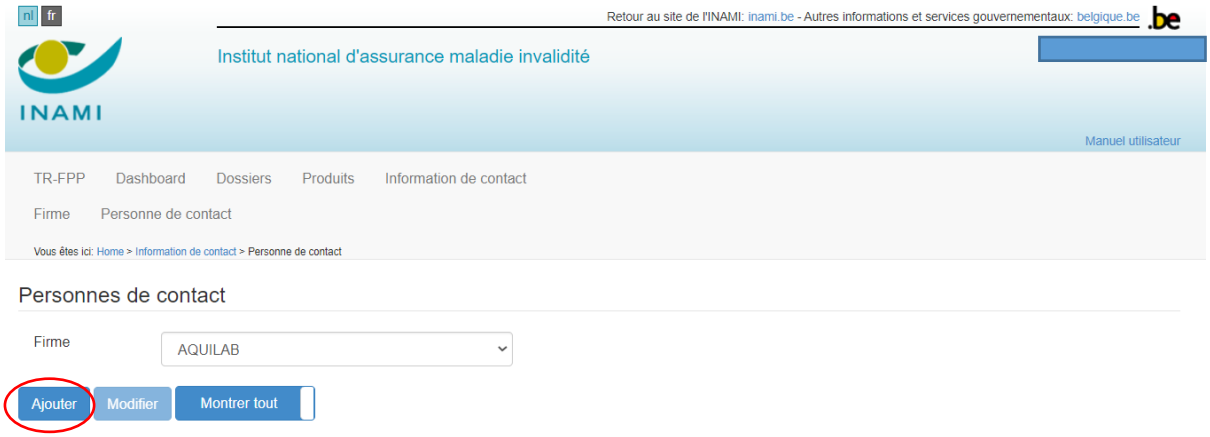
## 4.2. CONTACT PERSON(S)

As a minimum, each company must complete the data for one contact person for the files submitted to the CRPPP.

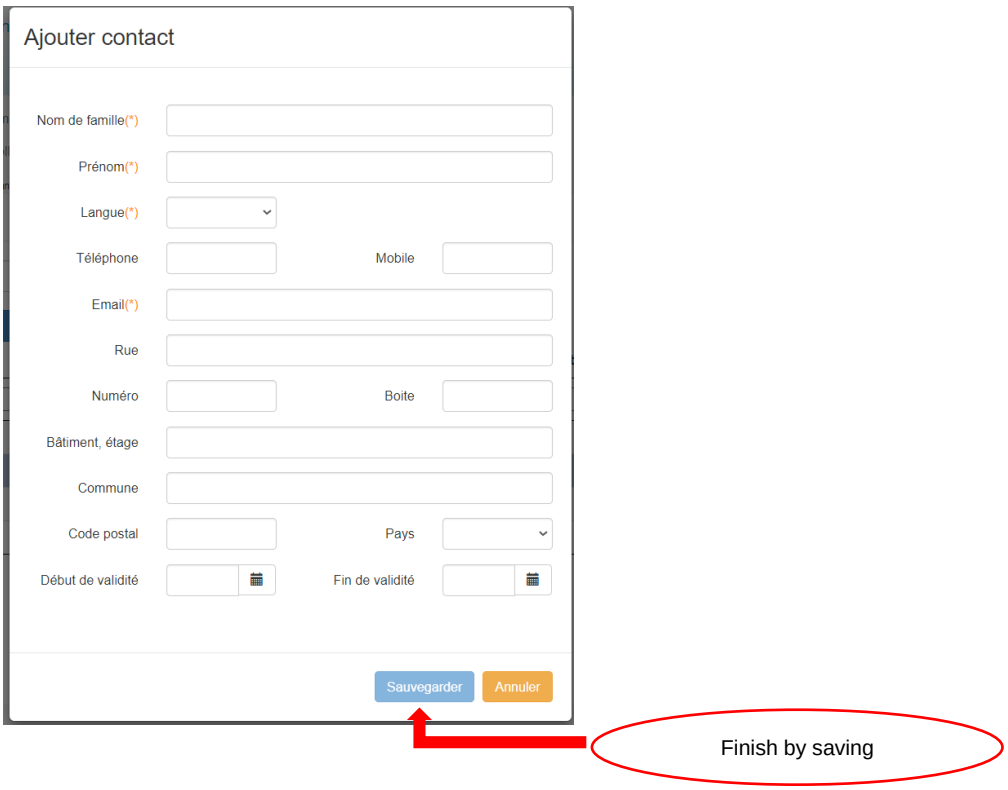
On the home page, select the "Contact information" menu

In "Contact Information": select and click: "Contact person"

In the "Contact person" menu, the name of the corresponding company is displayed: click "Add"



This will take you to the next form, where you can add the contact's identification and address data:



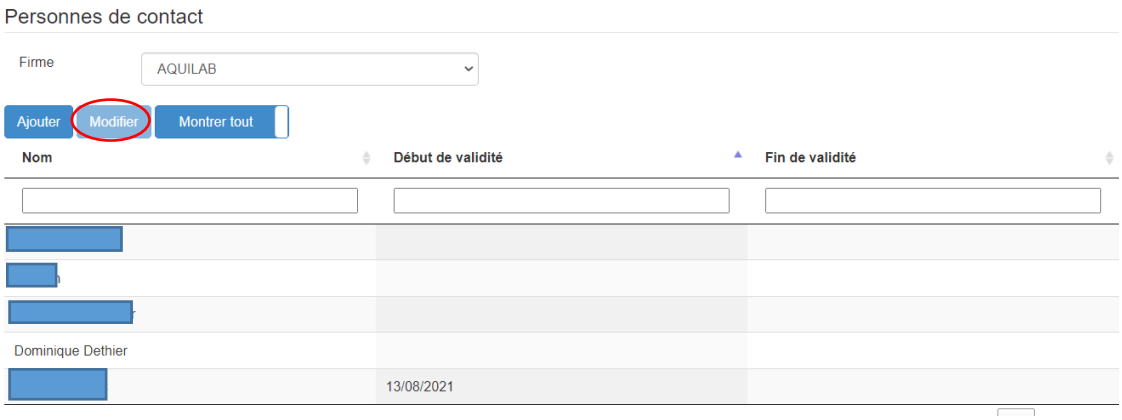

The following fields are mandatory and must be completed

| |
|---|
| Surname |
| First name |
| Language |
| Email |

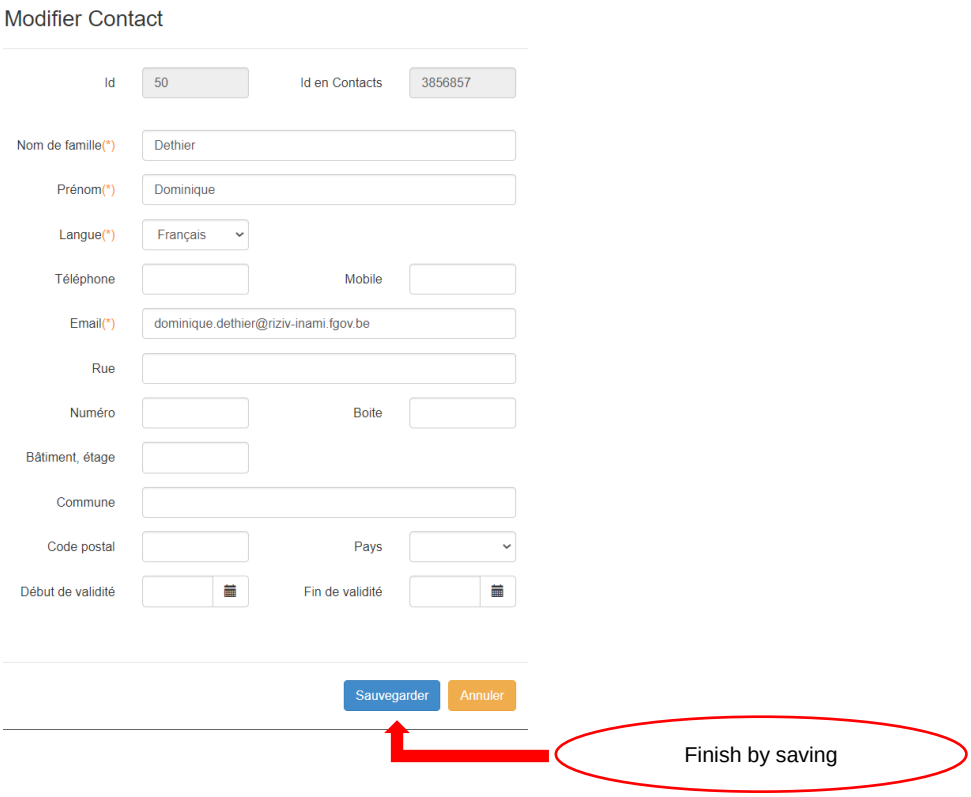
The other fields are optional but strongly recommended.

If a person is registered as a contact in a file and the person's address data is not entered, then the company's address data will be used for any further communication regarding the file.

To modify a contact person's data, select the contact whose data you want to modify from the list of contact persons for your company and click "Modify":




This will take you to the following form, where you can change the contact's identification and address data, as well as the contact's role or the "End of validity" of the person as a contact in this role:




Finish by saving

# 5. Creating a file

## 5.1. TYPES OF FILES

Below you will the instructions describing how to submit a complete and admissible file that meets the requirements of the current regulations using the tool provided to you.

These instructions relate to:

- applications for admission for reimbursement → one complete application is required per package
- 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 unavailability of a package, or changes that may affect the basis of reimbursement
- removal requests
- revisions

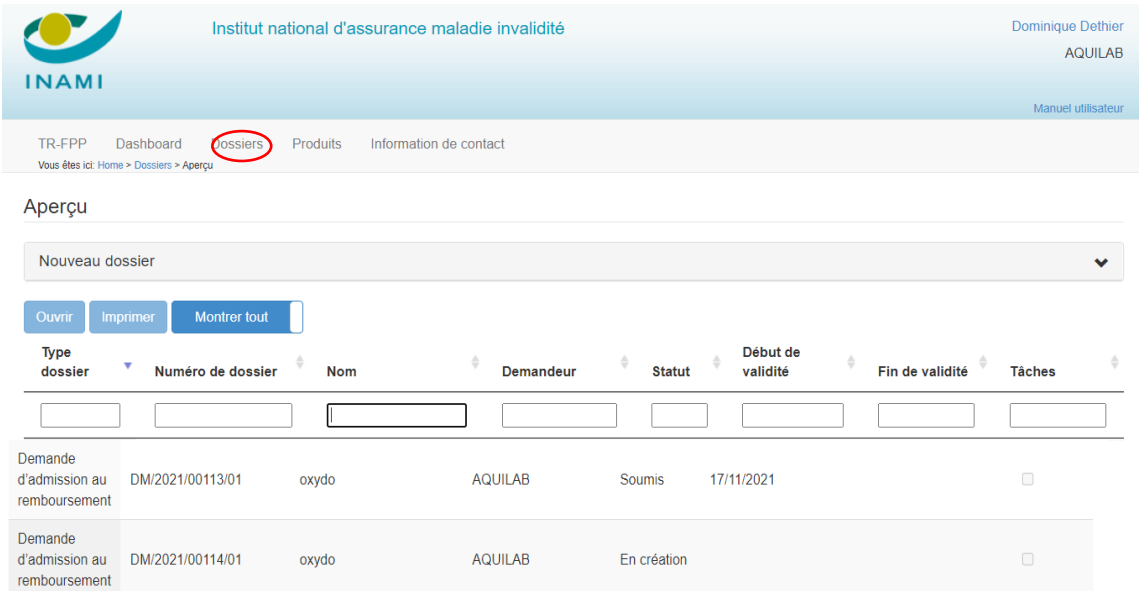
*These instructions do not replace the legal basis.*

## 5.2. LIST OF CURRENT FILES

This functionality gives you an overview of the application files submitted for your company.

From the home page, select the "Files" menu and click to see an overview of the application files submitted for your company and their status.

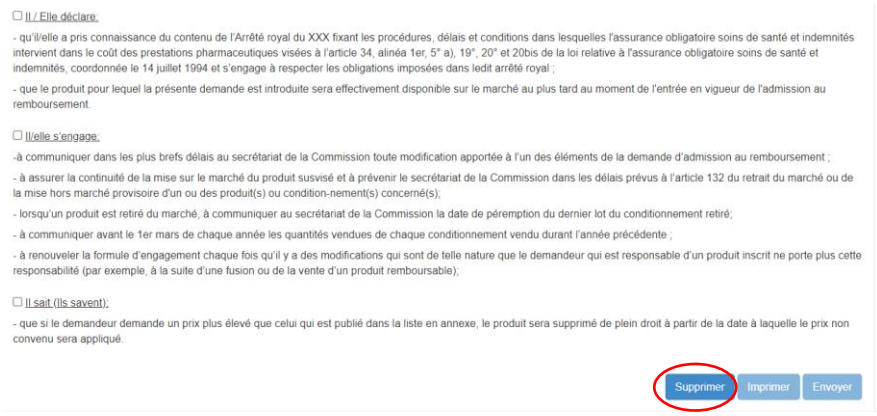
*Example:*



By entering one of the three search criteria (file type, file number, name, etc.), you can limit the number of files displayed in the table to those matching your search criteria.

Application files that are in the process of being prepared and which have not yet been sent to INAMI-RIZIV appear with the status "Creation". They can be modified by selecting the file in the table and clicking "Open". The details of the file as previously saved in the system are then displayed.

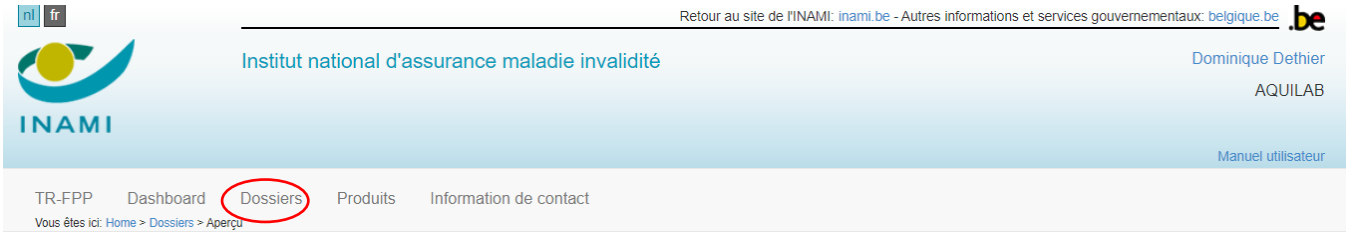
If you wish to cancel an application in progress, proceed as described above and click the "Submit" tab. At this point, you are given the option to delete the application by clicking "Delete". The application will no longer appear in the list of your current files.

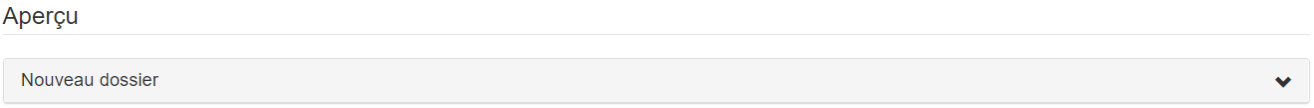



Completed files that have been sent electronically to INAMI-RIZIV appear with the status "Submitted". These files can be viewed but cannot be modified except for the contact person(s) which can be changed after submission.

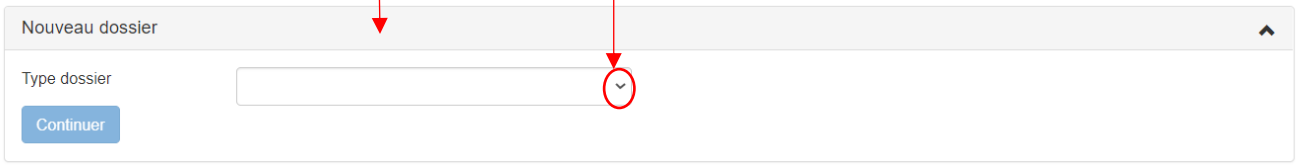
## 6. Submitting the application

From the home page, select the "Files" menu and click to see the overview that gives you the opportunity to create a new file.

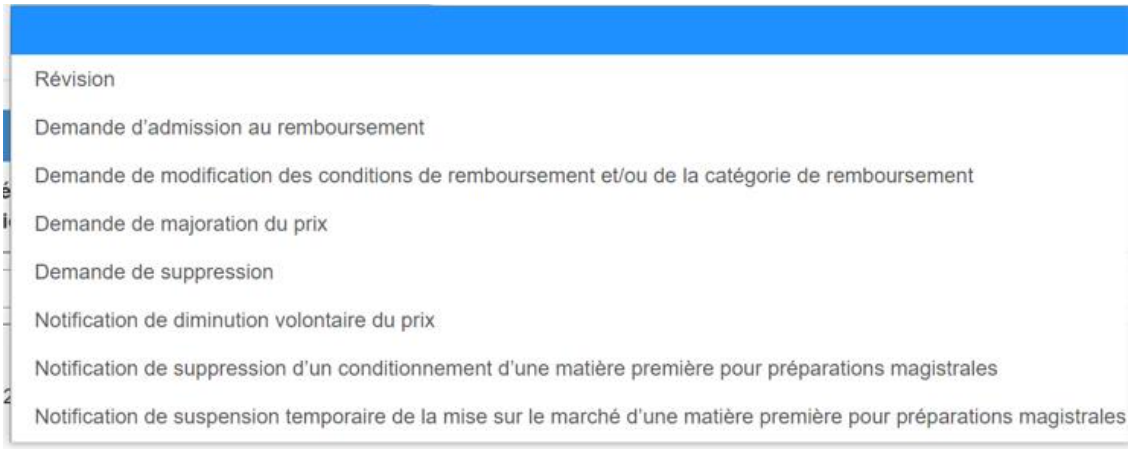


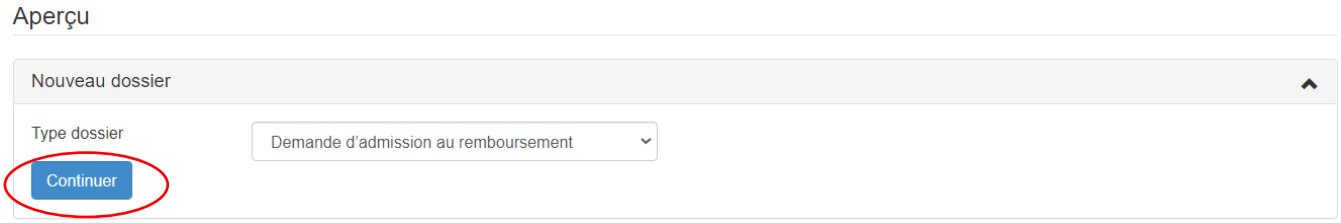

Then click the "New file" bar and choose the type of application you want to submit by clicking the "File type" drop-down menu




This drop-down menu allows you to choose the specific application type by clicking your selection.




Once you have made your choice, click "Continue".




We're going to through each "File type" option below

*PRELIMINARY REMARKS*

- A separate (complete) file must be submitted per product.

  By product, we mean a specific package and/or dosage of a product. This means that a 20-unit package and a 60-unit package of the same product, with the same dosage, are considered as two different products. Consequently, a separate form must be completed for each of these packages.

- It may be that when you want to enter a term, you cannot find it in the list of choices. If so, please report it to the following address: crppp-ctfpv@riziv-inami.fgov.be, with secr-farbel@riziv.fgov.be in cc.

  You will be notified once the list of choices has been updated.

- You can exit an application file that has been started or the application at any time. To complete an application that has been started and not submitted to INAMI-RIZIV, return to your list of applications, search for and select the application (it is listed under the "Creation" status and click "Open").

- Fields marked with an asterisk (*) are **MANDATORY**.

## 6.1. APPLICATION FOR ADMISSION FOR REIMBURSEMENT

After selecting the "Application for admission for reimbursement" file type, you access the first page of the application as follows:

You will find the following data:

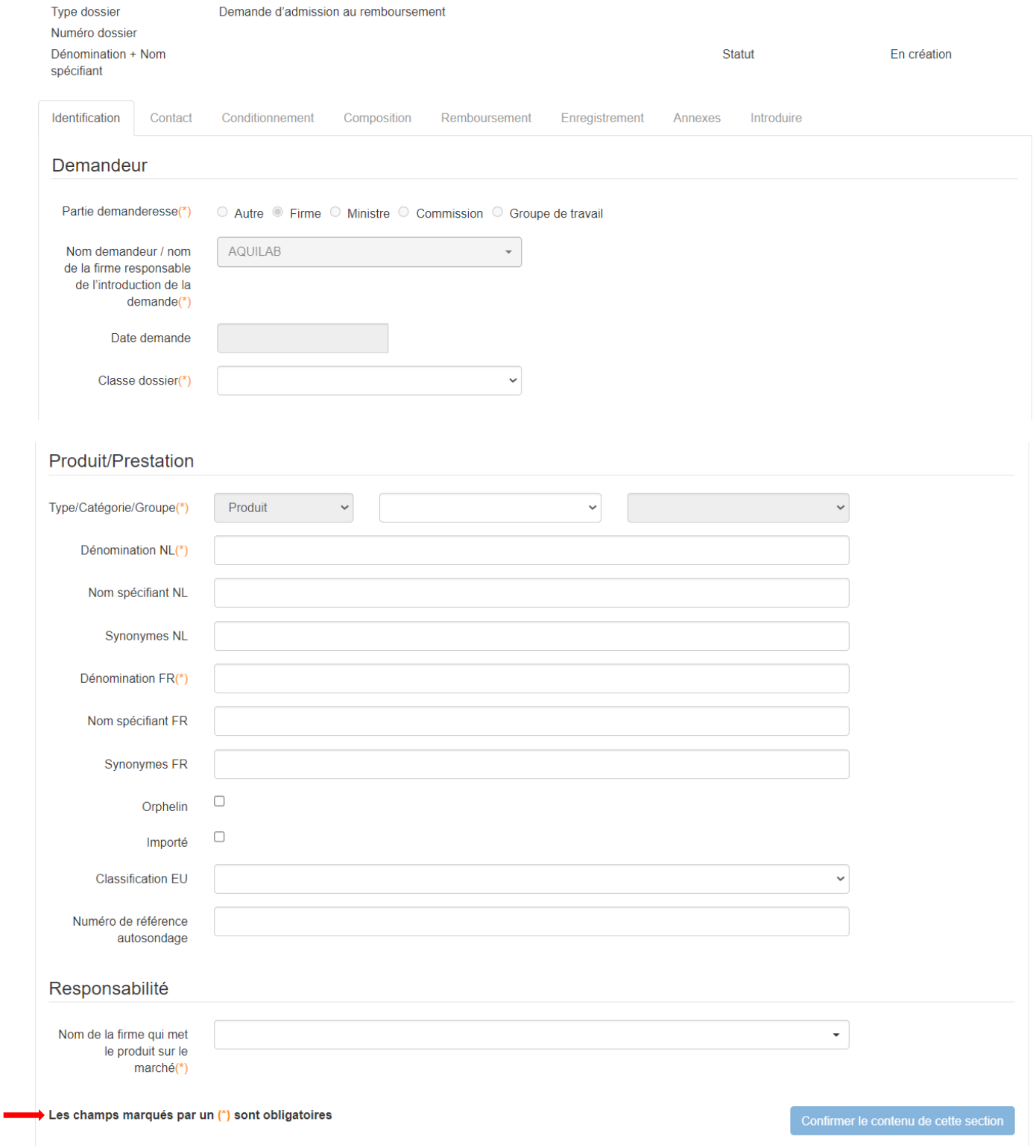
- The file type (field cannot be modified)
- The file number: this number is created automatically (field cannot be modified)
- The file status (field cannot be modified)
- The name + the specifying name

All this data forms the "header".

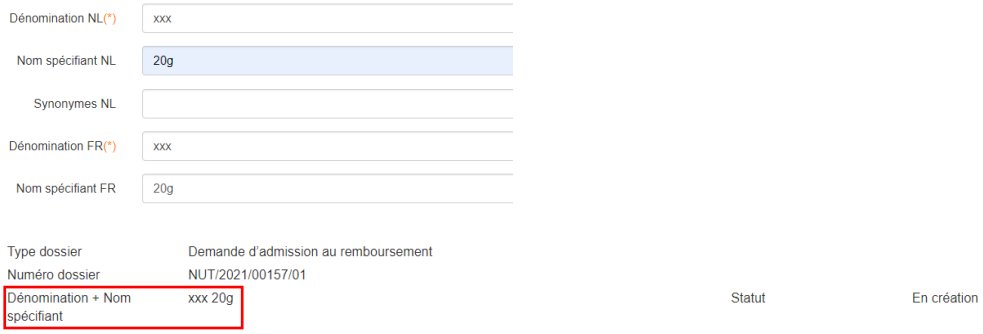
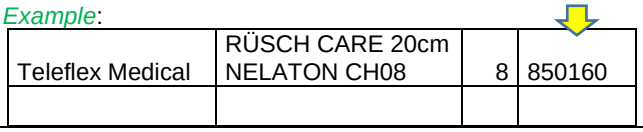
The application for admission forms are all structured along the same lines and consist of the following tabs:

- Identification
- Contact
- Packaging
- Composition
- Reimbursement
- Registration
- Attachments
- Submit

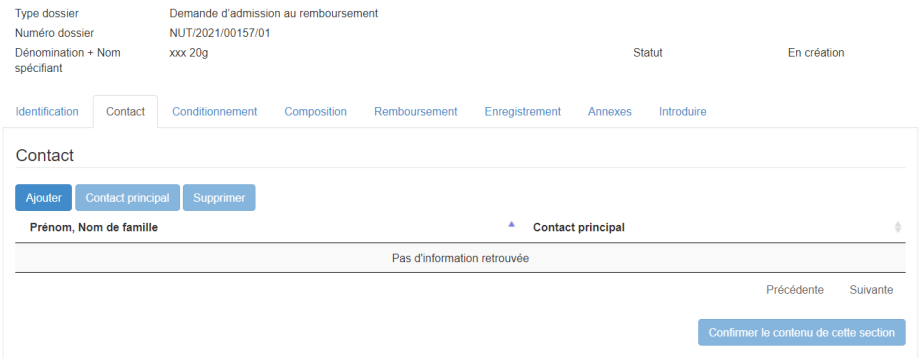
### 6.1.1. **Identification**



| Field name | Explanations/examples |
|---|---|
| | |
| **APPLICANT** | |
| | |
| Applicant party | Automatically filled |
| Applicant name/name of the company responsible for submitting the application | Automatically filled |
| Application date | Automatically filled |
| File class | Drop down menu - 3 possible choices:<br>- Administrative file<br>- Semi-administrative file<br>- File with added value |
| | |
| **PRODUCT/BENEFIT** | |
| | |
| Type | Automatically filled ("Product") |
| Category | Drop-down menu:<br>- Diagnostic resources and health care equipment<br>or<br>- Medical nutrition<br>or<br>- Magistral preparations |
| | |
| Group | Drop-down menu*:*<br>*Diagnostic resources and health care equipment*<br>- bladder irrigation solutions<br>- portable diffusers - cassettes<br>- oxygen concentrators<br>- hypertonic sodium chloride inhalation solution for the treatment of cystic fibrosis<br>- blood pressure monitors<br>- glucose meter - lancet holder - test strips - lancets<br>- self-catheterization catheters<br>- active dressings |
| | *Medical nutrition* |
| | *Magistral preparations*<br>- Active substance<br>- Excipient<br>- Ready-made medicinal product<br>- Passive dressing |
| Name FR and NL | Product name<br><br>*Example*: Paracetamol<br>Melolin<br>PKU Anamix Junior LQ fruits of the forest flavour |
| Specifying name FR and NL | = Additional specification of the packaging<br>= An addition to the "basic name" which distinguishes between different packages in the same range<br><br>*Example*:<br>Paracetamol **25g** → the specifying name is **25g**<br>Melolin **10 x (5x5cm)** → specifying name is **10 x (5x5cm)**<br>PKU Anamix Junior LQ fruits of the forest flavour **6 x 6 x 125 ml** → specifying name is **6 x 6 x 125 ml** |

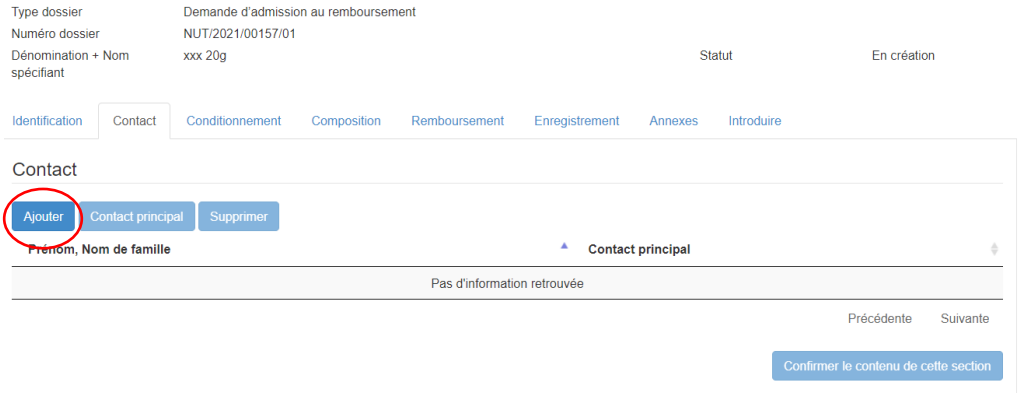
| | |
|---|---|
| | The product's name and specifying name will form the name of the file that you create and which you will find in the "header":<br>  <br> |
| Synonyms FR and NL | Only for products for raw materials for magistral preparations<br><br>*Example*:<br>Tosylchloramide sodium: synonym = **Chloramine** |
| Orphan | To be ticked if applicable |
| Imported | To be ticked if applicable |
| EU Classification | Only for medical devices (diagnostic resources and health care equipment, active dressings, passive dressings (included in the magistral preparations category) and self-catheterization catheters) via a drop-down menu.<br><br>This classification can be found in:<br>- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices<br>or in<br>REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices;<br>Or<br>- DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices<br>or in<br>REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices.<br><br>For other products: this does not apply |
| Self-catheterization reference number | *Only for self-catheterization catheters<br><br>= number of the company-specific article<br><br>*Example*:<br>  <br> |
| | |
| **LIABILITY** | |
| | |
| Name of the company that places the product on the market | = company name that will be published next to the product name<br>→ may be different from the company that signs the commitment |
| | |
| Once all fields are completed:<br><br>Click<br><br> <br> | |

### 6.1.2. **Contact**

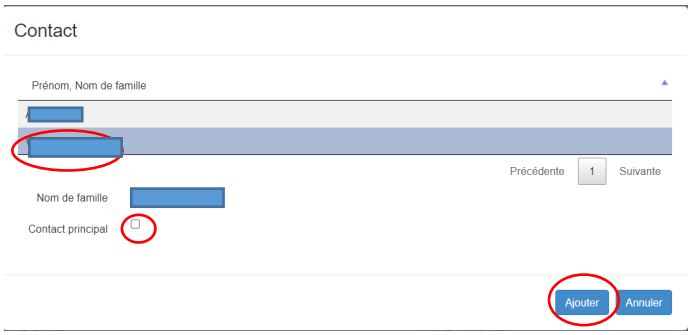



The first name and surname of the contact person(s) must be specified.

1) Click "Add"



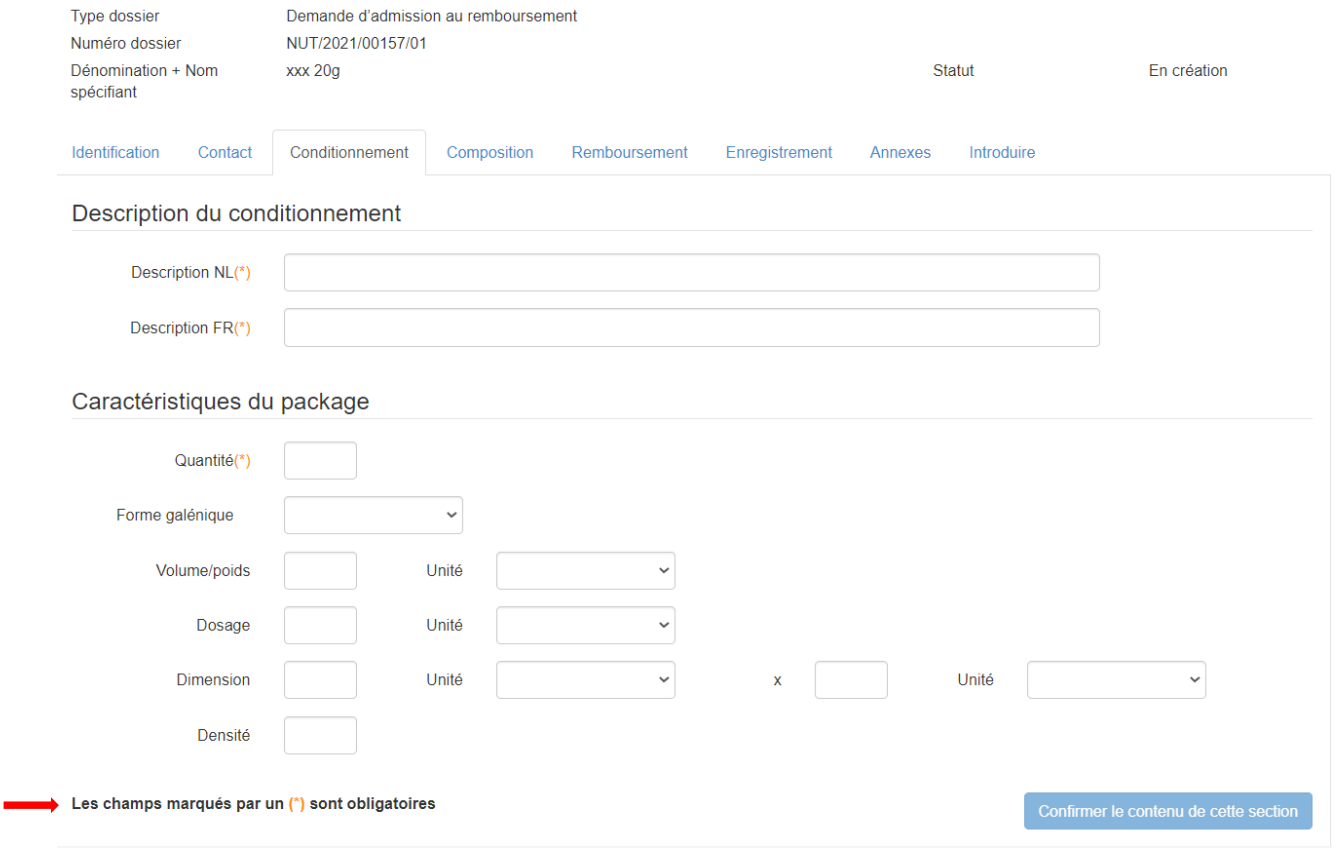

2) Choose the contact person(s) by clicking on their name and specify the primary contact by ticking " Contact principal ☐ " and click "Add".




3) "Confirm"

Once all fields are completed:

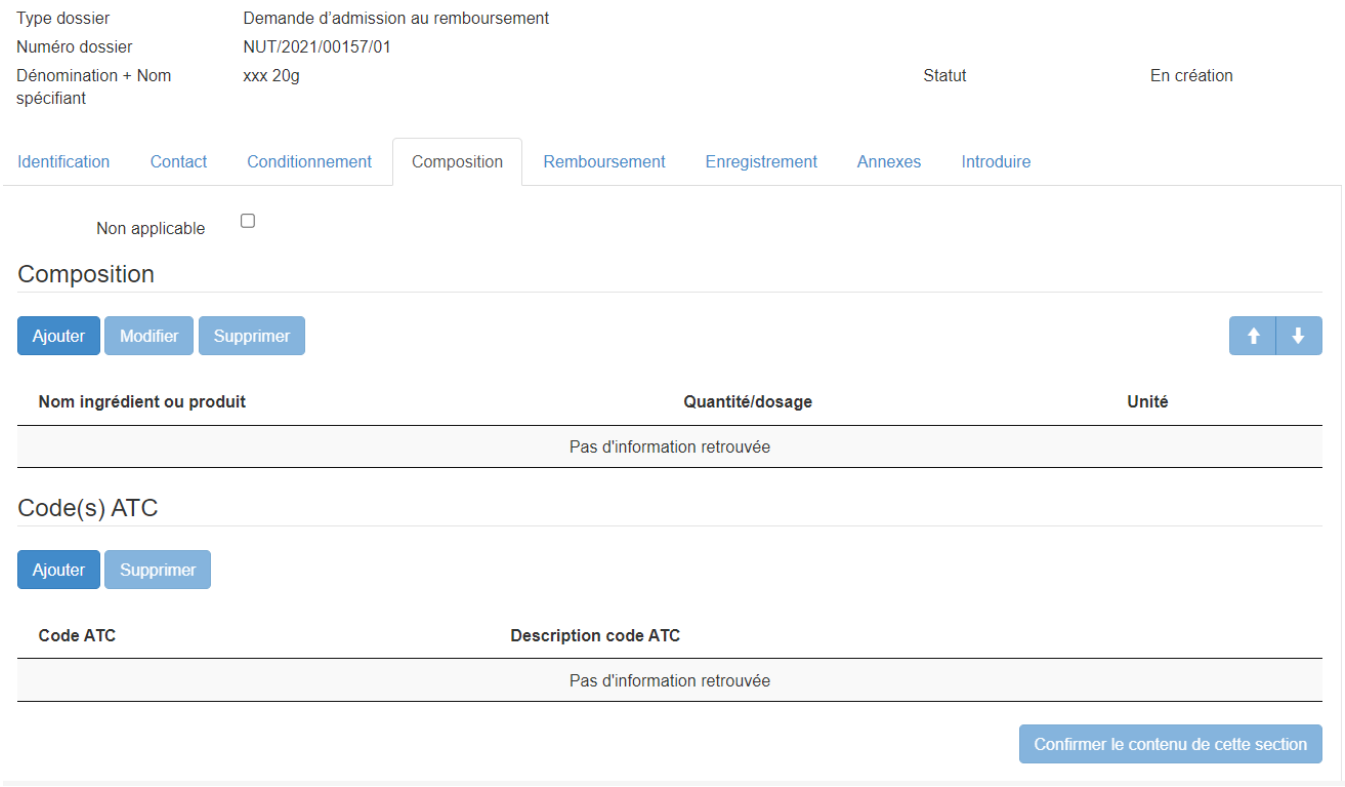
### 6.1.3. **Packaging**



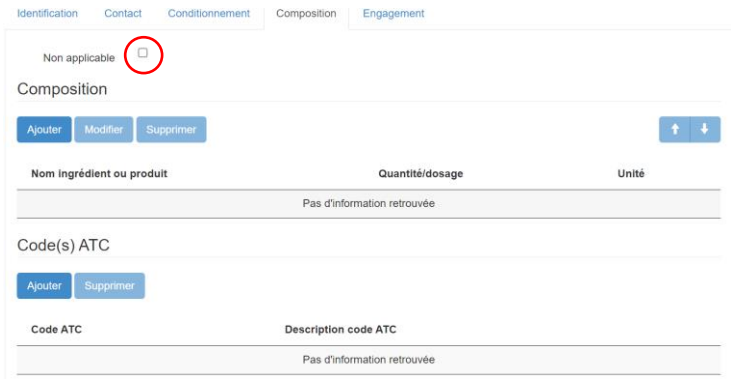
| Field name | Explanations/examples |
|---|---|
| | |
| **PACKAGING DESCRIPTION** | |
| | |
| Description NL and FR | = Full name of the product **as it will be published**<br><br>*Example*:<br>Active dressings: "Mepilex Border Lite 5 x (15cmx15cm)"<br>Medical nutrition: "PKU Anamix Junior LQ fruits of the forest flavour **6x6x**125 ml" |
| | |
| **PACKAGE CHARACTERISTICS** | |
| | |
| Quantity | = Total number of "units" in the package<br><br>*Example*:<br>Active dressings: Mepilex Bordre Lite **5 x** (15cmx15cm) → quantity = **5**<br>Magistrals: Paracetamol 25g package → quantity = **1**<br>Medical nutrition: PKU Anamix Junior LQ fruits of the forest flavour **6x6x**125 ml → quantity = **36** |
| | |
| Depending on the product category, the following data is strongly recommended | |
| | |
| Pharmaceutical form | Drop-down menu<br><br>*Mandatory* for products for magistral preparations |
| | |
| Volume/weight<br>Unit | = Weight or volume of product per unit<br>Unit in which the weight or volume is expressed can be selected in the drop-down menu<br><br>*Example*:<br>Magistrals: Paracetamol **25g** package → volume = 25/unit = g<br>Medical devices: ECOBAG bag **3L** → volume = 3/unit = L<br>Medical nutrition: PKU Anamix Junior LQ fruits of the forest flavour - packaging 6x6x**125 ml** → volume = 125/unit mL |
| | |
| Dosage<br>Unit | = product concentration/dosage per unit<br>Unit in which the concentration or dosage is expressed can be selected from the drop-down menu<br><br>*Example*:<br>Medical devices: MUCOCLEAR **6%** 60 x 4 mL hypertonic solution/hypertonische oplossing" → dosage = 6/unit = % |
| | |
| Dimensions<br>Unit | = size/dimension of the product<br>Unit in which the size or dimension is expressed can be selected from the drop-down menu<br><br>*Example*:<br>Active dressings: Mepilex Bordre Lite 5x (**15cmx15cm**) → dimension 1 = 15/unit 1 = cm --- dimension 2 = 15/unit 2 = cm<br><br> <br><br>Self-catheterization catheters: ACTREEN® LITE CATH Tiemann - **CH 08 - 45 CM**<br><br>The diameter must be included in the catheter's dimensions.<br> |
| | |
| Density | Only for products for magistral preparations |

Once all fields are completed:

## 6.1.4. **Composition**

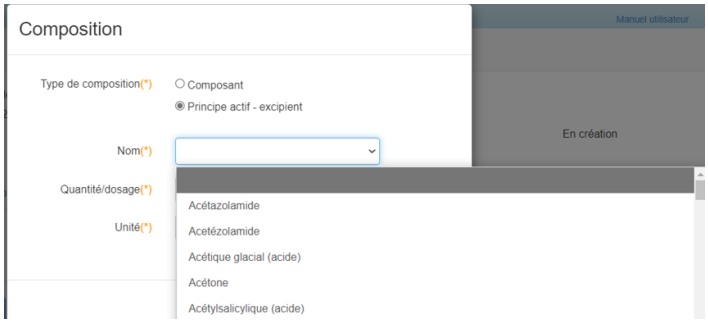
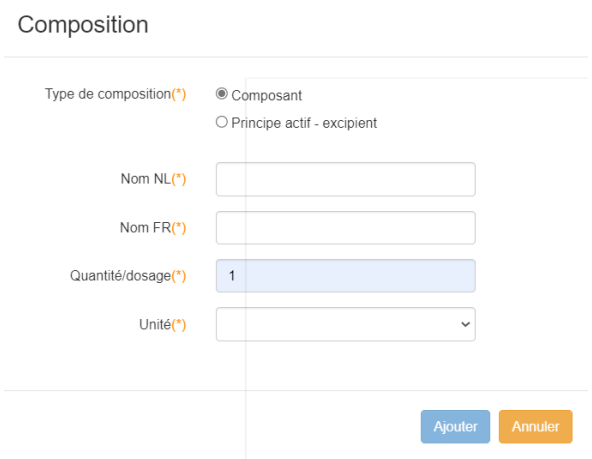


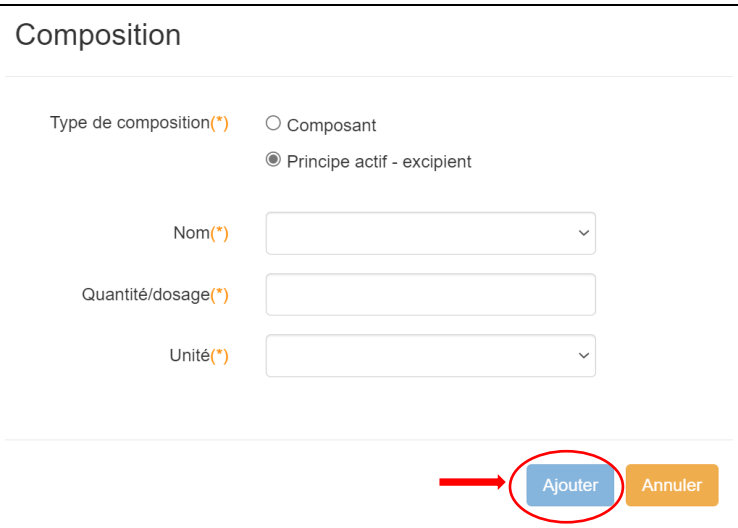

If "Composition" and "ATC codes" are not applicable: tick "**Not applicable** ☐"



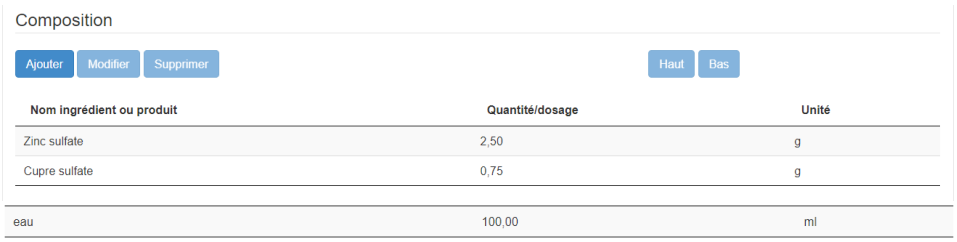

*Example*:
Medical devices: OMRON Blood Pressure Monitor

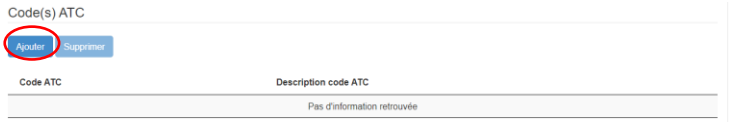
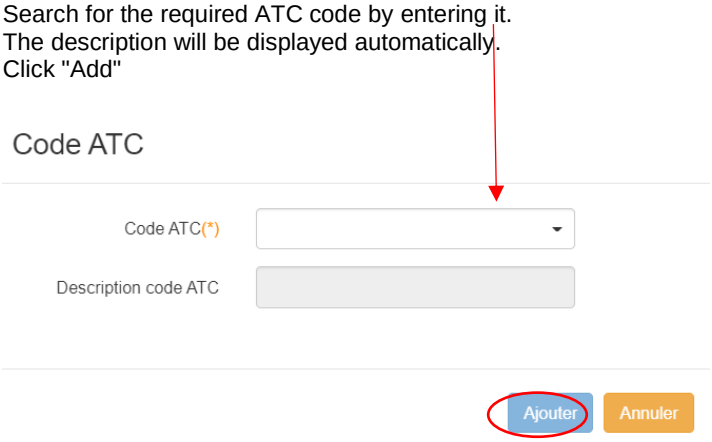
In other cases, complete the "COMPOSITION" and "ATC CODE(S)" fields

| Field name | Explanations/examples |
|---|---|
| | |
| **COMPOSITION** | = complete product composition<br><br>Click "Add" as many times as an product/excipient/active substance needs to be added:<br> <br><br><br>You are then taken to the "Composition" document where you choose the composition type.<br><br>The choice of "*Active substance*" and "*Excipient*" mainly concerns active ingredients for magistral preparations and medical nutrition and in a few cases medical devices (for *example*: MUCOCLEAR = hypertonic solution).<br>Choose the active substance/excipient from the drop-down menu and click on the relevant product.<br><br>  <br><br><br>If an active substance/excipient does not appear in the drop-down menu, please contact the General Secretariat on 02/739.77.41 or send an email to the following address: crppp-ctfpv@riziv-inami.fgov.be, with secr-farbel@riziv-inami.fgov.be in cc.<br><br>The "*Component*" choice concerns medical devices in particular.<br>Complete the fields provided for this purpose.<br><br>  <br><br><br>The unit in which the quantity or dosage of the active substance/excipient/component is expressed can be selected from the drop-down menu<br><br>After entering each active substance/excipient/component and completing the "Quantity/dosage" and "Unit" fields, click "Add". |




*Example:* Dalibour Water

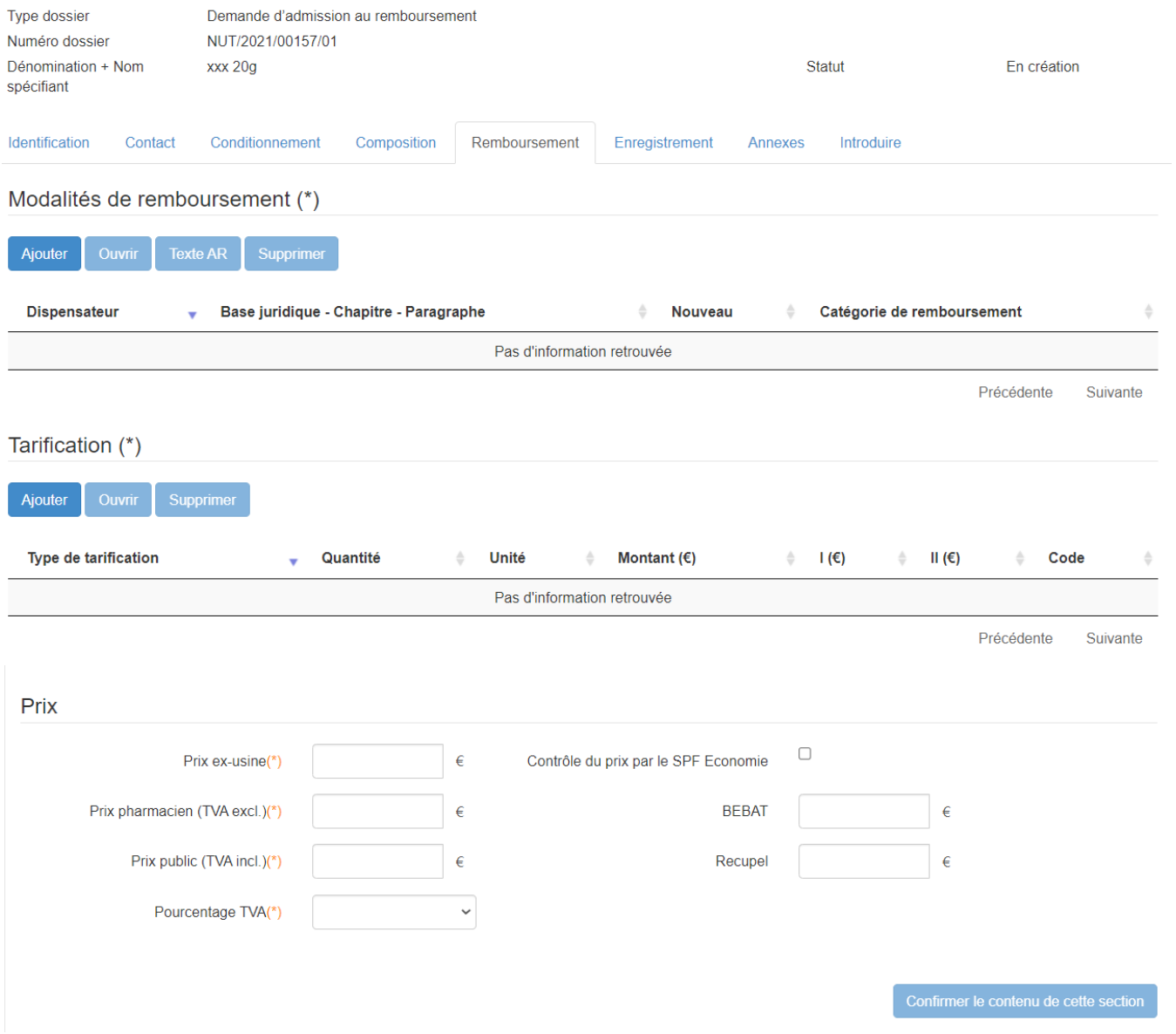


| | |
|---|---|
| **ATC CODE** | The classification to be used is that established by the "WHO Collaborating Centre for Drug Statistics Methodology" in Oslo.<br><br>Note: "ATC code" means "5th level ATC code" (e.g. A01AA01).<br>Only if a specific 5th level code has not been assigned, can a higher level be entered.<br><br>Click "Add" as many times as a code needs to be added:<br>  <br><br><br>Search for the required ATC code by entering it.<br>The description will be displayed automatically.<br>Click "Add"<br>  <br><br><br>*Example:* Dalibour Water<br> <br> |

Once all fields are completed:

Click → Confirmer le contenu de cette section

## 6.1.5. **Reimbursement**

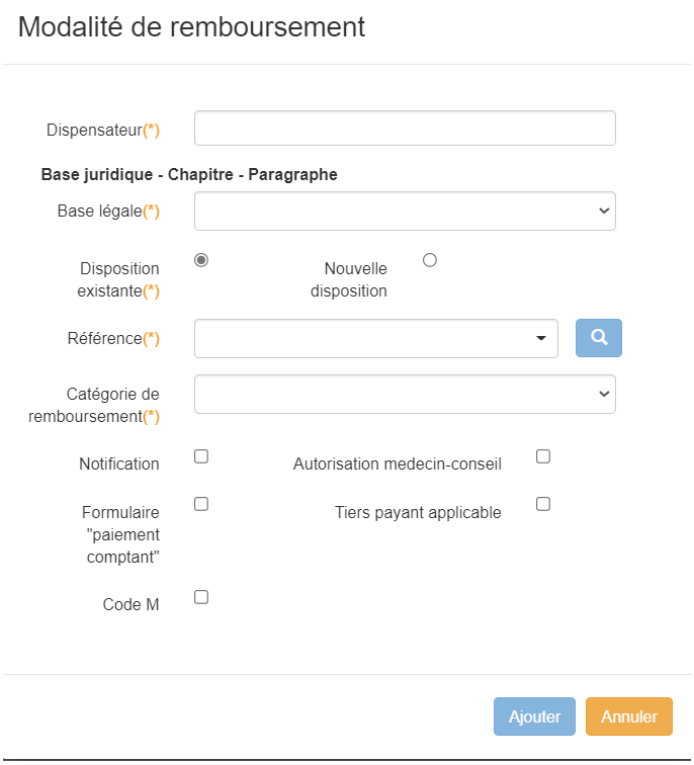
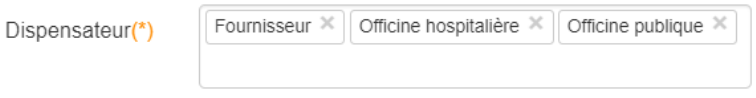



Specify your **proposed reimbursement terms and pricing system here.**
Enter the data related to your product's **price structure**.

Note:

The pricing system requested MUST match the dispensing requested in the reimbursement conditions (dispensing by a public pharmacy, hospital pharmacy or by a supplier).

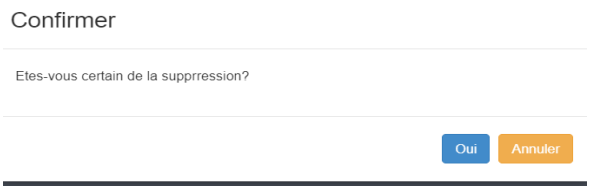
If a reimbursement condition has been entered for dispensing by a public pharmacy, hospital pharmacy or by a supplier, then a public pharmacy, hospital pharmacy (inpatient and/or outpatient) or supplier pricing system MUST also exist.

| Field name | Explanations/examples | |
|---|---|---|
| | | |
| **REIMBURSEMENT TERMS** | Click "Add" to propose reimbursement terms<br>  | |
| | Fields marked with an asterisk (*) are MANDATORY. | |
| | | |
| | **DISPENSER** | You can choose from the following dispensers:<br>- Supplier (only for the dispensing of medical devices and self-management equipment in the context of care pathways and the "education and self-management of care" programme)<br>- Hospital pharmacy<br>- Public pharmacy<br><br>You can select multiple dispensers at one time within the same framework (as long as the reimbursement terms are the same for each of them. Otherwise, proposals must be made individually for each dispenser).<br>  |
| | **LEGAL BASIS CHAPTER PARAGRAPH** | |
| | LEGAL BASIS | The legal basis of the reimbursement condition(s)<br>(Drop-down menu) |
| | EXISTING PROVISION<br>Or<br>NEW PROVISION | You can either refer to an existing provision by adding a product to expand the range.<br><br>Or you can propose a new provision. In which case, you select the "New provision" option<br><br>To modify previously entered data, select the line to be modified and click the "Open" button. |

You can then modify your data.
Then click the "Modify" button.

To delete previously entered data, select the line to be deleted.

The following screen appears:



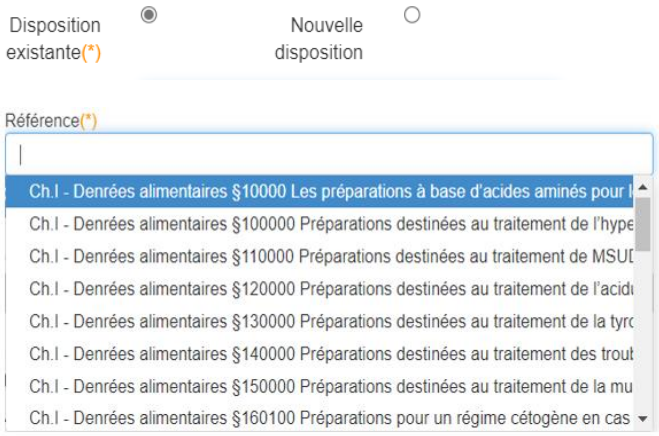

Then click "Yes".

A product may be listed in multiple chapters and be reimbursable under several different reimbursement categories,.... In this case, the different entries must be referred to separately.

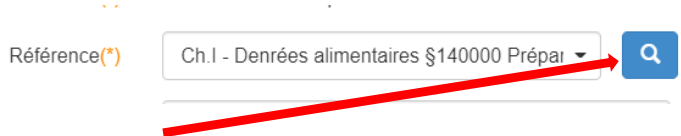
1. Existing provision

Click "Reference" to access the list of choices for the existing chapter/paragraph.
Click on the selected reimbursement terms
Once you have made your choice, you can consult the entire reimbursement conditions for the selected chapter/paragraph

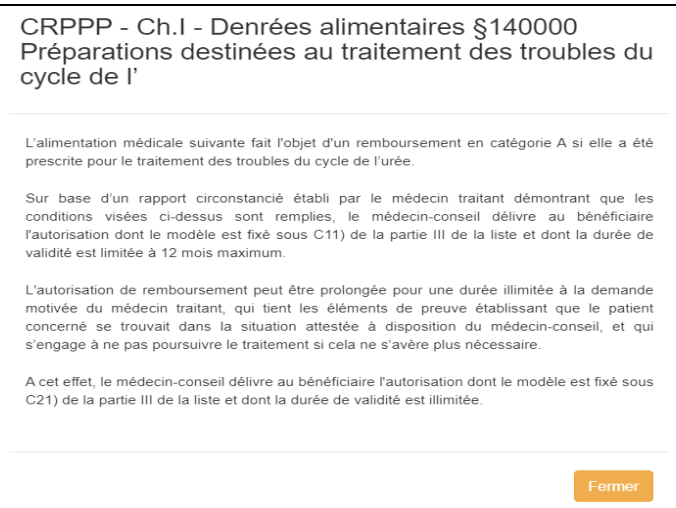
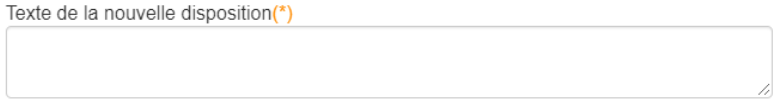
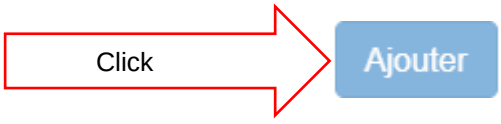
*Example*:



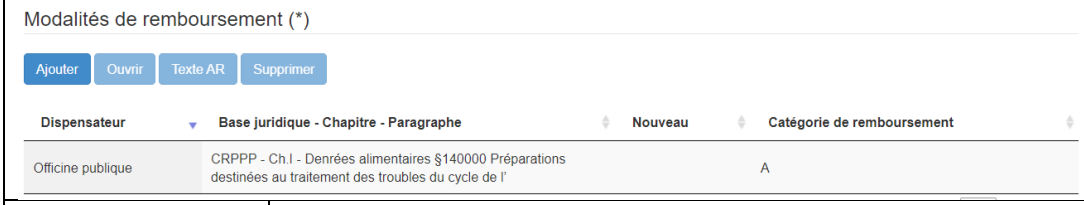

Make your choice




Click the magnifying glass to see the reimbursement conditions as follows:

| | | |
|---|---|---|
| | |  <br>Click "Close" after consulting the text<br><br>2. <u>New provision</u><br><br>Enter your proposed text in the "Text of the new provision" field provided for this purpose.<br>Specify whether it is a new chapter/paragraph/section/sub-section.<br><br>  <br><br>*Example*:<br>"TITLE 3. Products for magistral preparations - Chapter IV - new § "xxxxxxxxx". |
| | REIMBURSEMENT CATEGORY | Reimbursement category (drop-down menu) |
| | | |
| | - NOTIFICATION<br>- MEDICAL OFFICER AUTHORISATION<br>- "CASH PAYMENT" FORM<br>- APPLICABLE THIRD PARTY PAYMENT | If applicable, tick the appropriate reimbursement condition.<br><br>"Applicable third party payer" means either the statement "applicable third party payer" itself or any other written statement as specified in the regulations. |
| | | |
| | M CODE | If applicable, tick "M Code"<br><br>An M code means that more than one package can be prescribed on the same prescription, while guaranteeing reimbursement for each of the packages prescribed. |
| | | |
| | Once all fields are completed:<br><br>  | |
| You can then view the proposed reimbursement terms | | |

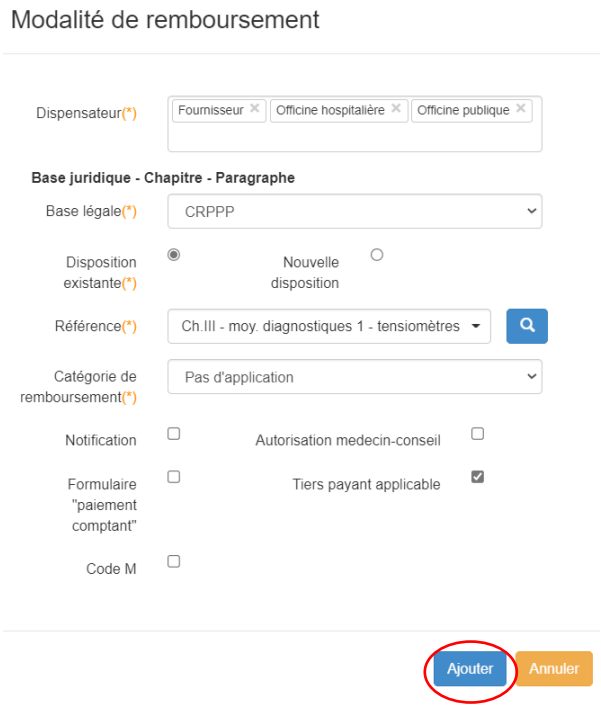
*Example*:

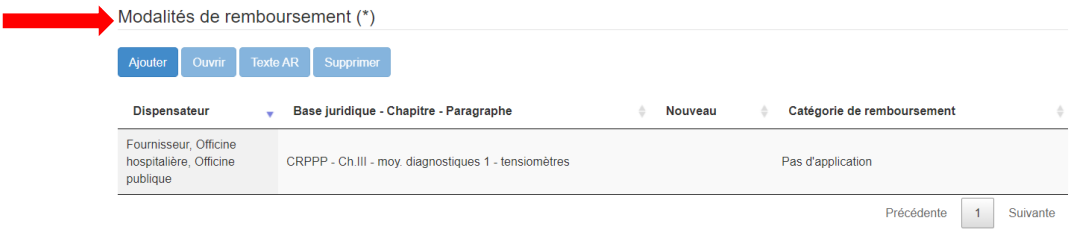



In this list, you can also view the data entered by clicking the "Open" button after selecting the line for which you want to view the data.
You can delete the data entered by clicking the "Delete" button after selecting the appropriate line.
You can also consult the text of the corresponding regulation (in the case of an "existing provision") by clicking the "RD text" button after selecting the relevant line.

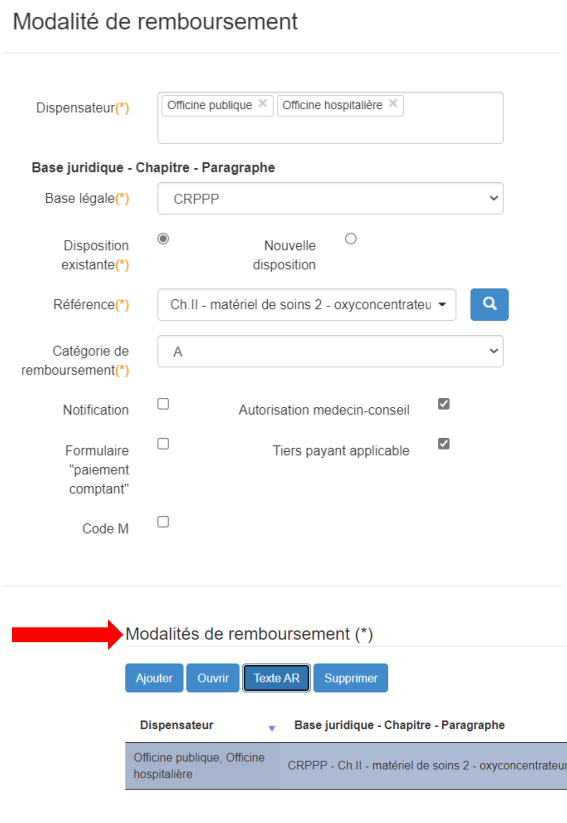
***A few complete practical examples of the "REIMBURSEMENT" tab***

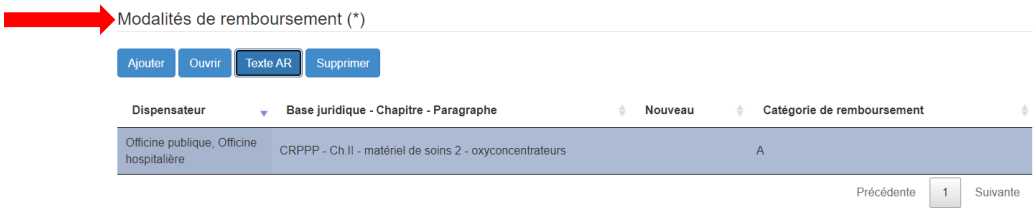
*Example 1. Medical device (OMRON blood pressure monitor - semi-administrative file - firm Aquilab)*



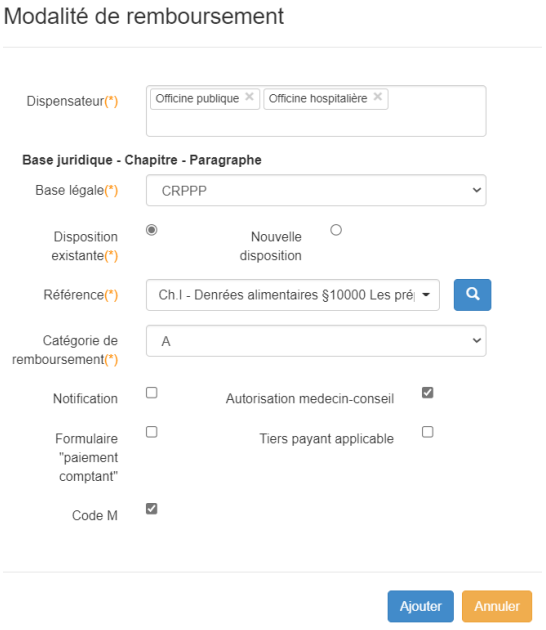



*Example 2. Medical device (AIRSEP VITAL OXYGEN CONCENTRATOR - firm Aquilab)*

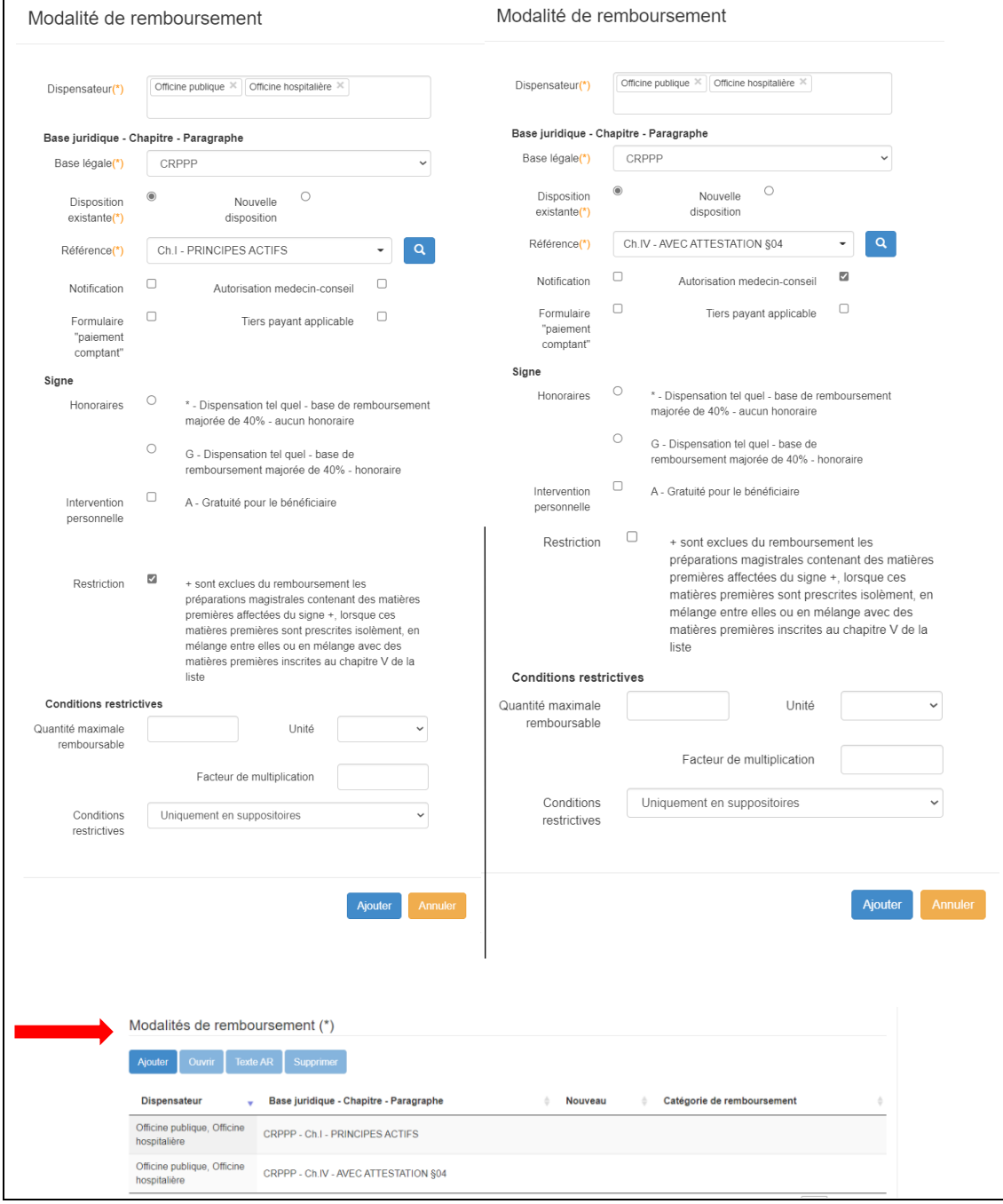


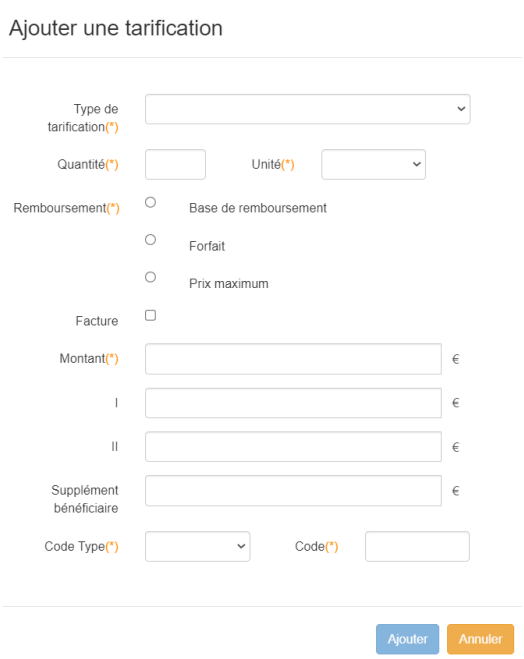




*Example 3: Food for special medical purposes (PKU Anamix vanilla 6 x (6 x 125 ml) - firm Aquilab)*



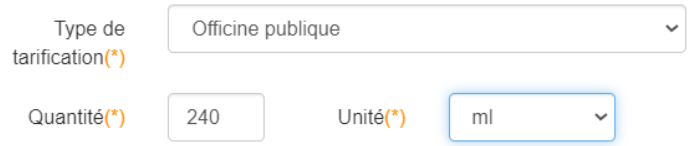
*Example 4. Raw material for magistral preparation (Paracetamol powder 25g - firm Aquilab)*



| | | |
|---|---|---|
| **PRICING SYSTEM** | Click "Add" to make a pricing system proposal<br>  <br> | |
| | Fields marked with an asterisk (*) are MANDATORY. | |
| | | |
| | TYPE OF PRICING SYSTEM | The type of pricing system (drop-down menu).<br>If you are proposing a pricing system for multiple types of dispensing, you must complete the "Add a pricing system" table as many times as there are "Types of pricing system".<br><br>The requested pricing system must match the dispensing requested in the reimbursement conditions, i.e., outpatient hospital dispensing, inpatient hospital dispensing, dispensing by a public pharmacy or by a supplier.<br><br>The pricing system for dispensing by a supplier can only be used for the dispensing of medical devices and self-management equipment in the context of care pathways and the "education and self-management of care" programme. |
| | QUANTITY | Number of units by which the product will be priced in the selected dispensing.<br><br>For dispensing by the supplier or in public pharmacies, the pricing system relates to the package.<br>For dispensing by the hospital pharmacist, the pricing system is per unit. |
| | UNIT | The units by which the product will be priced in the selected dispensing.<br><br>**!!!** For the pricing system of oxygen concentrators, the units to be selected are:<br>- Installation by the supplier<br>- Rental and maintenance<br>- Single use humidifier<br>- Pharmacist's fee (= fee for therapy support and pricing system coordination) |

*Example*
*Medical device: MUCOCLEAR 6%*:

| Criterium<br>Criteria | Code<br>Code | Benaming en verpakkingen<br>Name and packaging | Opm.<br>Obs. | Prijs<br>Price | Basis van tege-moetk.<br>Basis of reimbur-sement | I | II |
|---|---|---|---|---|---|---|---|
| B | | MUCOCLEAR 6% (Henrotech) | | | | | |
| | 2456-010 | 60 x 4 mL hyper-tonic solution / hypertonische oplossing | M | 58.79 | 58.79 | 8.00 | 12.10 |



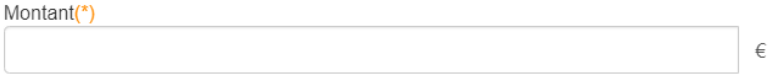

Public pharmacy = full package pricing system → 60 x 4 mL = 240 mL

REIMBURSEMENT

Tick the appropriate box.
You can choose between:

- basis of reimbursement
- flat rate
- maximum price

Then propose the basis of reimbursement/flat rate/maximum price using the "Amount" field




Where applicable, for medical devices and food for special medical purposes, the basis of reimbursement is the public price of the product.

!!! In the case of products for magistral preparations, please note a basis of reimbursement of "0". The basis of reimbursement is calculated by the Commission according to the rules set out in the regulations.

!!! For the pricing types "Hospital practice - outpatients" and "Hospital practice - inpatients", the "Amount" box must not be filled in..

If applicable, next propose the amounts of the beneficiaries' personal contributions using fields I and II.

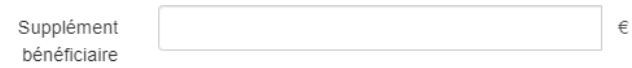
- column I = contribution of the beneficiary referred to in Article 37 § 19 of the Law who is entitled to enhanced insurance cover
- column II = contribution of other beneficiaries

For food for special medical purposes and medical devices, the beneficiaries' contributions are set out in the corresponding regulations:

- Royal Decree of 24 October 2002 establishing beneficiaries' personal contribution to the cost of food for special medical purposes reimbursable within the framework of the compulsory health care and benefits insurance
- Royal Decree of 24 October 2002 establishing beneficiaries' personal contribution to the cost of diagnostic resources and health care equipment reimbursable within the framework of the compulsory health care and benefits insurance

!!! This does not apply to products for magistral preparations or in the context of dispensing by the hospital pharmacy to ambulant and hospitalised patients

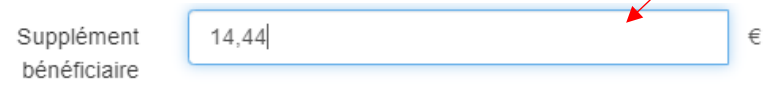
In some cases (e.g. blood pressure monitors, self-catheterisation probes), the beneficiary will have to pay a supplement.




*Example – blood pressure monitors VEROVAL DUO CONTROL LARGE*

| CNK Code/ Code CNK | Benaming Dénomination | BEBAT (excl. TVA – excl. BTW) | RECUPEL (excl. TVA – excl. BTW) | Apothekerprijs (incl. BTW, BEBAT, RECUPEL) Prix pharmacien (incl. TVA, BEBAT, RECUPEL) | Toeslag rechthebbende Supplément bénéficiaire |
|---|---|---|---|---|---|
| 3730918 7114523* | VEROVAL DUO CONTROL LARGE Paul Hartman | 0,0630 | 0,3306 | 74,44 € | 14,44 € |

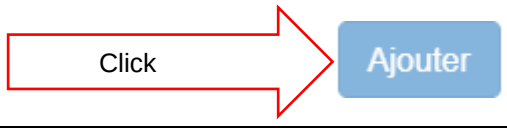
The amount of 14.44 should then be entered in the box




Then complete in the CNK codes <u>for both dispensing by public pharmacy and supplier</u> (one and the same CNK for both if applicable).

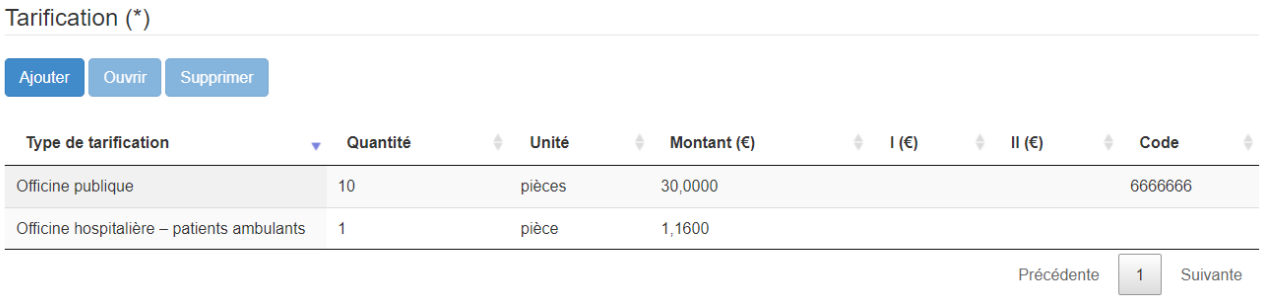
- click "code type": CNK will appear then click the word "CNK".
- then enter the CNK code in the second box

Once all fields are completed:



You can then view the proposed pricing system

*Example*:




In this table, you can also view the data entered by clicking the "Open" button after selecting the line for which you want to view the data.
You can delete the data entered by clicking the "Delete" button after selecting the appropriate line.

**PRICE**

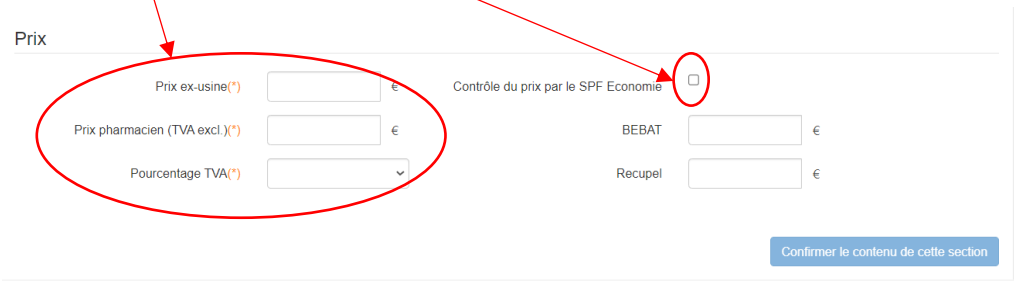
You can access the following table under **<u>medical devices and medical nutrition</u>**:

The price structure must be completed along with, for blood pressure and blood glucose meters, the BEBAT and RECUPEL amounts,

Note: for blood pressure monitors, blood glucose meters/test strips/lancets, portable diffusers/
cassettes and for oxygen concentrators: *the public price* MUST not be entered.
Enter "0" in the field

OR

In the following table for **<u>products for magistral preparations</u>**:
The price structure must be completed and, if applicable, tick "Price control by FPS Economy*"



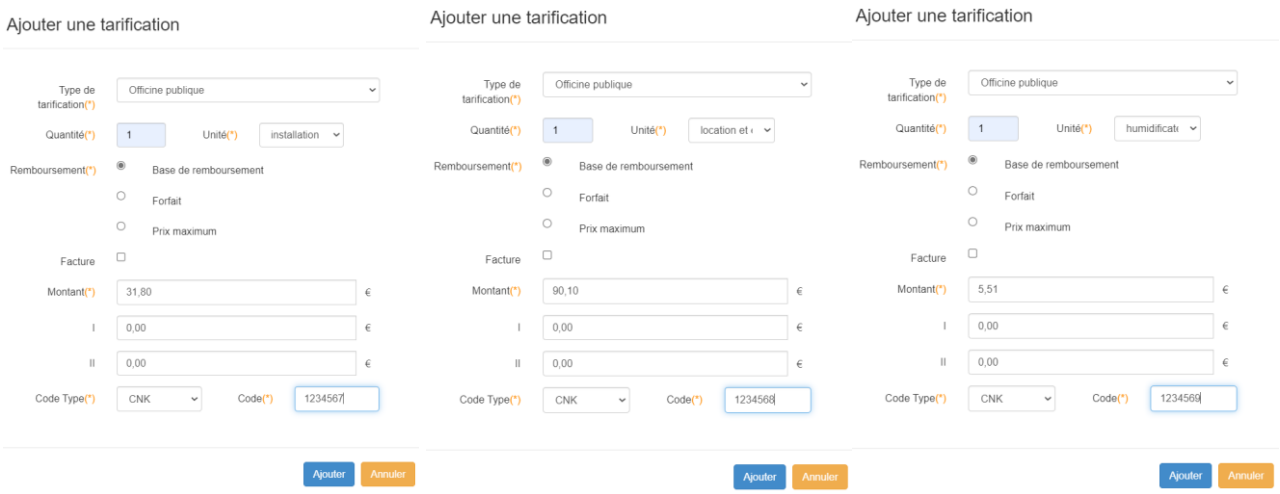

*these are reimbursable active substances included in at least one therapeutic magistral preparation. The list of these raw materials is included in the Ministerial Decree of 13 JUNE 2014 designating the list of raw materials that are subject to the provisions of Title 2 of Book V of the Belgian Code of Economic Law.

Once all fields are completed:

Click → Confirmer le contenu de cette section

***A few complete practical examples of the "PRICING SYSTEM" tab***

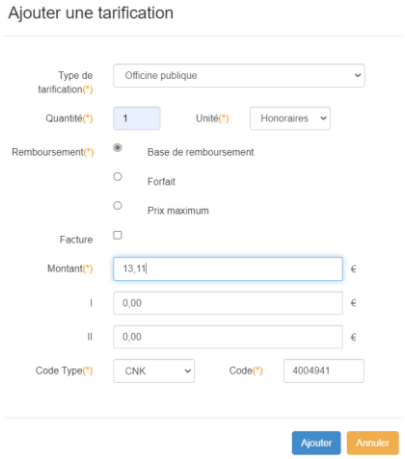
*Example 1. Medical device (AIRSEP OXYGEN CONCENTRATOR - firm Aquilab)*

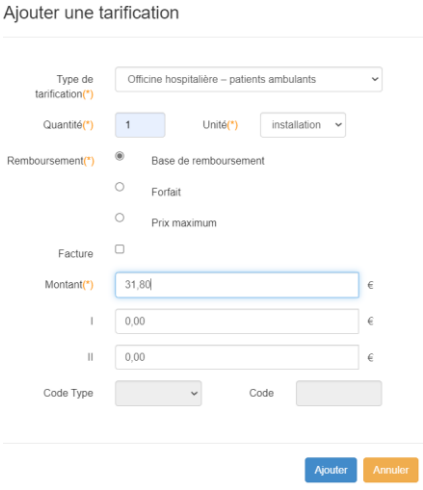


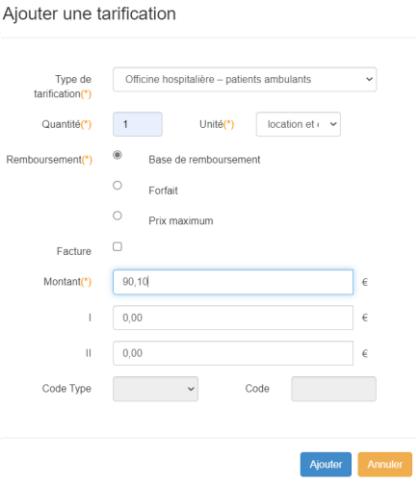


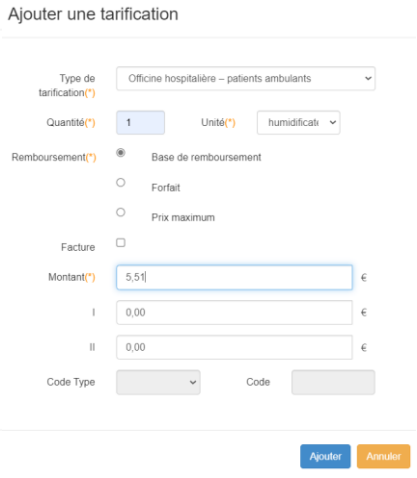


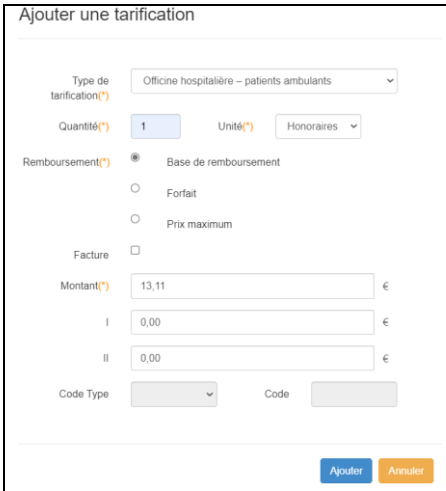


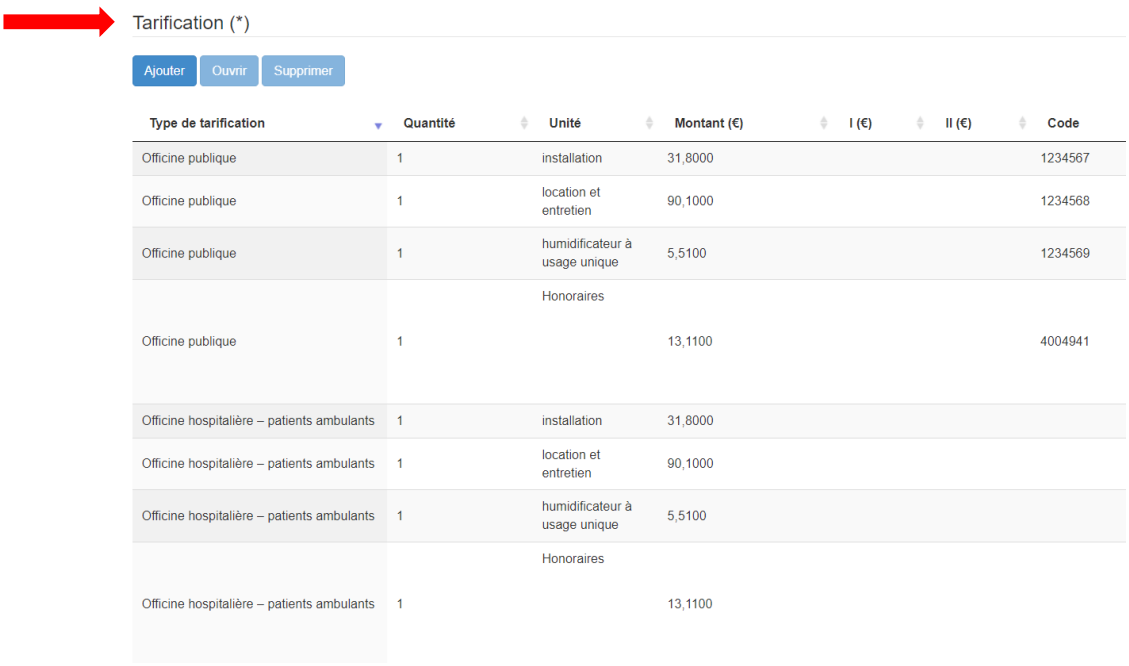



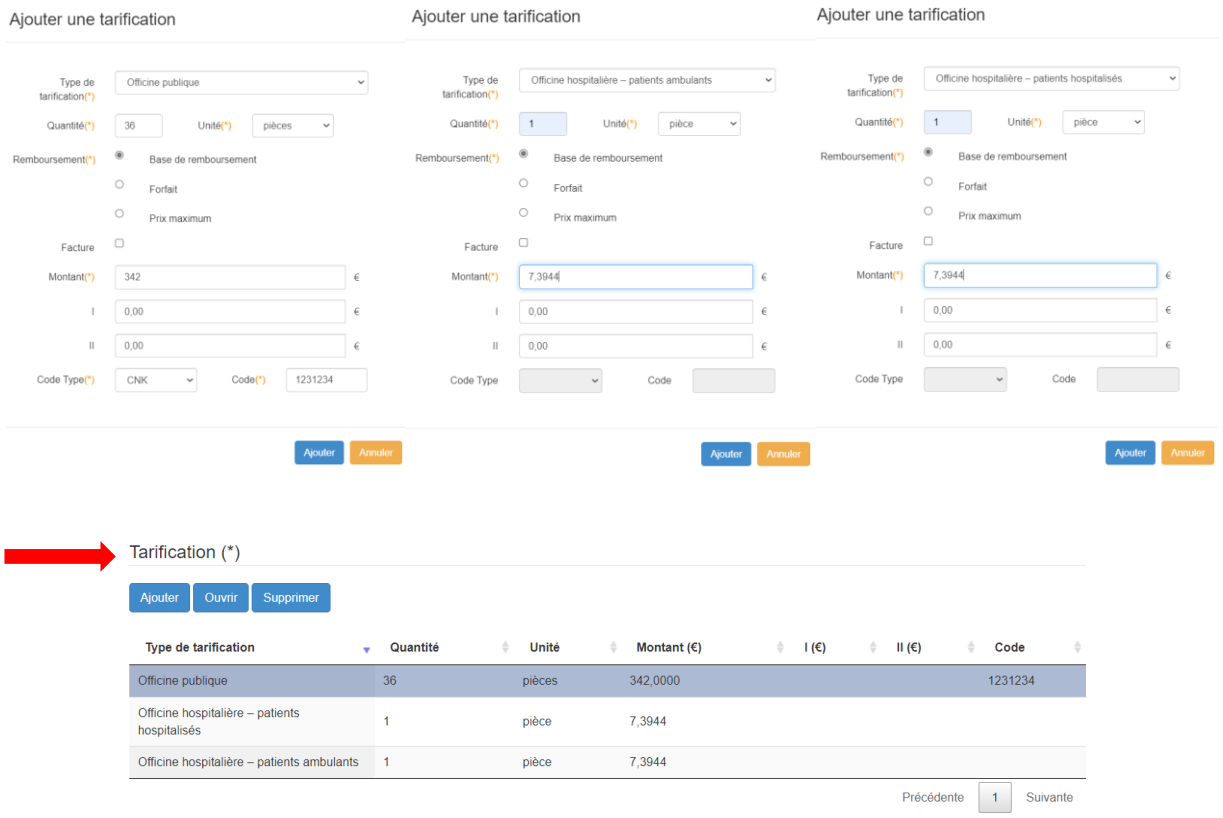



**!!!** the pharmacist's fee is not a fixed amount but an annually indexed amount.
The fee amounts can be consulted on the INAMI-RIZIV website.



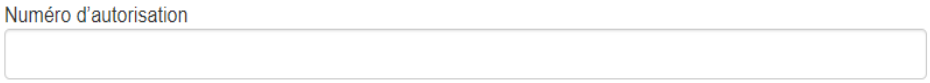

| Type de tarification | Quantité | Unité | Montant (€) | I (€) | II (€) | Code |
|---|---|---|---|---|---|---|
| Officine publique | 1 | installation | 31,8000 | | | 1234567 |
| Officine publique | 1 | location et entretien | 90,1000 | | | 1234568 |
| Officine publique | 1 | humidificateur à usage unique | 5,5100 | | | 1234569 |
| Officine publique | 1 | Honoraires | 13,1100 | | | 4004941 |
| Officine hospitalière – patients ambulants | 1 | installation | 31,8000 | | | |
| Officine hospitalière – patients ambulants | 1 | location et entretien | 90,1000 | | | |
| Officine hospitalière – patients ambulants | 1 | humidificateur à usage unique | 5,5100 | | | |
| Officine hospitalière – patients ambulants | 1 | Honoraires | 13,1100 | | | |

*Example 3: Food for special medical purposes (PKU Anamix vanilla 6 x (6 x 125 ml) - firm Aquilab)*




## 6.1.6. **Registration**

- For raw materials for magistral preparations: enter the authorisation number (except for flavours)

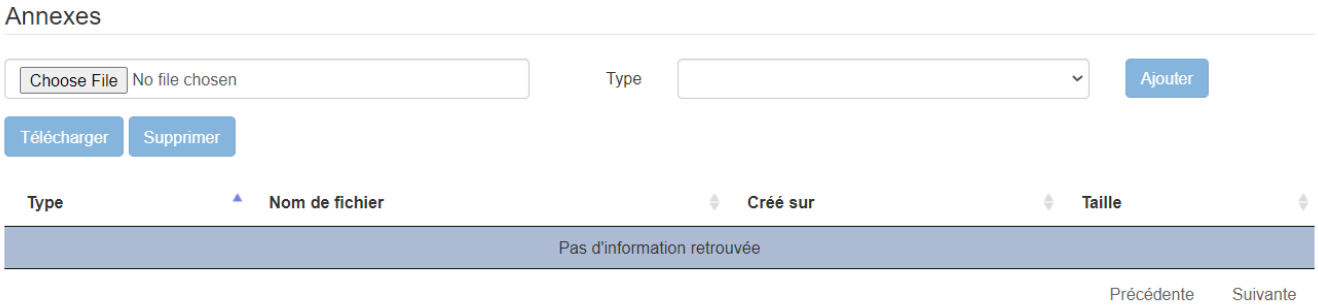



- For food for special medical purposes: enter the FPS Public Health notification number

Once all fields are completed:

Click → Confirmer le contenu de cette section

### 6.1.7. **Attachments**

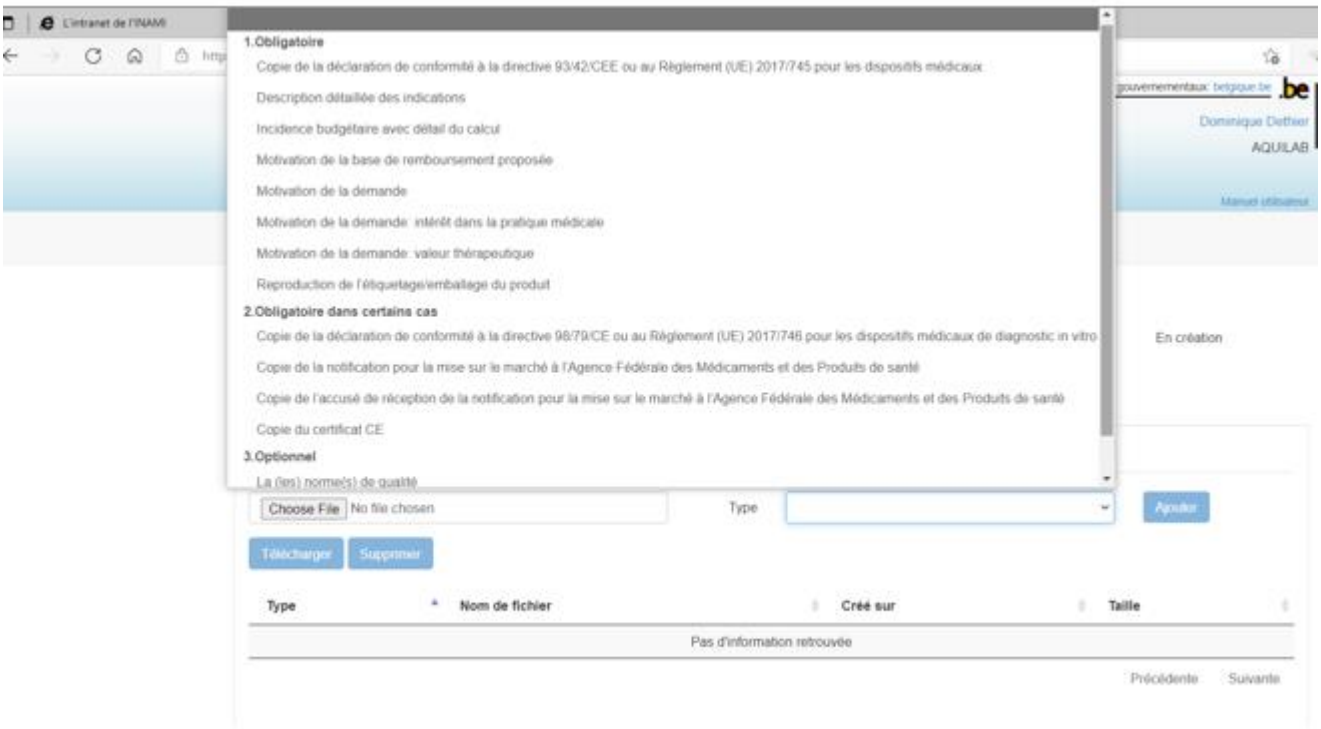



In this section, you must add the mandatory attachments to support the application (WORD documents, PDF documents,...).

1. The required/recommended attachments are specified in the "Type" attribute and depend on the file class (administrative/semi-administrative or with added value) and the product category (diagnostic resources and health care equipment/magistral preparations or medical nutrition).

   They are classified into 3 types:
   - Mandatory
   - Mandatory in some cases
   - Optional

   Select the file type to be sent from the list



The list of attachments is as follows:

A. ADMINISTRATIVE FILE

| Attachment | Diagnostic resources/health care equipment | | | Medical nutrition | | | Products for magistral preparations | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mandatory | Mandatory in some cases (highlighted in the description of the attachment or specified in brackets below) | Optional | Mandatory | Mandatory in some cases (highlighted in the description of the attachment or specified in brackets below) | Optional | Mandatory | Mandatory in some cases (highlighted in the description of the attachment or specified in brackets below) | Optional |
| Reason for the application: therapeutic value | X | | | X | | | X | | |
| Reason for the application: consideration in the medical practice | X | | | X | | | X | | |
| Reason for the application: epidemiological elements | | | | | | | | | |
| Reason for the proposed basis of reimbursement | X | | | X | | | X | | |
| Budgetary impact with calculation details | X | | | X | | | X | | |
| Estimated quantities sold in Belgium | | | | | | | X | | |
| 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 | | | | X | | | | | |
| Copy of the acknowledgement of receipt of the notification file to the Directorate General for Animals, Plants and Food of the Federal Public Service Health, Food Chain Safety and Environment | | | | X | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: a copy of the notification for placing on the market to the Federal Agency for Medicines and Health Products for class 1 medical devices and for in vitro diagnostic medical devices | | X | | | | | | X (concerns passive dressings) | |
| If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: copy of the acknowledgement of receipt of the notification for placing on the market to the Federal Agency for Medicines and Health Products for class 1 medical devices and for in vitro diagnostic medical devices | | X | | | | | | X (concerns passive dressings) | |
| Authorisation for the placing on the market or authorisation for the placing on the market of sterile products | | | | | | | X | | |
| Detailed description of indications | X | | | X | | | | | |
| Reproduction of the labelling/ packaging of the product | X | | | X | | | | | |
| Information on the label, the description of the primary packaging and any secondary packaging | | | | | | | | | |
| Patient information leaflet | | | X | | | X | | | |
| The quality standard(s) set by the Minister : -blood pressure monitors : Quality ISO 81060- 2 :2018/Amd 1 :2020) -glucometers and test strips : Quality ISO 15197 (2015) | X | | | | | | | | |

B. SEMI-ADMINISTRATIVE FILE/FILE WITH ADDED VALUE

| Attachment | Diagnostic resources/health care equipment | | | Medical nutrition | | | Products for magistral preparations | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mandatory | Mandatory in some cases (highlighted in the description of the attachment or specified in brackets below) | Optional | Mandatory | Mandatory in some cases (highlighted in the description of the attachment or specified in brackets below) | Optional | Mandatory | Mandatory in some cases (highlighted in the description of the attachment or specified in brackets below) | Optional |
| Reason for the application: therapeutic value including<br>- Added value (only for files with added value)<br>- Usefulness - safety (adverse effects)<br>- Applicability (contraindications) - comfort | X | | | X | | | X | | |
| Reason for the application: therapeutic value → specify the following: Product protected by a patent or not | | | | | | | X | | |
| Reason for the application: consideration in the medical practice | X | | | X | | | X | | |
| Reason for the application: epidemiological | | | X | | | X | X | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| elements | | | | | | | | | |
| Reason for the proposed basis of reimbursement | X | | | X | | | X | | |
| Budgetary impact with calculation details including:<br>- Target group<br>- Estimated number of beneficiaries<br>- Presumed duration of treatment<br>- Frequency of administration in disorders for which the product can be administered<br>- Cost of treatment/Budgetary impact on an annual basis | X | | | X | | | X | | |
| Budgetary impact with calculation details including:<br>- Estimated volumes<br>- Comparison with reimbursable alternatives<br>- Ratio of insurance cost to therapeutic value | | | X | | | X | | | X |
| 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 | | | | X | | | | | |
| Copy of the acknowledgement of receipt of the notification file to the Directorate General for Animals, Plants and Food of the Federal Public Service Health, Food Chain Safety and Environment | | | | X | | | | | |
| If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: a copy of the notification for placing on the market to the Federal Agency for Medicines and Health Products for class 1 medical devices and for in vitro diagnostic medical devices | | X | | | | | | X (concerns passive dressings) | |
| If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: copy of the acknowledgement of receipt of the notification for placing on the market to the Federal Agency for Medicines and Health Products for class 1 medical devices and for in vitro diagnostic medical devices | | X | | | | | | X (concerns passive dressings) | |
| Authorisation for the placing on the market or authorisation for the placing on the market of sterile products | | | | | | | X | | |
| Detailed description of indications | X | | | X | | | | | |

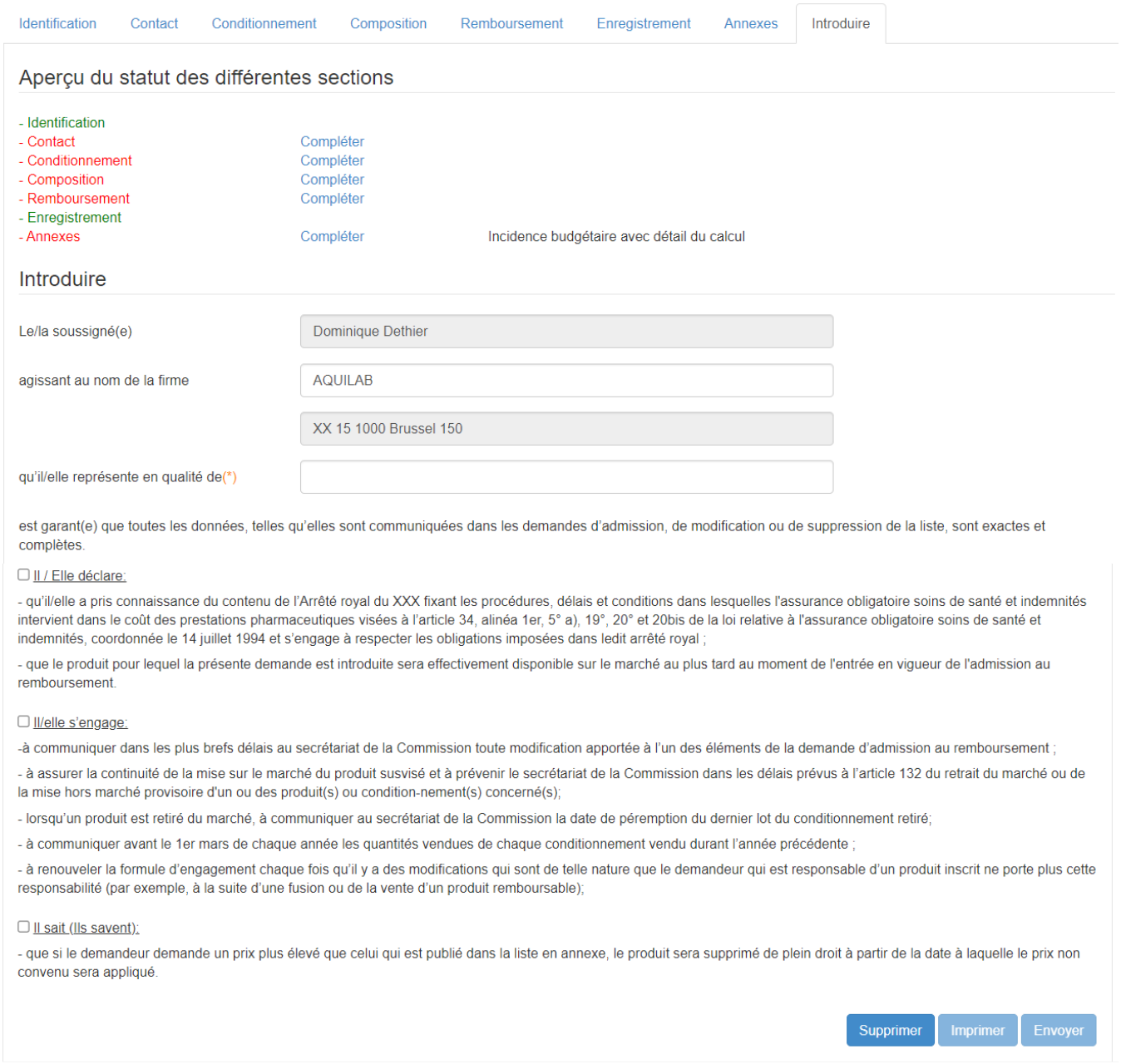
| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Reproduction of the labelling/ packaging of the product | X | | | X | | | | | |
| Information on the label, the de-scription of the primary packaging and any secondary packaging | | | | | | | X | | |
| Patient information leaflet | | | X | | | X | | | |
| Detailed description of indications | X | | | X | | | | | |
| The quality standards set by the Minister : -blood pressure monitors : Quality ISO 81060- 2 :2018/Amd 1 :2020) -glucometers and test strips : Quality ISO 15197 (2015) | X | | | | | | | | |
| Directions for use | X | | | X | | | | | |
| Most recently published clinical studies relating to existing experi-ence with the product | X | | | X | | | X | | |

2. To send the aforementioned documents as attachments, click the "Choose File" button, then select the file to be sent, and click the "Add" button. Repeat these steps if multiple attachments need to be sent.

The added attachments appear in the box below.

*Example*:

### 6.1.8. **Submit**

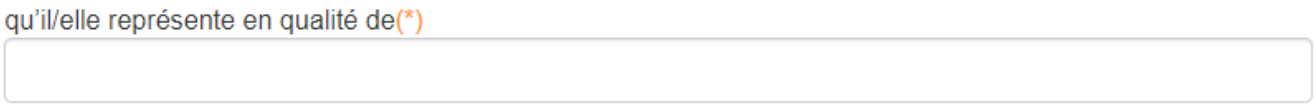

Identification
Contact
Conditionnement
Composition
Remboursement
Enregistrement
Annexes
Introduire
Aperçu du statut des différentes sections
- Identification
- Contact
Compléter
- Conditionnement
Compléter
- Composition
Compléter
- Remboursement
Compléter
- Enregistrement
- Annexes
Compléter
Incidence budgétaire avec détail du calcul
Introduire
Le/la soussigné(e)
Dominique Dethier
agissant au nom de la firme
AQUILAB
XX 15 1000 Brussel 150
qu'il/elle représente en qualité de(*)
est garant(e) que toutes les données, telles qu'elles sont communiquées dans les demandes d'admission, de modification ou de suppression de la liste, sont exactes et complètes.
Il / Elle déclare:
- qu'il/elle a pris connaissance du contenu de l'Arrêté royal du XXX fixant les procédures, délais et conditions dans lesquelles l'assurance obligatoire soins de santé et indemnités intervient dans le coût des prestations pharmaceutiques visées à l'article 34, alinéa 1er, 5° a), 19°, 20° et 20bis de la loi relative à l'assurance obligatoire soins de santé et indemnités, coordonnée le 14 juillet 1994 et s'engage à respecter les obligations imposées dans ledit arrêté royal ;
- que le produit pour lequel la présente demande est introduite sera effectivement disponible sur le marché au plus tard au moment de l'entrée en vigueur de l'admission au remboursement.
Il/elle s'engage:
-à communiquer dans les plus brefs délais au secrétariat de la Commission toute modification apportée à l'un des éléments de la demande d'admission au remboursement ;
- à assurer la continuité de la mise sur le marché du produit susvisé et à prévenir le secrétariat de la Commission dans les délais prévus à l'article 132 du retrait du marché ou de la mise hors marché provisoire d'un ou des produit(s) ou condition-nement(s) concerné(s);
- lorsqu'un produit est retiré du marché, à communiquer au secrétariat de la Commission la date de péremption du dernier lot du conditionnement retiré;
- à communiquer avant le 1er mars de chaque année les quantités vendues de chaque conditionnement vendu durant l'année précédente ;
- à renouveler la formule d'engagement chaque fois qu'il y a des modifications qui sont de telle nature que le demandeur qui est responsable d'un produit inscrit ne porte plus cette responsabilité (par exemple, à la suite d'une fusion ou de la vente d'un produit remboursable);
Il sait (Ils savent):
- que si le demandeur demande un prix plus élevé que celui qui est publié dans la liste en annexe, le produit sera supprimé de plein droit à partir de la date à laquelle le prix non convenu sera appliqué.
Supprimer
Imprimer
Envoyer

This tab gives you an overview of the status of each of the other tabs (green = "complete" or red = "to be completed").

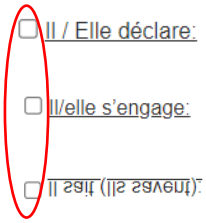
1. Where necessary, fill in any incomplete tabs.

To open an incomplete tab, click "Complete". You can also open the tab by clicking on it.

2. Complete the following field with your title:




3. After reading the terms of the commitment, tick the following 3 boxes:



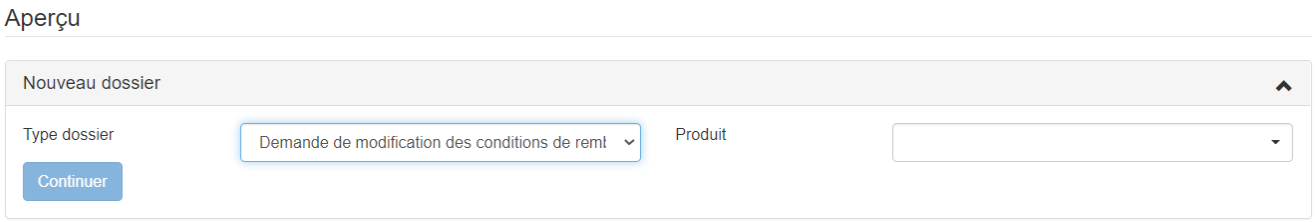

4. To print the application, click "Print". This will generate a pdf containing the different data in the application.

5. Click "Send" to send the application to INAMI-RIZIV. In this case, the application is closed and the application search screen is displayed. Once submitted, the application can still be viewed from the list of current files but cannot be modified.

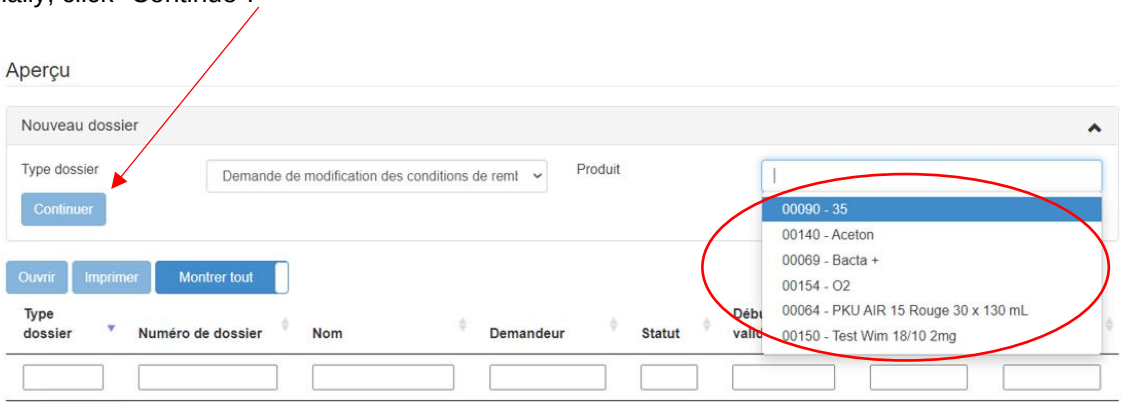
6. If you click "Delete", your application will be deleted.

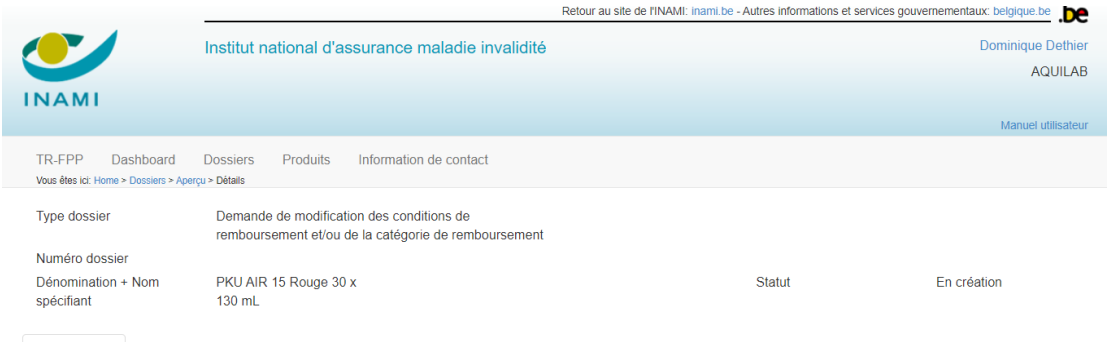
## 6.2. APPLICATION TO CHANGE THE REIMBURSEMENT CONDITIONS AND/OR REIMBURSEMENT CATEGORY

After selecting the "Application to change the reimbursement conditions and/or reimbursement category" file type, you access the first page as follows:




Since you can only change the reimbursement conditions/category of a product that is already reimbursable, select the product by clicking the "Product" field.
Select the product for which you want to submit a change request.
Finally, click "Continue".



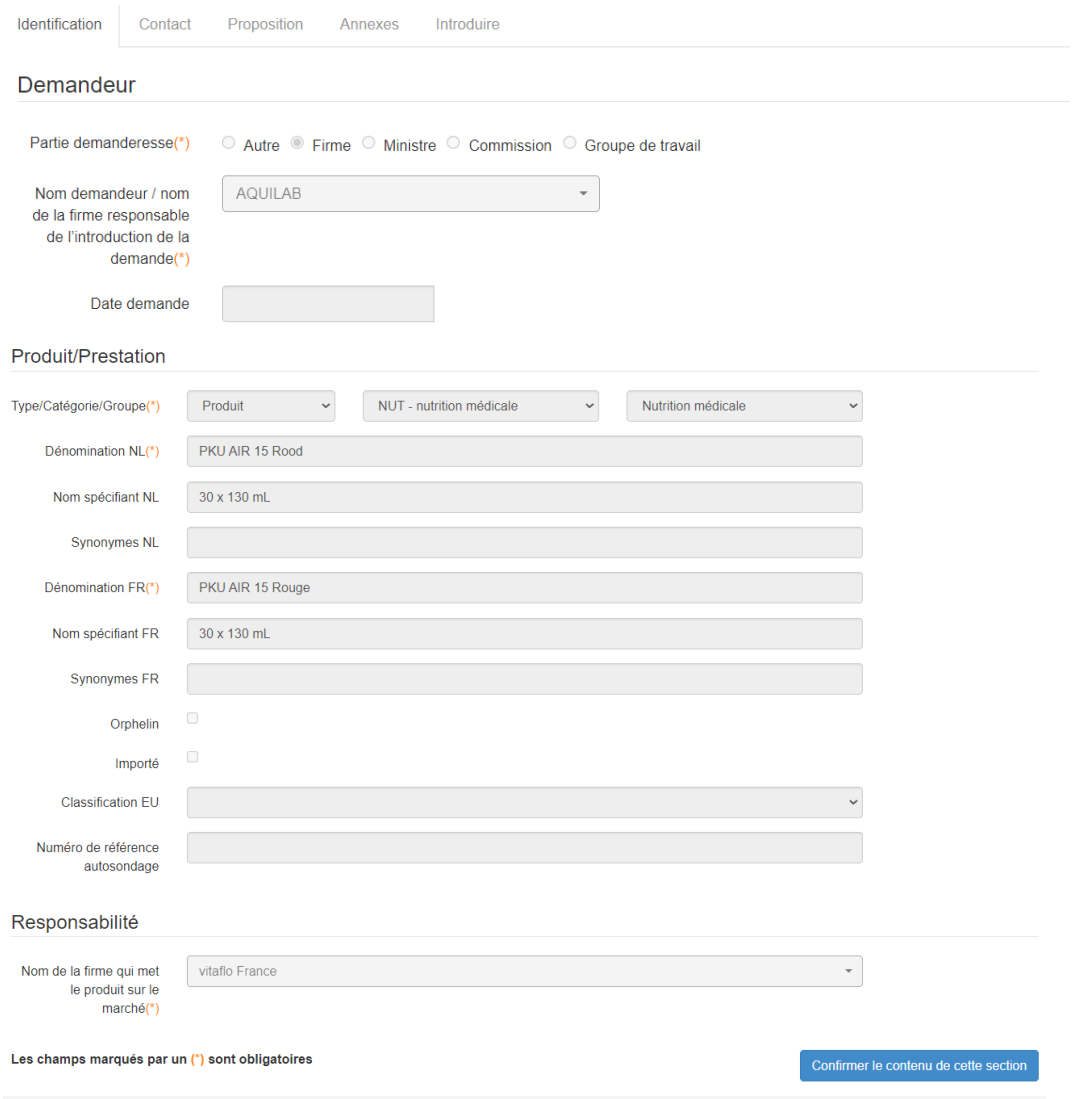

The identification data for the selected product is displayed automatically.
This includes the following data:

- The file type
- The file number: this number is created automatically
- The file status
- The name + the specifying name

These fields cannot be modified.
All this data forms the "header".

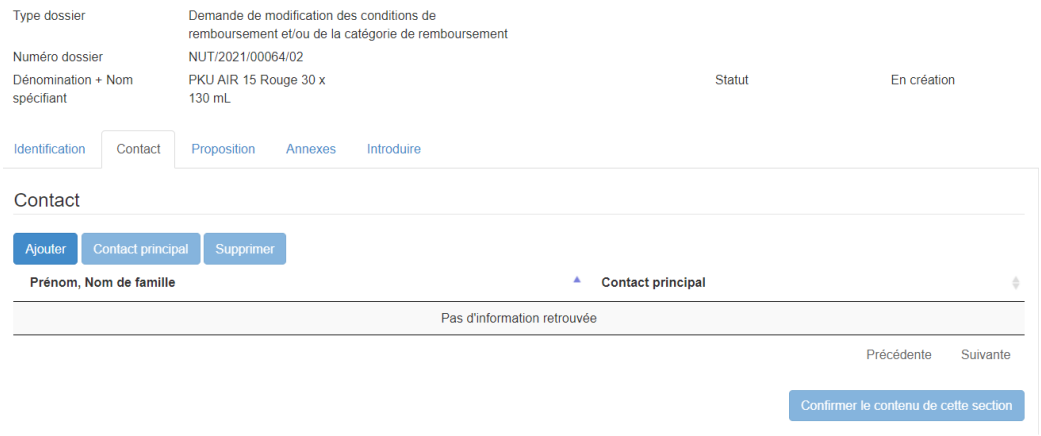
The application forms to change the reimbursement conditions/reimbursement category are all structured in the same way and contain the following tabs:
- Identification
- Contact
- Proposal
- Attachments
- Submit

### 6.2.1. **Identification**



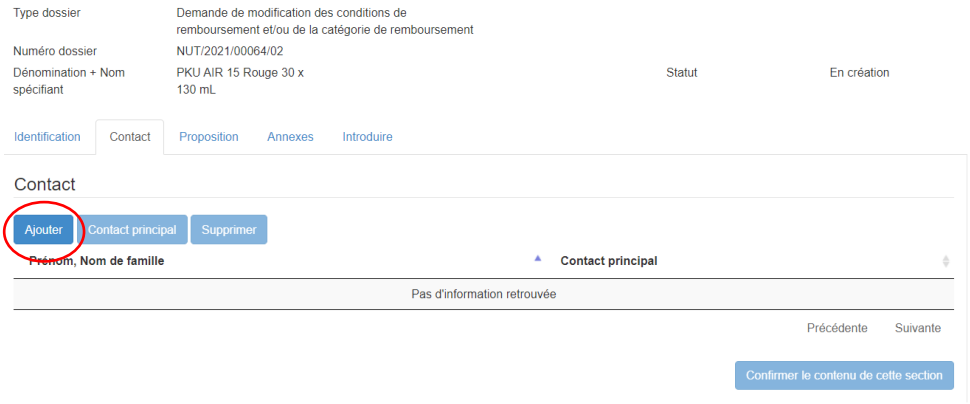

The fields are <u>automatically</u> completed:

## 6.2.2. **Contact**

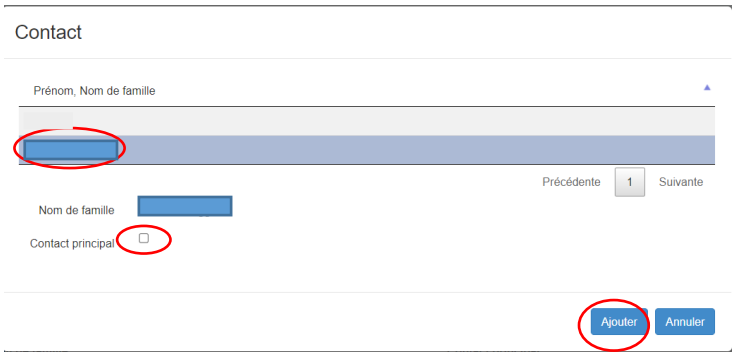



The first name and surname of the contact person(s) must be specified.

1) Click "Add"



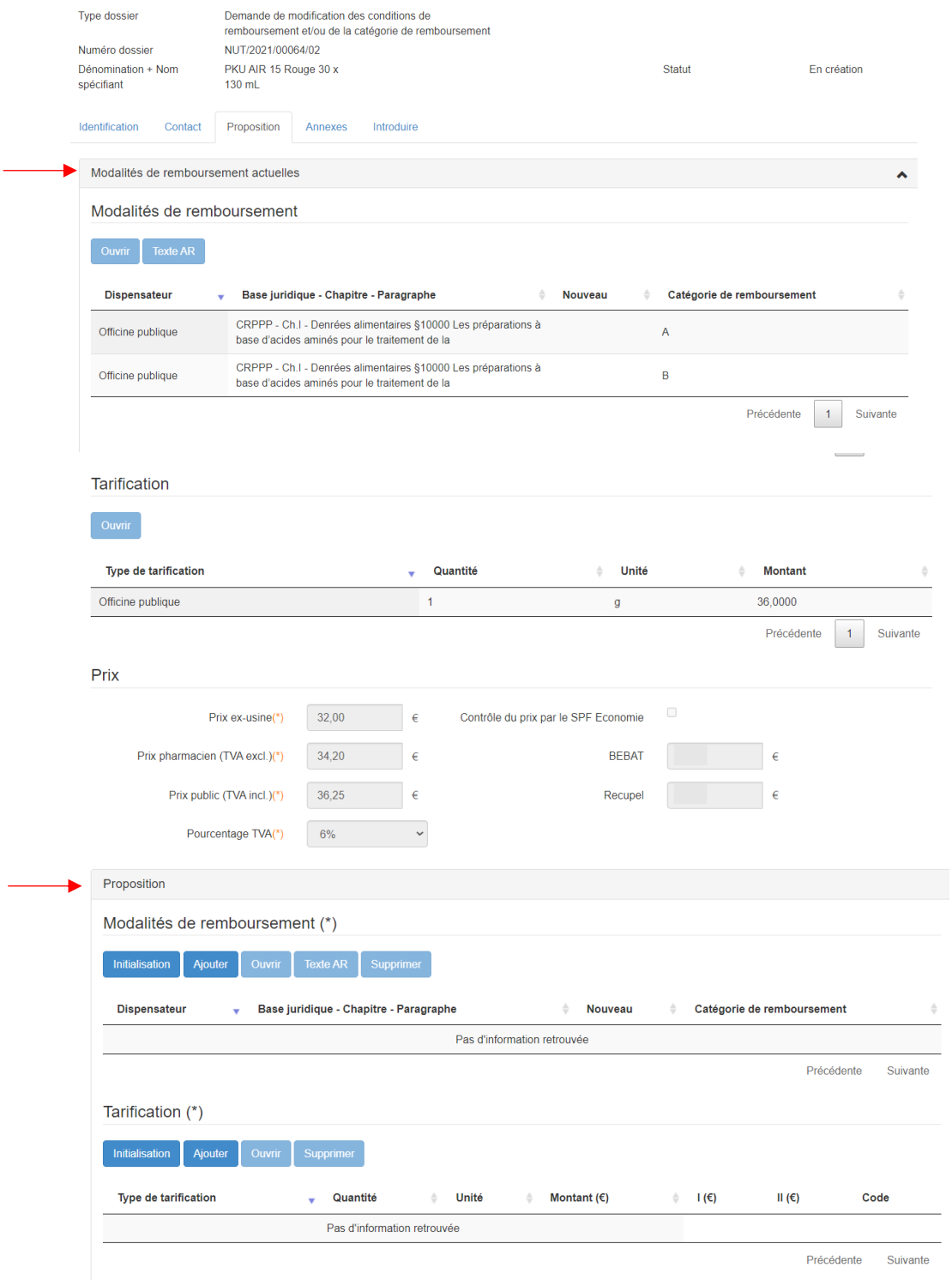

2) Choose the contact person(s) by clicking on their name and specify the primary contact by ticking " Contact principal ☐ " and click "Add".




3) "Confirm"

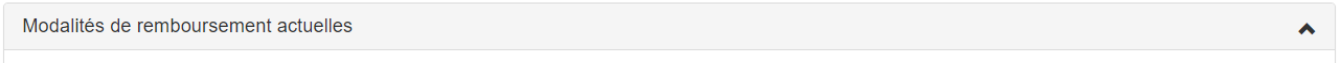
Once all fields are completed:

## 6.2.3. **Proposal**



2 sections are displayed:

- Current reimbursement terms
- Proposal

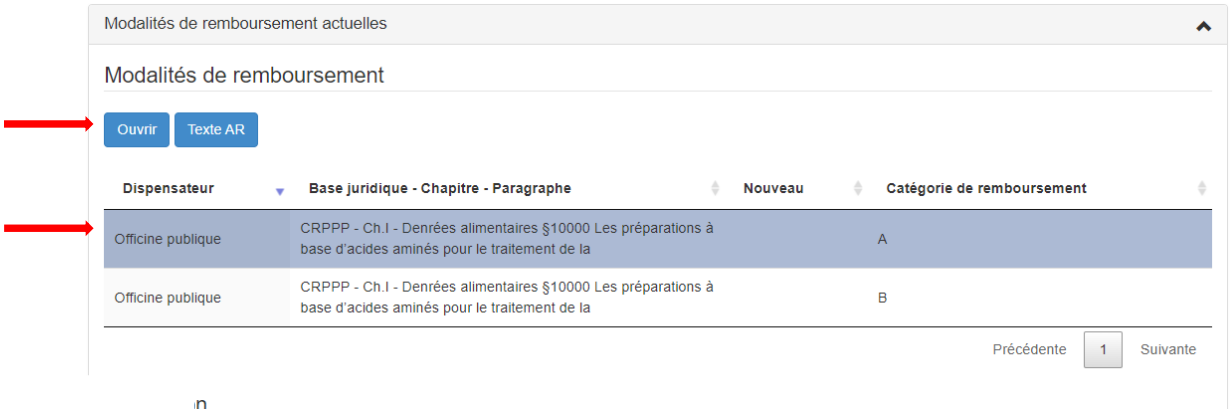



The product's current reimbursement terms/pricing system/price structure are automatically displayed.

*1. Reimbursement terms*

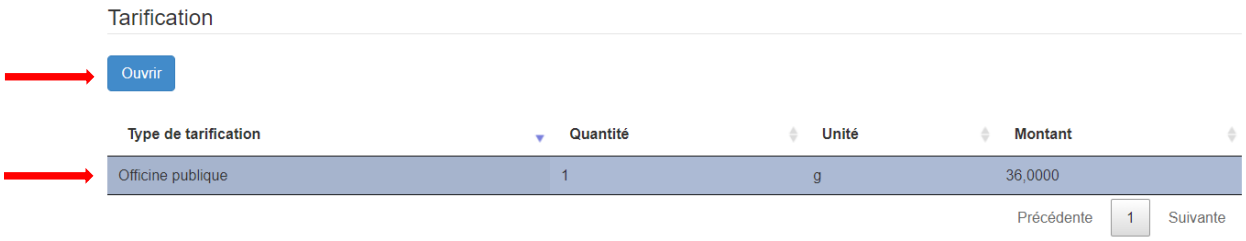
To view the current text of the reimbursement terms, select the relevant line and click "RD Text".

To view the current reimbursement terms, select the relevant line and click "Open".

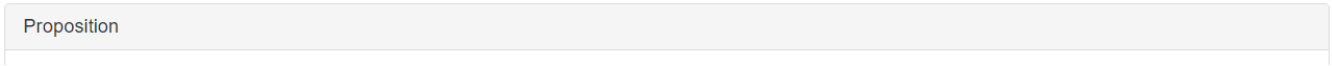



*2. Pricing system*

To view the current pricing system, select the relevant line and click "Open".




To change the current reimbursement terms/pricing system, go to the "Proposal" section



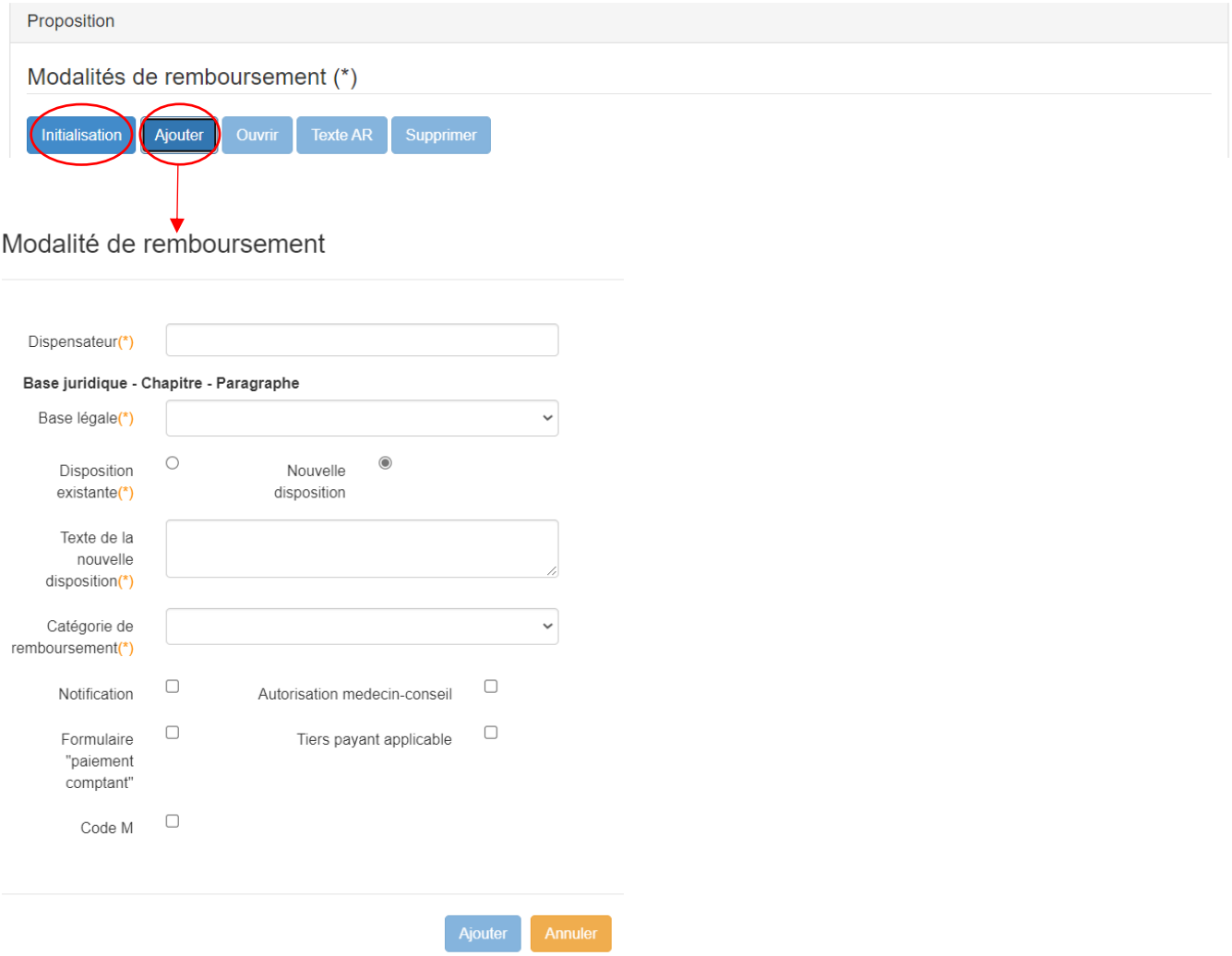

You can then specify your **proposed reimbursement terms and pricing system.**
You can add/modify/delete reimbursement terms and
price structures.

### *6.2.3.1. **ADD***

#### *6.2.3.1.1.* If you wish to *ADD reimbursement terms*.

Load the reimbursement terms in the current situation by clicking the "Initialise" button.
The current reimbursement terms then apply, meaning that these terms will always apply (otherwise, go to section 6.2.3.3. below).

You can then add another reimbursement term to these retained current reimbursement terms, by clicking the "Add" button.



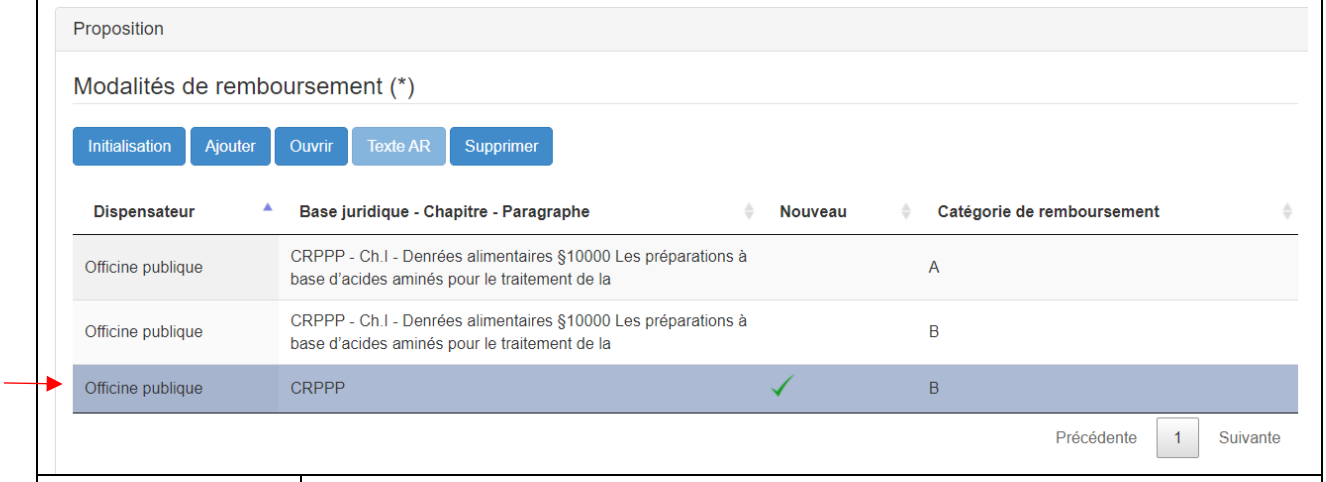

Fields marked with an asterisk (*) are MANDATORY.

| Field name | Explanations/examples |
|---|---|
| | |
| **DISPENSER** | You can choose from the following dispensers:<br>- Supplier (only for the dispensing of medical devices and self-management equipment in the context of care pathways and the "education and self-management of care" programme)<br>- Hospital pharmacy<br>- Public pharmacy<br><br>You can select multiple dispensers at one time within the same framework (as long as the reimbursement terms are the same for each of them. Otherwise, proposals must be made individually for each dispenser). |

| | |
|---|---|
| | Dispensateur(*) Fournisseur × Officine hospitalière × Officine publique × |
| **LEGAL BASIS CHAPTER PARAGRAPH** | |
| LEGAL BASIS | The legal basis of the reimbursement condition(s) (drop-down menu) |
| NEW PROVISION | Select the "New provision" option.<br><br>Enter your proposed text in the "Text of the new provision" field provided for this purpose. Specify whether it is a new chapter/paragraph/section/sub-section.<br><br>Texte de la nouvelle disposition(*)<br><br>*Example*:<br>"TITLE 3. Products for magistral preparations - Chapter IV - new § "xxxxxxxxx". |
| REIMBURSEMENT CATEGORY | Reimbursement category (drop-down menu) |
| | |
| - NOTIFICATION<br>- MEDICAL OFFICER AUTHORISATION<br>- "CASH PAYMENT" FORM<br>- APPLICABLE THIRD PARTY PAYMENT | If applicable, tick the appropriate reimbursement condition.<br><br>"Applicable third party payer" means either the statement "applicable third party payer" itself or any other written statement as specified in the regulations. |
| | |
| M CODE | If applicable, tick "M Code"<br><br>An M code means that more than one package can be prescribed on the same prescription, while guaranteeing reimbursement for each of the packages prescribed. |
| | |
| Once all fields are completed:<br><br>Click → Ajouter | |

You can then view the proposed reimbursement terms

*Example*:

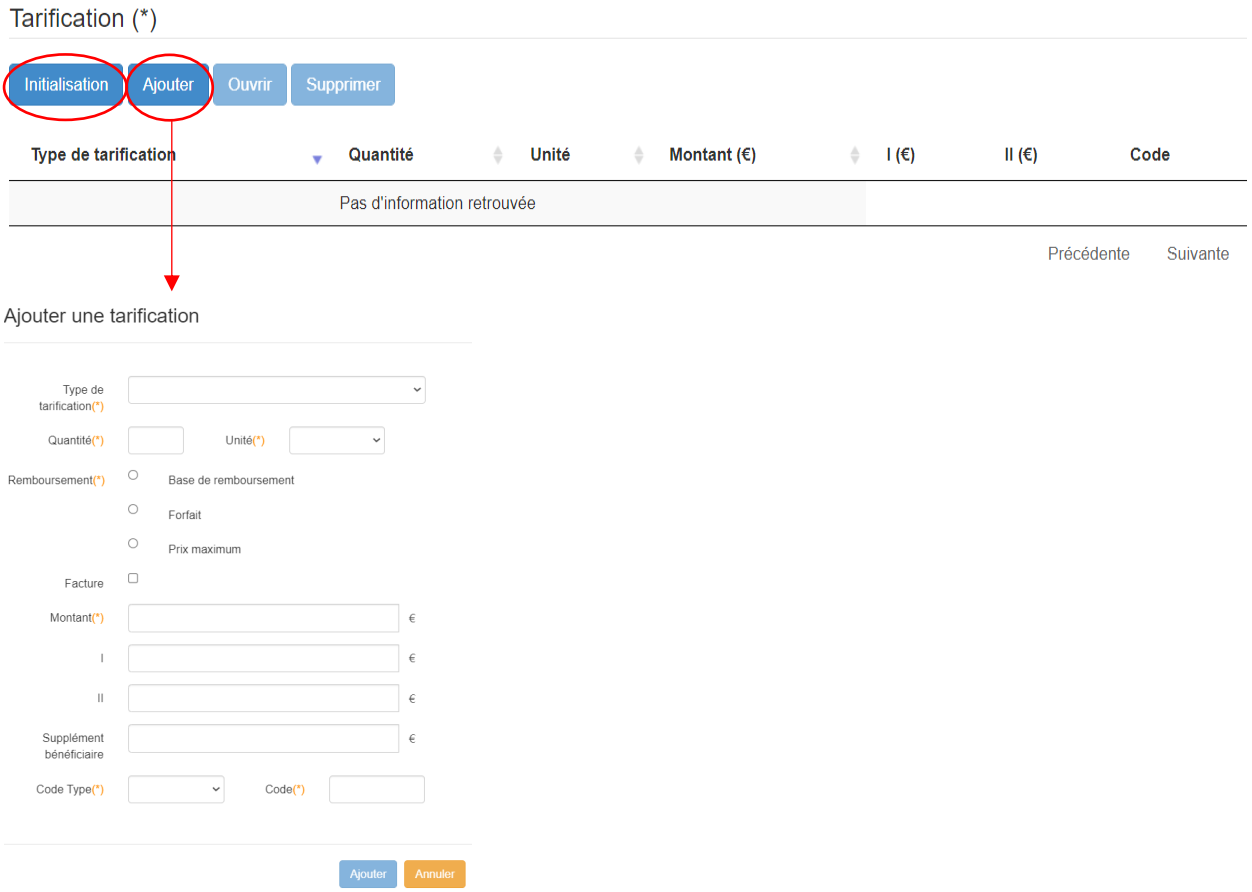



In this section, you can also view the new data entered by clicking the "Open" button after selecting the line for which you want to view the data.
You can delete the data entered by clicking the "Delete" button after selecting the appropriate line.

*6.2.3.1.2.* If you wish to *ADD a pricing system*.

Load the pricing system in the current situation by clicking the "Initialise" button.
The current pricing system then applies, which means that this pricing system will always apply (otherwise, go to section 6.2.3.3. below).

You can then add another pricing system to this retained current pricing system, by clicking the "Add" button.



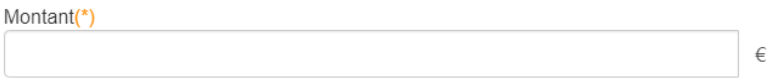

Fields marked with an asterisk (*) are MANDATORY.

| Field name | Explanations/examples |
|---|---|
| | |
| TYPE OF PRICING SYSTEM | The type of pricing system (drop-down menu).<br>If you are proposing a pricing system for multiple types of dispensing, you must complete the "Add a pricing system" table as many times as there are "Types of pricing system".<br><br>The requested pricing system must match the dispensing requested in the reimbursement conditions, i.e., outpatient hospital dispensing, inpatient hospital dispensing, dispensing by a public pharmacy or by a supplier.<br><br>The pricing system for dispensing by a supplier can only be used for the dispensing of medical devices and self-management equipment in the context of care pathways and the "education and self-management of care" programme. |
| | |
| QUANTITY | Number of units by which the product will be priced in the selected dispensing. |

| | |
|---|---|
| | For dispensing by the supplier or in public pharmacies, the pricing system relates to the package.<br>For dispensing by the hospital pharmacist, the pricing system is per unit. |
| UNIT | The units by which the product will be priced in the selected dispensing.<br><br>**!!!** For the pricing system of oxygen concentrators, the units to be selected are:<br>- Installation by the supplier<br>- Rental and maintenance<br>- Single use humidifier<br>- Pharmacist's fee (= fee for therapy support and pricing system coordination)<br><br>*Example*<br>*Medical device: MUCOCLEAR 6%*: |

| Criterium Criteria | Code Code | Benaming en verpakkingen Name and packaging | Opm. Obs. | Prijs Price | Basis van tege-moetk. Basis of reim-burse-ment | I | II |
|---|---|---|---|---|---|---|---|
| B | | MUCOCLEAR 6 (Henrotech) | | | | | |
| | 2456-010 | 60 x 4 mL hypertonic solution/ hypertonische oplossing | M | 58.79 | 58.79 | 8.00 | 12.10 |

Public pharmacy = full package pricing system → 60 x 4 mL = 240 mL

| | |
|---|---|
| | |
| REIMBURSEMENT | Tick the appropriate box.<br>You can choose between:<br>- basis of reimbursement<br>- flat rate<br>- maximum price<br><br>Then propose the basis of reimbursement/flat rate/maximum price using the "Amount" field<br>  <br><br><br>Where applicable, for medical devices and food for special medical purposes, the basis of reimbursement is the public price of the product.<br><br>!!! In the case of products for magistral preparations, please note a basis of reimbursement of "0". The basis of reimbursement is calculated by the Commission according to the rules set out in the regulations.<br><br>!!! For the tariff types " Officine hospitalière – patients ambulants " and " Officine hospitalière – patients hospitalisés ", the box "Montant" should not be filled in<br><br> <br> |

If applicable, next propose the amounts of the beneficiaries' personal contributions using fields I and II.

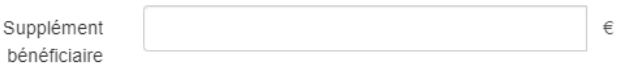
- column I = contribution of the beneficiary referred to in Article 37 § 19 of the Law who is entitled to enhanced insurance cover
- column II = contribution of other beneficiaries

For food for special medical purposes and medical devices, the beneficiaries' contributions are set out in the corresponding regulations:

- Royal Decree of 24 October 2002 establishing beneficiaries' personal contribution to the cost of food for special medical purposes reimbursable within the framework of the compulsory health care and benefits insurance
- Royal Decree of 24 October 2002 establishing beneficiaries' personal contribution to the cost of diagnostic resources and health care equipment reimbursable within the framework of the compulsory health care and benefits insurance

!!! This does not apply to products for magistral preparations or in the context of dispensing by the hospital pharmacy to ambulant and hospitalised patients

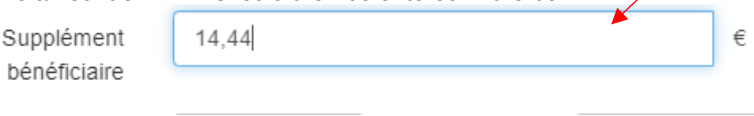
In some cases (e.g. blood pressure monitors, self-catheterisation probes), the beneficiary will have to pay a supplement.




*Example – blood pressure monitors VEROVAL DUO CONTROL LARGE*

| CNK Code/ Code CNK | Benaming Dénomination | BEBAT (excl. TVA – excl. BTW) | RECUPEL (excl. TVA – excl. BTW) | Apothekerprijs (incl. BTW, BEBAT, RECUPEL) Prix pharmacien (incl. TVA, BEBAT, RECUPEL) | Toeslag rechthebbende Supplément bénéficiaire |
|---|---|---|---|---|---|
| 3730918 7114523* | VEROVAL DUO CONTROL LARGE Paul Hartman | 0,0630 | 0,3306 | 74,44 € | 14,44 € |

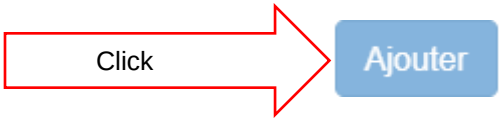
The amount of 14.44 should then be entered in the box




Then complete in the CNK codes for both dispensing by public pharmacy and supplier (one and the same CNK for both if applicable).

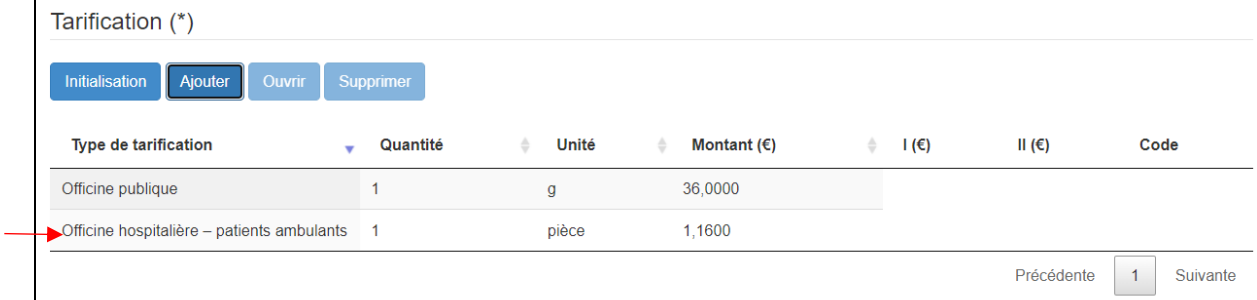
- click "code type": CNK will appear then click the word "CNK".
- then enter the CNK code in the second box

Once all fields are completed:



You can then view the proposed pricing system

*Example*:



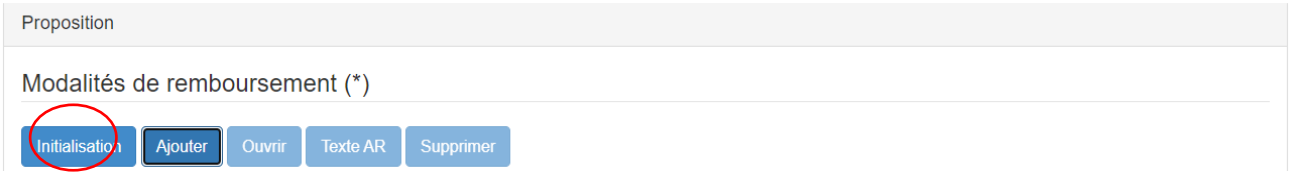

In this section, you can also view the new data entered by clicking the "Open" button after selecting the line for which you want to view the data.
You can delete the data entered by clicking the "Delete" button after selecting the appropriate line.

Once all fields are completed:

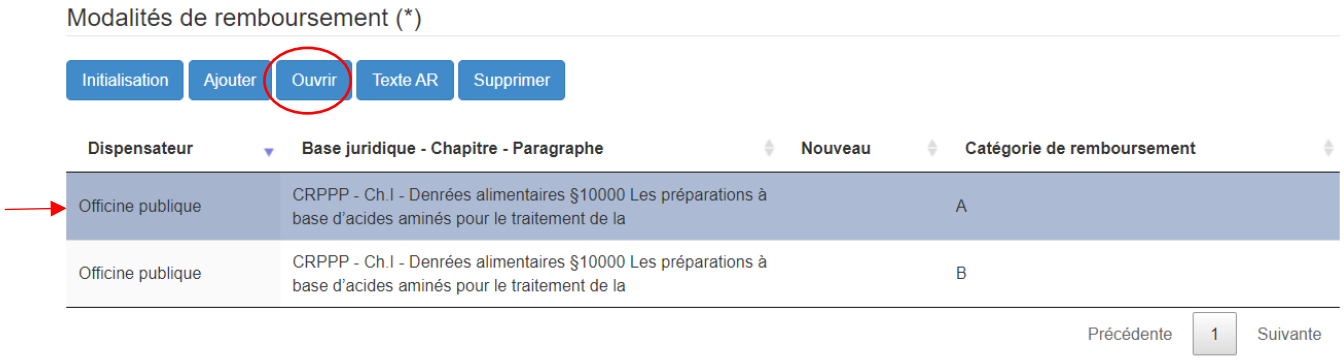
### *6.2.3.2. **MODIFY***

6.2.3.2.1. If you wish to *MODIFY the reimbursement terms*.

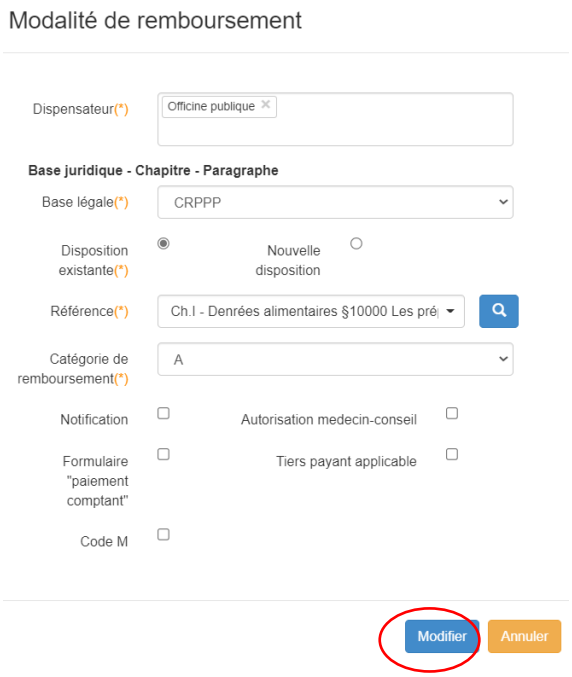
Load the reimbursement terms in the current situation by clicking the "Initialise" button.
You can then change these reimbursement terms.




Then select the line to be modified and click the "Open" button.




Modify the fields according to your new proposal and click "Modify".

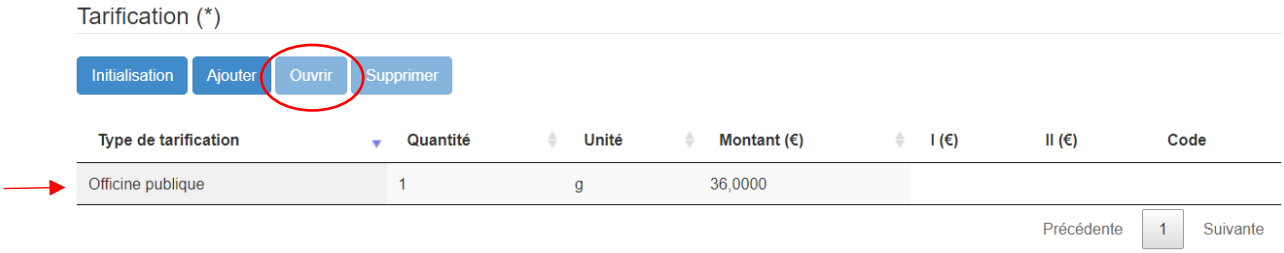



The new reimbursement terms appear in the proposed reimbursement terms.

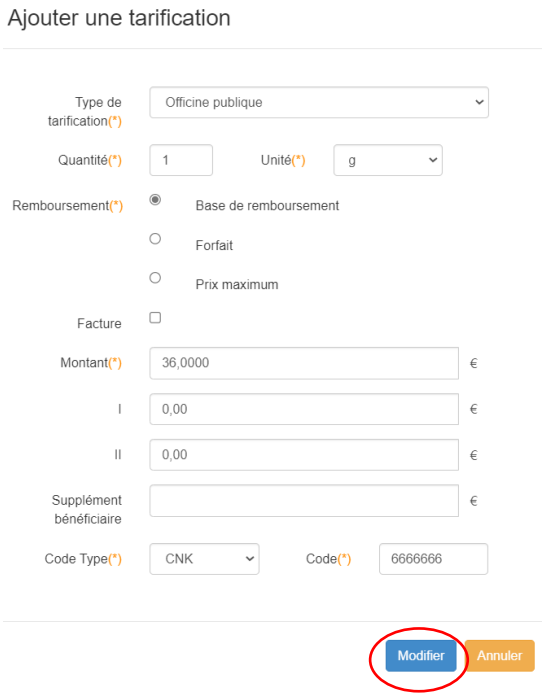
6.2.3.2.2. If you wish to *MODIFY the pricing system*.

Load the pricing system in the current situation by clicking the "Initialise" button.
You can then change this pricing system.

Select the line to be modified and click the "Open" button.




Modify the fields according to your new proposal and click "Modify".




The new price structure appears in the proposed pricing system.

Once all fields are completed:

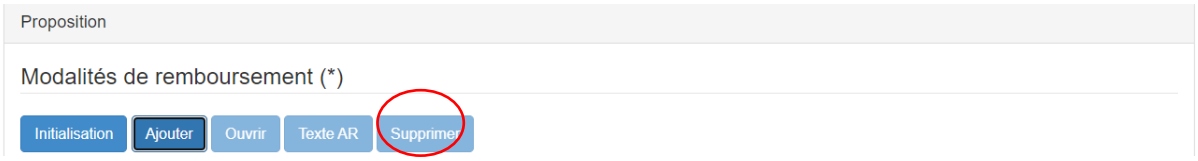
Click → Confirmer le contenu de cette section

### 6.2.3.2. ***DELETE***

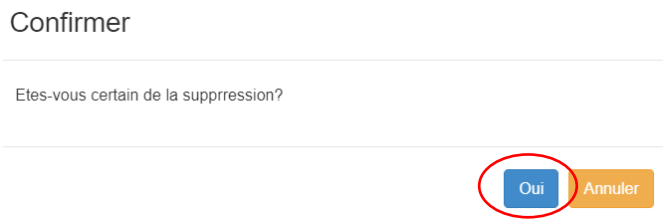
#### 6.2.3.2.1. If you wish to *DELETE the reimbursement terms*.

Load the reimbursement terms in the current situation by clicking the "Initialise" button.
You can then delete these reimbursement terms.

Select the line to be modified and click the "Delete" button.




Then confirm your deletion request by clicking "Yes".

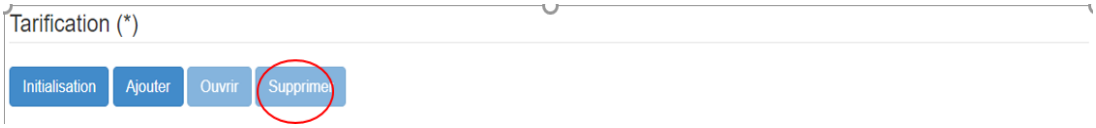



The reimbursement terms no longer appear in the proposed reimbursement terms.

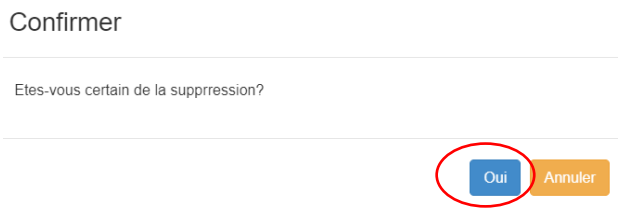
6.2.3.3.2. If you wish to *DELETE a pricing system*.

Load the pricing system in the current situation by clicking the "Initialise" button.
You can then delete this price structure.

Select the line to be modified and click the "Delete" button.



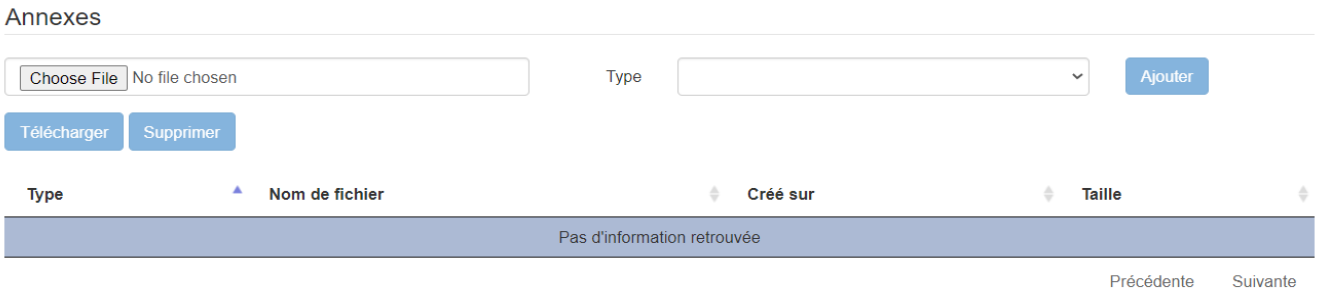

Then confirm your deletion request by clicking "Yes".




The new price structure no longer appears in the proposed pricing system.
Once all fields are completed:

Upon approval, the formulated proposal will completely replace the current reimbursement terms/price structure.

### 6.2.4. **Attachments**




In this section, you must add the mandatory attachments to support the application (WORD documents, PDF documents,...).

1. The required/recommended attachments are specified in the "Type" attribute and depend on the product category (diagnostic resources and health care equipment/magistral preparations or medical nutrition).

   They are classified into 3 types:
   - Mandatory
   - Mandatory in some cases
   - Optional

   Select the file type to be sent from the list

The list of attachments is as follows:

| Attachment | Diagnostic resources/health care equipment | | | Medical nutrition | | | Products for magistral preparations | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mandatory | Mandatory in some cases (highlighted in the description of the attachment or specified in brackets below) | Optional | Mandatory | Mandatory in some cases (highlighted in the description of the attachment or specified in brackets below) | Optional | Mandatory | Mandatory in some cases (highlighted in the description of the attachment or specified in brackets below) | Optional |
| Reason for the application: therapeutic value | X | | | X | | | X | | |
| Reason for the application: consideration in the medical practice | X | | | X | | | X | | |
| Reason for the application: epidemiological elements | | | X | | | X | | | X |
| Budgetary impact with calculation details including:<br>- Target group<br>- Estimated number of beneficiaries<br>- Presumed duration of treatment<br>- Frequency of administration in disorders for which the product can be administered<br>- Cost of treatment/Budgetary impact on an annual basis<br>- Estimated volume<br>- Comparison with reimbursable therapeutic alternatives<br>- Ratio of insurance cost to therapeutic value | X | | | X | | | X | | |
| Copy of the declaration of compliance with Directive 93/42/EEC or Regulation (EU) 2017/745 for medical devices | | X | | | | | | 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 | | | | | | 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 | | | | X | | | | | |
| Copy of the acknowledgement of receipt of the notification file to the Directorate General for Animals, Plants and Food of the Federal Public Service Health, Food Chain Safety and Environment | | | | X | | | | | |

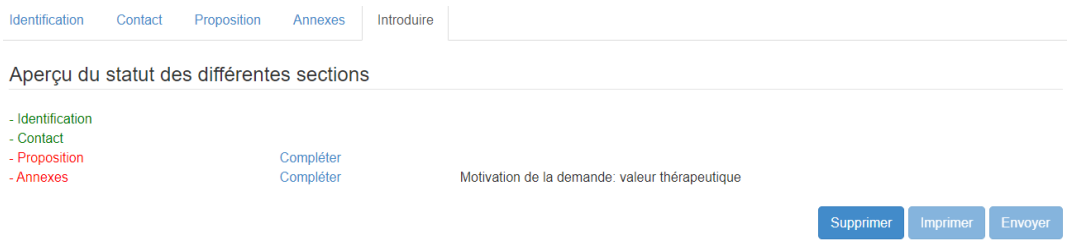
| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: a copy of the notification for placing on the market to the Federal Agency for Medicines and Health Products for class 1 medical devices and for in vitro diagnostic medical devices | | X | | | | | | X | |
| If the manufacturer or the manufacturer's authorised representative outside Europe is in Belgium: copy of the acknowledgement of receipt of the notification for placing on the market to the Federal Agency for Medicines and Health Products for class 1 medical devices and for in vitro diagnostic medical devices | | X | | | | | | X | |
| Authorisation for the placing on the market or authorisation for the placing on the market of sterile products | | | | | | | X | | |
| Detailed description of indications | X | | | X | | | X | | |
| Reproduction of labelling/ packaging of the product | X | | | X | | | | | |
| Information on the label, the description of the primary packaging and any secondary packaging | | | | | | | X | | |
| Patient information leaflet | | | X | | | X | | | |
| ~~The quality standard(s) set by the Minister~~ | | | | | | | | | |
| Most recently published clinical studies relating to existing experience with the product | X | | | X | | | X | | |

2. To send the aforementioned documents as attachments, click the "Choose File" button, then select the file to be sent, and click the "Add" button. Repeat these steps if multiple attachments need to be sent.

The added attachments appear in the box below.

*Example*:

### 6.2.5. **Submit**




1. This tab gives you an overview of the status of each of the other tabs (green = "complete" or red = "to be completed"). Where necessary, fill in any incomplete tabs.

To open an incomplete tab, click "Complete". You can also open the tab by clicking on it.

2. To print the application, click "Print". This will generate a pdf containing the different data in the application.

3. Click "Send" to send the application to INAMI-RIZIV. In this case, the application is closed and the application search screen is displayed. Once submitted, the application can still be viewed from the list of current files but cannot be modified.

4. If you click "Delete", your application will be deleted.

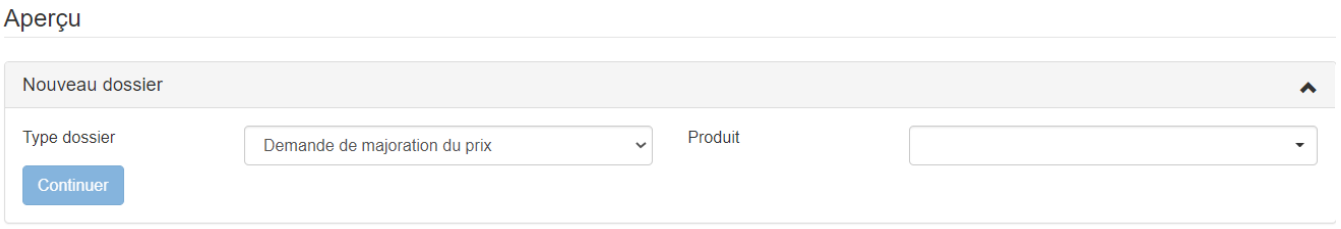
## 6.3. APPLICATION FOR A PRICE INCREASE

### *6.3.1. Preliminary remark*

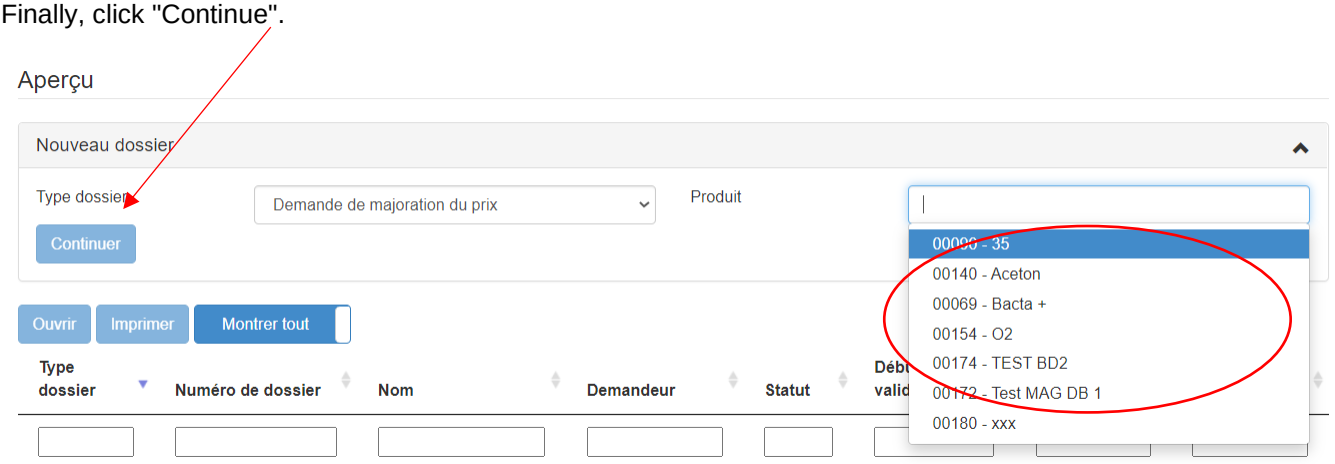
The purpose of the application is not to receive approval (or not) for the application to increase the price applied to the product but to receive an opinion on the possible adjustment of the basis of reimbursement/flat rate/maximum price applied to the product following the price increase.

### *6.3.2. Price increase for a reimbursable product or one or more package(s) of a reimbursable product*

After selecting the "Application for a price increase" file type, you access the first page as follows:




Since you can only change the basis of reimbursement for a product that is already reimbursable, select the product by clicking the "Product" field.
Select the product for which you want to submit a change request.
Finally, click "Continue".



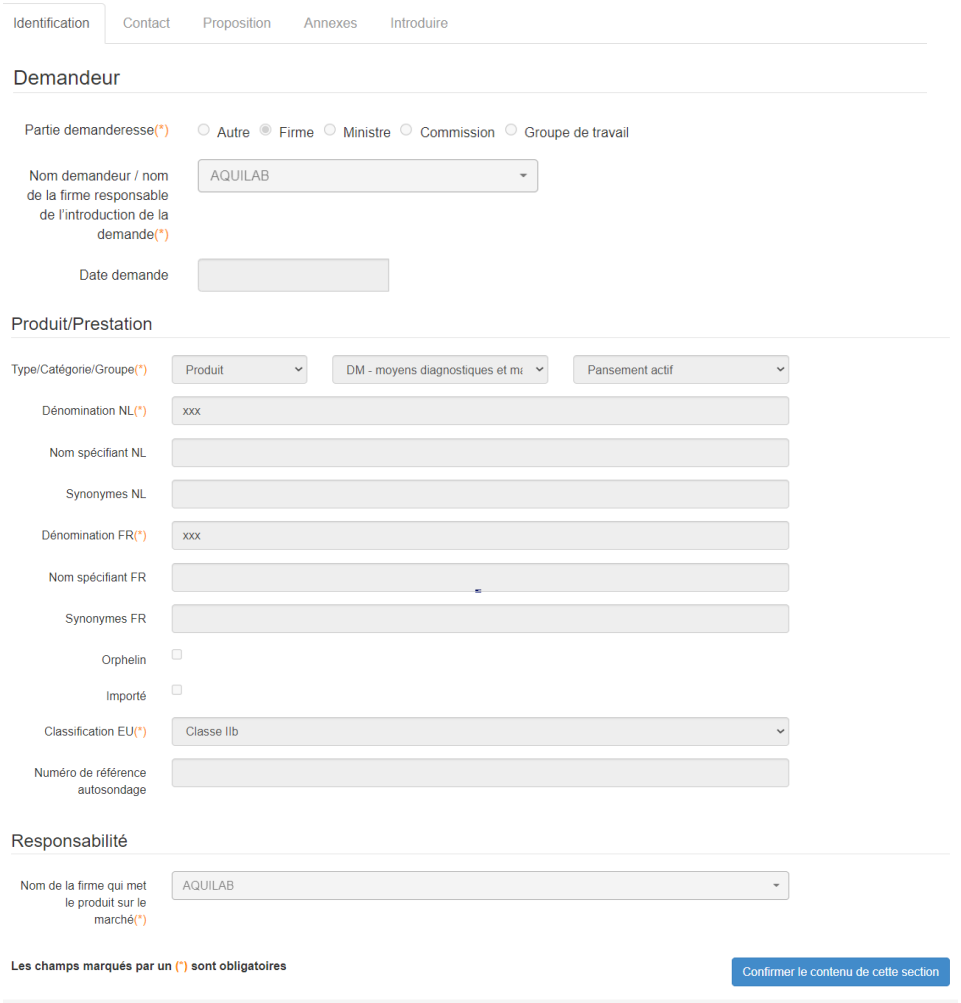
The identification data for the selected product is displayed automatically.
This includes the following data:

- The file type
- The file number: this number is created automatically
- The file status
- The name + the specifying name

These fields cannot be modified.
All this data forms the "header".

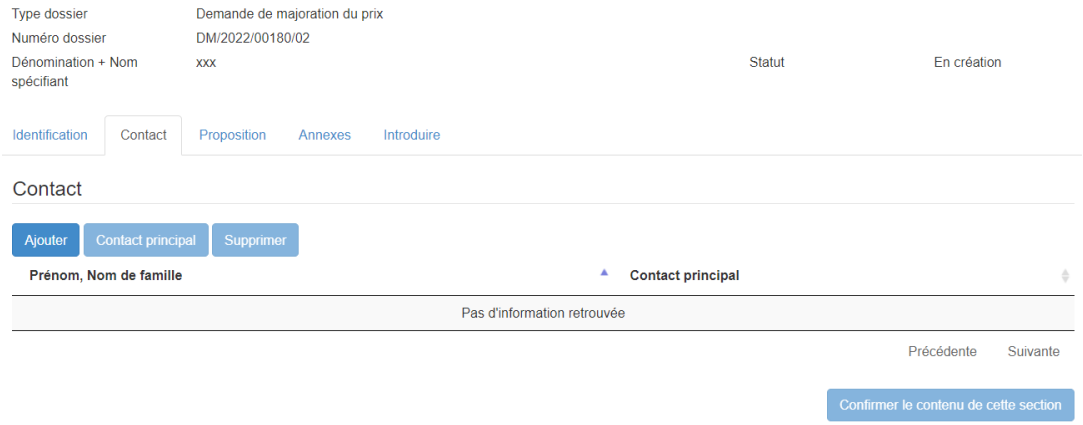
The application forms for a price increase are all structured along the same lines and consist of the following tabs:
- Identification
- Contact
- Proposal
- Attachments
- Submit

### 6.3.2.1. **Identification**



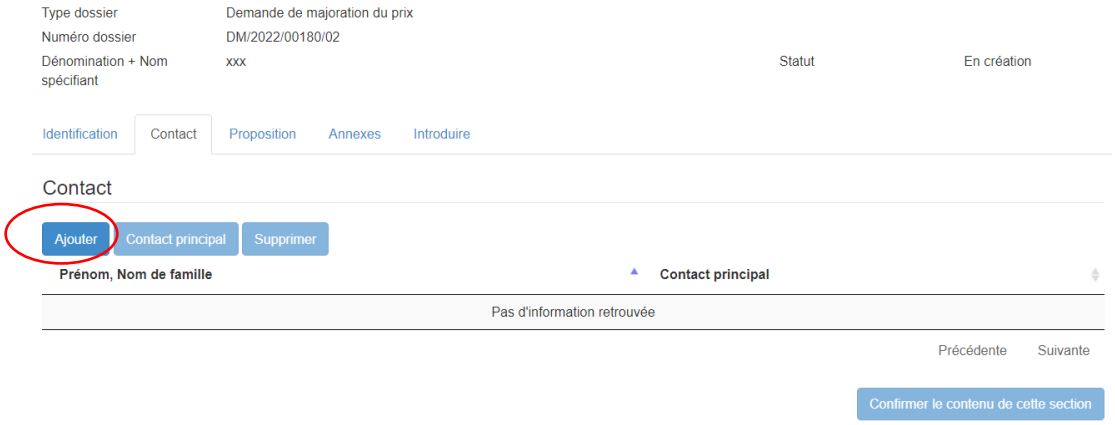

The fields are automatically completed:

### 6.3.2.2. **Contact**

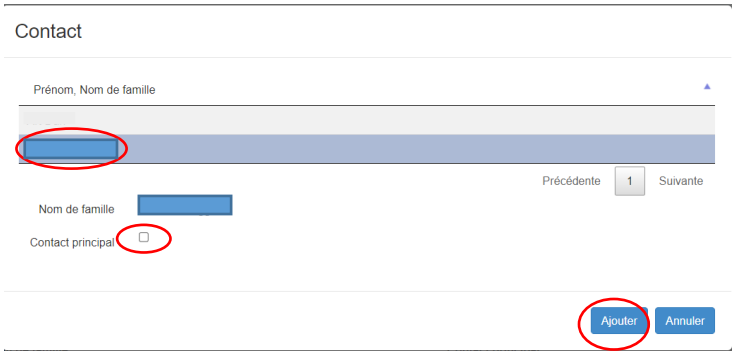



The first name and surname of the contact person(s) must be specified.

1) Click "Add"



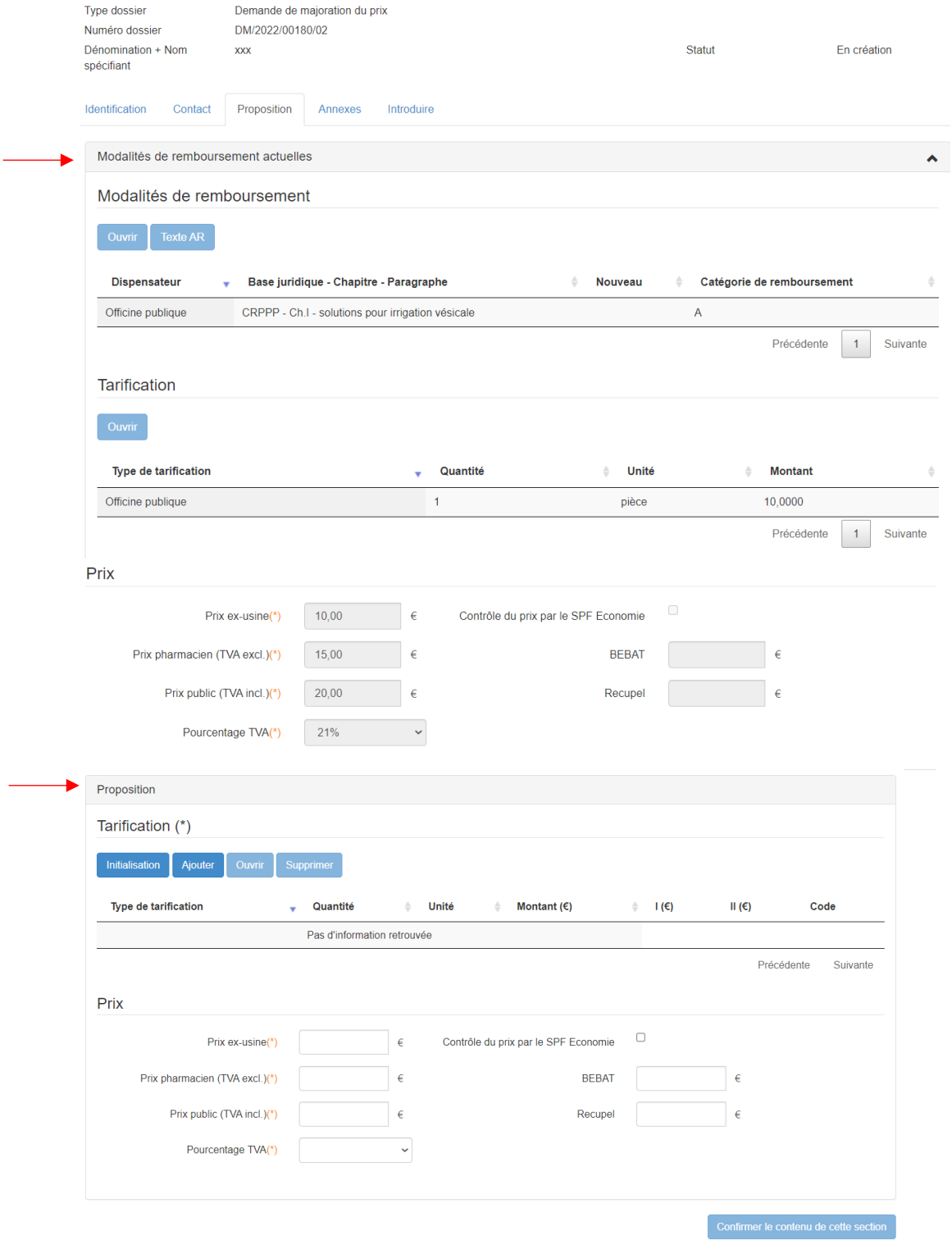

2) Choose the contact person(s) by clicking on their name and specify the primary contact by ticking " Contact principal ☐ " and click "Add".




3) "Confirm"

Once all fields are completed:

## 6.3.2.3. **Proposal**



2 sections are displayed:

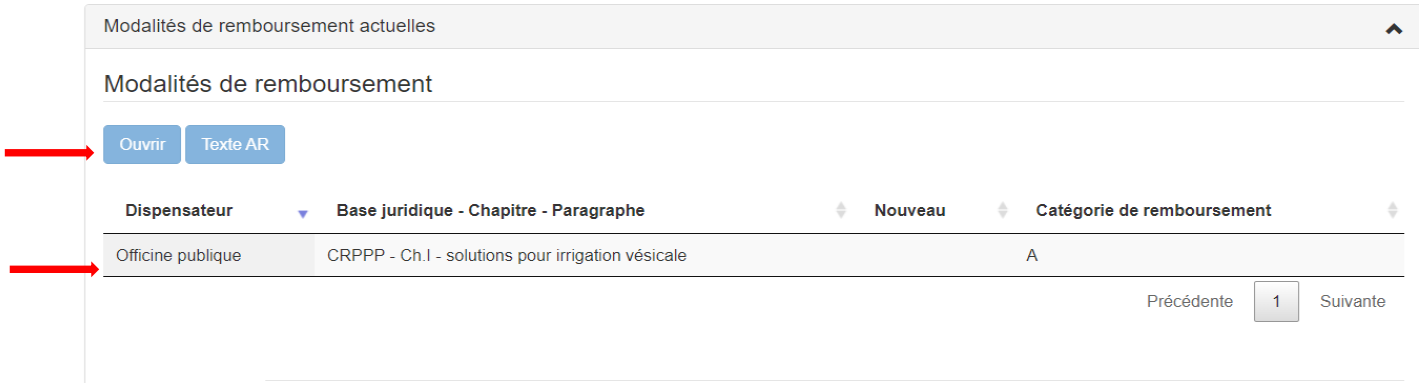
- Current reimbursement terms
- Proposal

The product's current reimbursement terms/pricing system/price structure are automatically displayed.

*1. Reimbursement terms*

To view the current text of the reimbursement terms, select the relevant line and click "RD Text".

To view the current reimbursement terms, select the relevant line and click "Open".

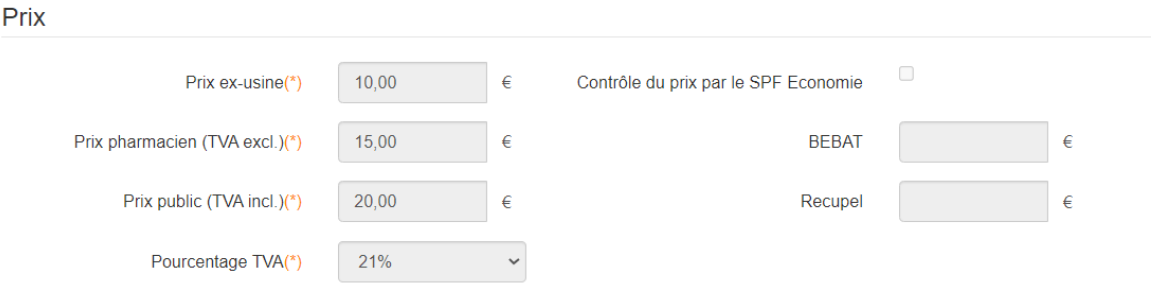



*2. Pricing system*

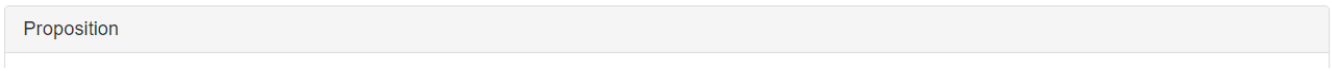
To view the current pricing system, select the relevant line and click "Open".

*3. Price*

The data for the "current" price structure is displayed.



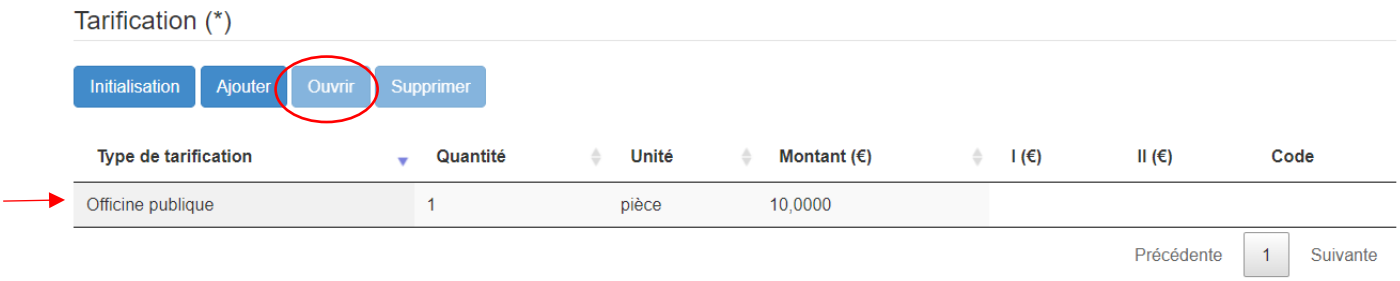
To change the current pricing system/price structure, go to the "Proposal" section




Then specify your **proposed price and pricing system.**
You can change the pricing system according to the proposed new price structure.

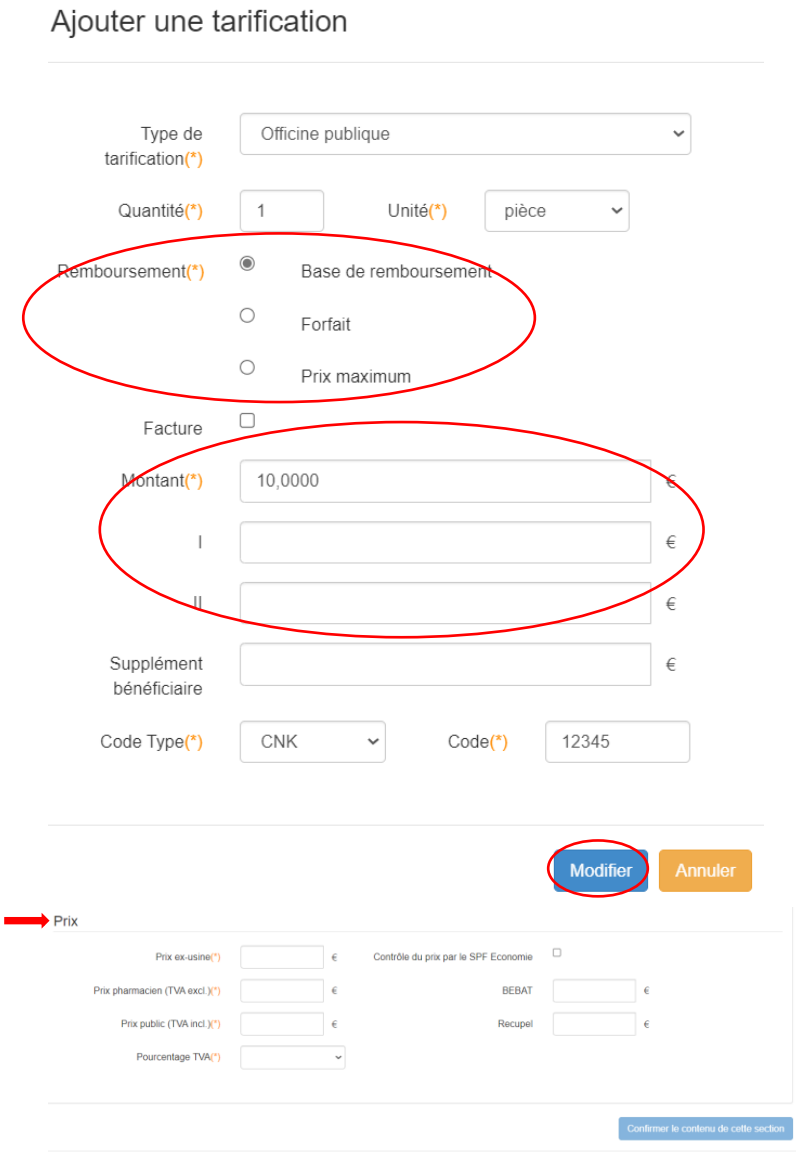
Load the pricing system in the current situation by clicking the "Initialise" button.
You can then change this pricing system.

Select the line to be modified and click the "Open" button.




Modify the fields according to your new proposal and click "Modify".

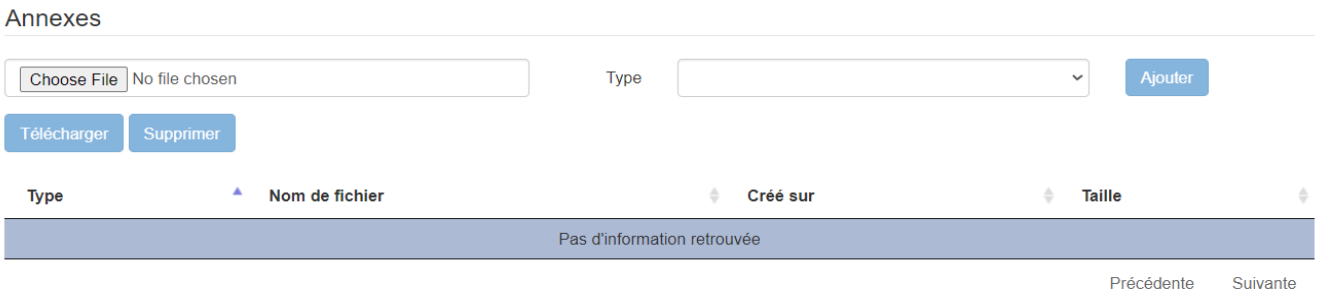
Since the application is for a price increase, the proposed pricing system change will ONLY affect the amount of the basis of reimbursement/flat rate/maximum price in accordance with the new price structure that must also be proposed.




Once all fields are completed:

Click → Confirmer le contenu de cette section

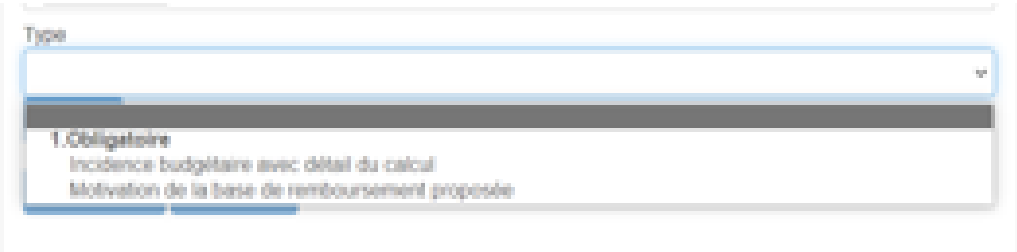
6.3.2.4. **Attachments**




In this section, you must add the mandatory attachments to support the application (WORD documents, PDF documents,...).

1. The mandatory attachments are specified in the "Type" attribute.

   Select the file type to be sent from the list




The list of attachments is as follows:

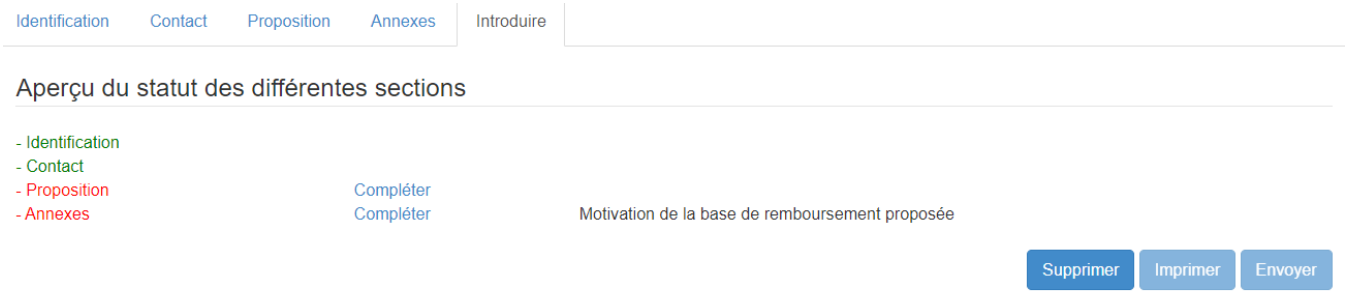
| Diagnostic resources/health care equipment - Medical nutrition - Products for magistral preparations | |
|---|---|
| | |
| Attachments | Mandatory |
| | |
| Budgetary impact with calculation details including:<br>- Target group<br>- Estimated number of beneficiaries<br>- Presumed duration of treatment<br>- Frequency of administration in disorders for which the product can be administered<br>- Cost of treatment/Budgetary impact on an annual basis<br>- Estimated volume | X |
| Calculation method for the new basis of reimbursement/flat rate/maximum amount | X |

2. To send the aforementioned documents as attachments, click the "Choose File" button, then select the file to be sent, and click the "Add" button. Repeat these steps if multiple attachments need to be sent.

The added attachments appear in the box below.

*Example*:

6.3.2.5. **Submit**




1. This tab gives you an overview of the status of each of the tabs (green = "complete" or red = "to be completed"). Where necessary, fill in any incomplete tabs.

To open an incomplete tab, click "Complete". You can also open the tab by clicking on it.

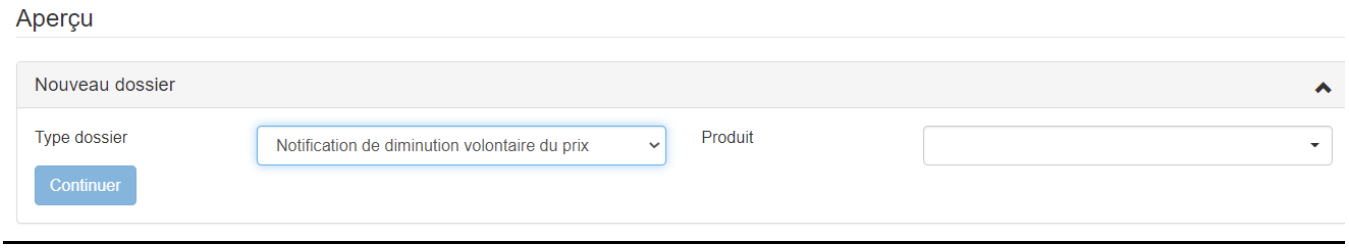
2. To print the application, click "Print". This will generate a pdf containing the different data in the application.

3. Click "Send" to send the application to INAMI-RIZIV. In this case, the application is closed and the application search screen is displayed. Once submitted, the application can still be viewed from the list of current files but cannot be modified.

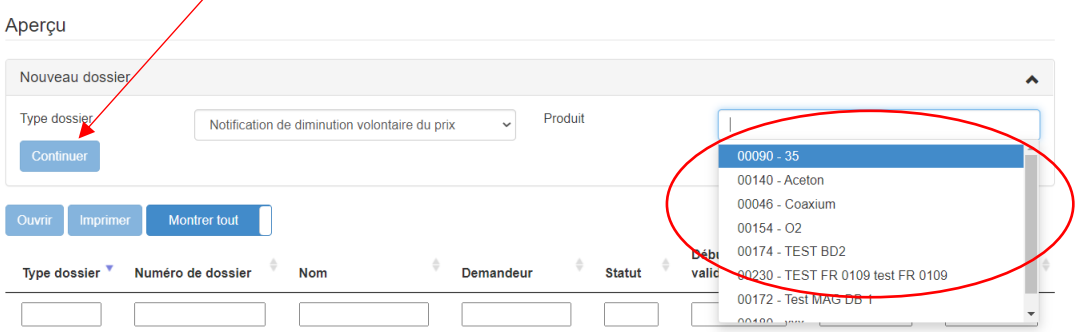
4. If you click "Delete", your application will be deleted.

## 6.4. NOTIFICATION OF A VOLUNTARY PRICE REDUCTION

After selecting the "Notification of a voluntary price reduction" file type, you access the first page as follows:




Since you can only change the basis of reimbursement for a product that is already reimbursable, select the product by clicking the "Product" field.
Select the product for which you want to submit a change request.
Finally, click "Continue".



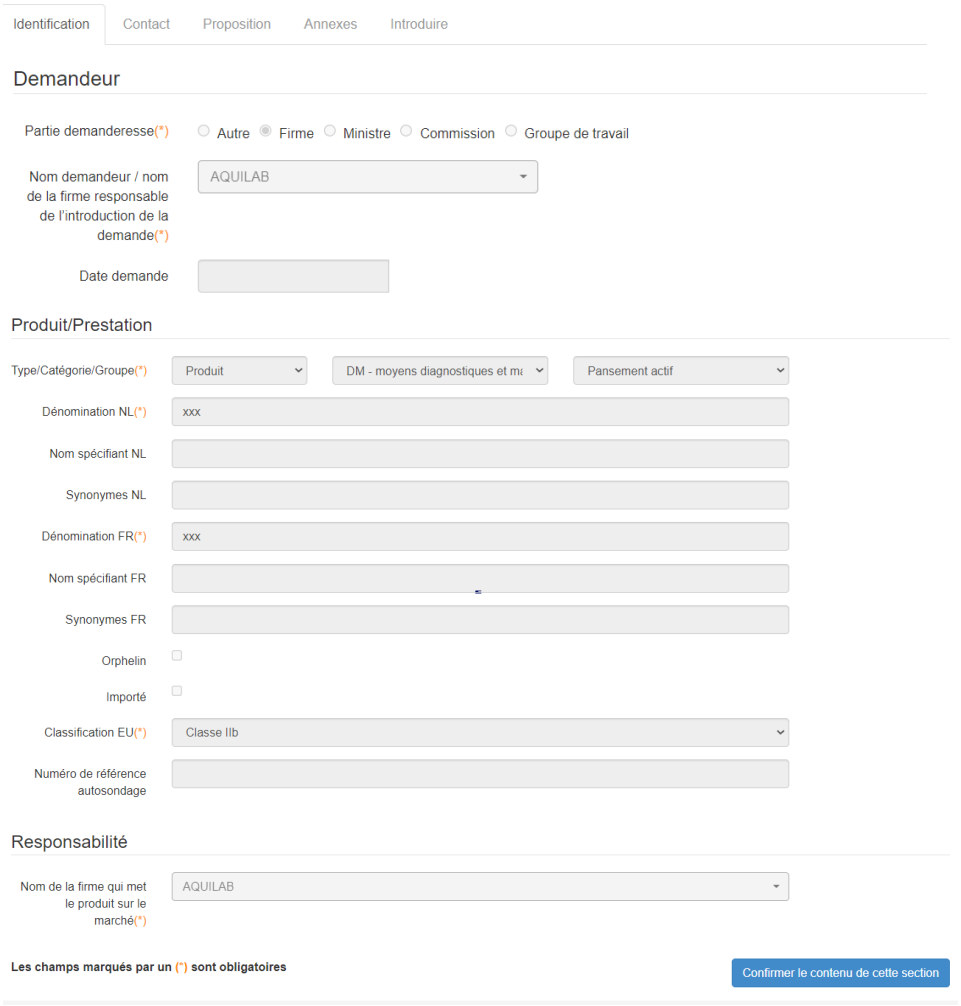
The identification data for the selected product is displayed automatically.
This includes the following data:

- The file type
- The file number: this number is created automatically
- The file status
- The name + the specifying name

These fields cannot be modified.
All this data forms the "header".

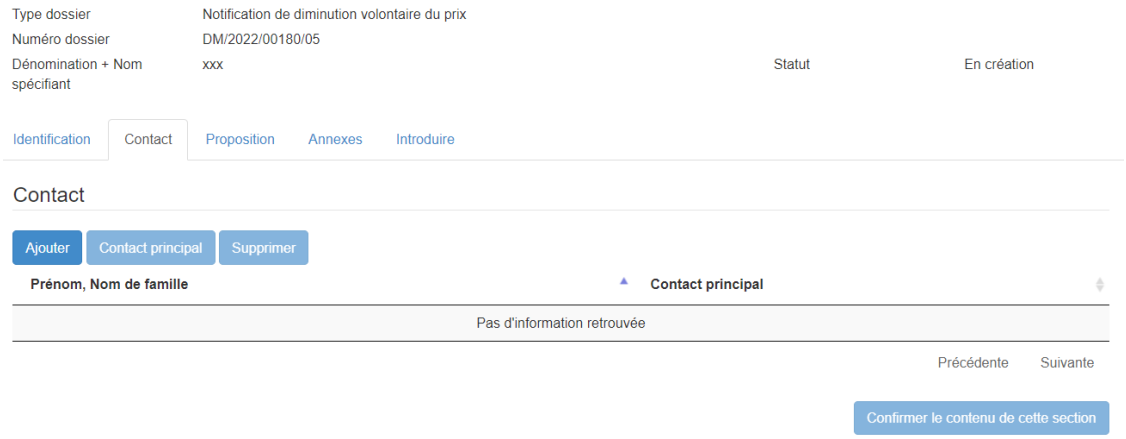
The application forms for a notification of a voluntary price reduction are all structured along the same lines and consist of the following tabs:
- Identification
- Contact
- Proposal
- Attachments
- Submit

### 6.4.1. **Identification**



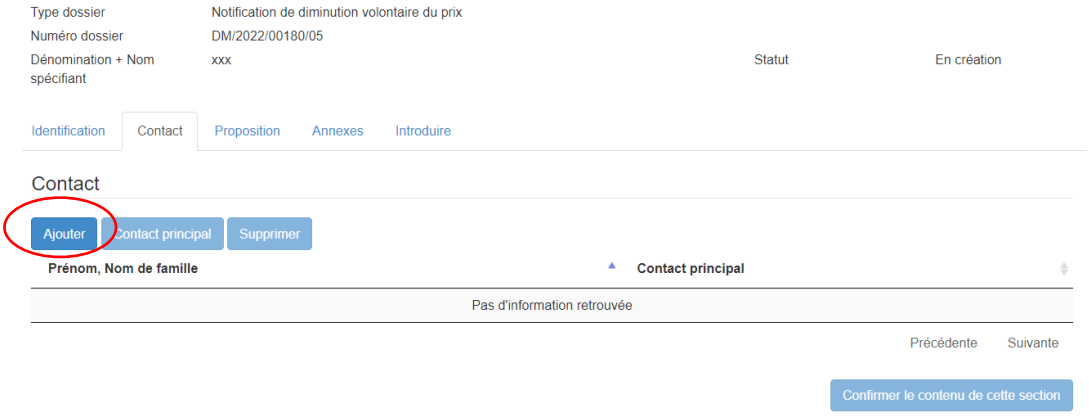

The fields are automatically completed:

### 6.4.2. **Contact**

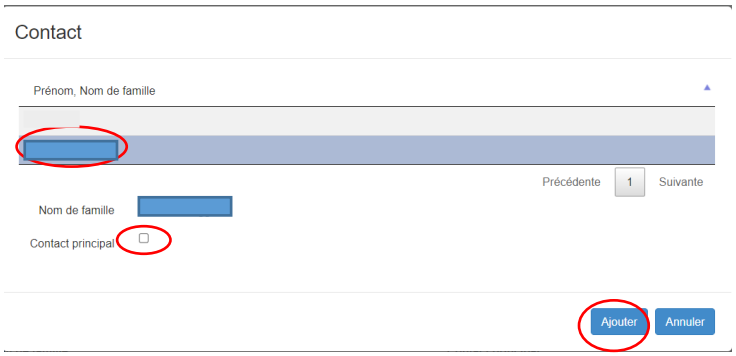



The first name and surname of the contact person(s) must be specified.

1) Click "Add"




2) Choose the contact person(s) by clicking on their name and specify the primary contact by ticking " Contact principal ☐ " and click "Add".




3) "Confirm"

Once all fields are completed:

## 6.4.3. **Proposal**

| | | | |
|---|---|---|---|
| Type dossier | Notification de diminution volontaire du prix | | |
| Numéro dossier | DM/2022/00180/03 | | |
| Dénomination + Nom spécifiant | xxx | Statut | En création |

Identification | Contact | Proposition | Annexes | Introduire

Modalités de remboursement actuelles

### Modalités de remboursement

Ouvrir | Texte AR

| Dispensateur | Base juridique - Chapitre - Paragraphe | Nouveau | Catégorie de remboursement |
|---|---|---|---|
| Officine publique | CRPPP - Ch.I - solutions pour irrigation vésicale | | A |

Précédente 1 Suivante

### Tarification

Ouvrir

| Type de tarification | Quantité | Unité | Montant |
|---|---|---|---|
| Officine publique | 1 | pièce | 10,0000 |

Précédente 1 Suivante

### Prix

| | | | | | |
|---|---|---|---|---|---|
| Prix ex-usine(*) | 10,00 | € | Contrôle du prix par le SPF Economie | ☐ | |
| Prix pharmacien (TVA excl.)(*) | 15,00 | € | BEBAT | | € |
| Prix public (TVA incl.)(*) | 20,00 | € | Recupel | | € |
| Pourcentage TVA(*) | 21% | | | | |

Proposition

### Tarification (*)

Initialisation | Ajouter | Ouvrir | Supprimer

| Type de tarification | Quantité | Unité | Montant (€) | I (€) | II (€) | Code |
|---|---|---|---|---|---|---|
| Pas d'information retrouvée | | | | | | |

Précédente Suivante

### Prix

| | | | | | |
|---|---|---|---|---|---|
| Prix ex-usine(*) | | € | Contrôle du prix par le SPF Economie | ☐ | |
| Prix pharmacien (TVA excl.)(*) | | € | BEBAT | | € |
| Prix public (TVA incl.)(*) | | € | Recupel | | € |
| Pourcentage TVA(*) | | | | | |

Confirmer le contenu de cette section

2 sections are displayed:

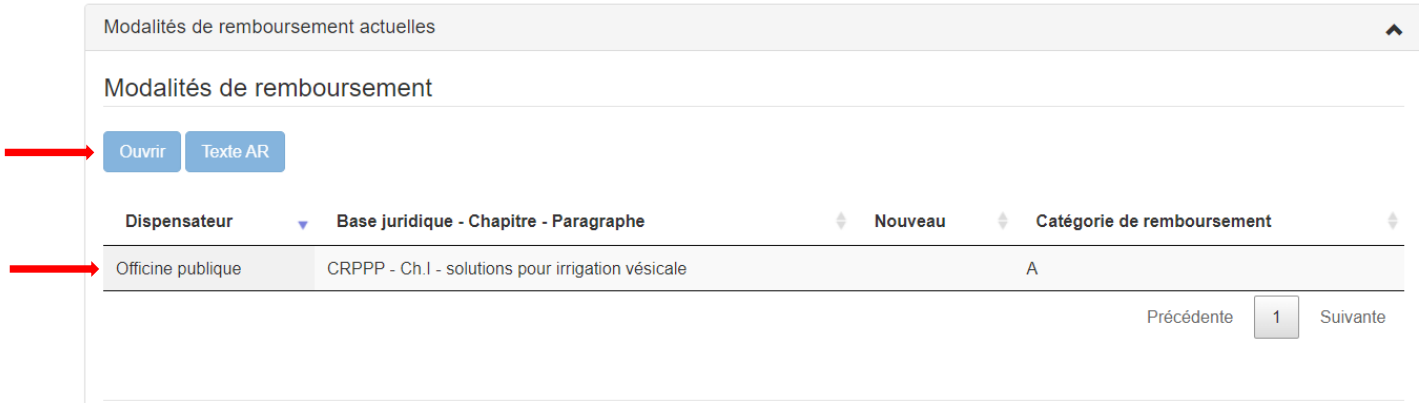
- Current reimbursement terms
- Proposal

The product's current reimbursement terms/pricing system/price structure are automatically displayed.

*1. Reimbursement terms*

To view the current text of the reimbursement terms, select the relevant line and click "RD Text".

To view the current reimbursement terms, select the relevant line and click "Open".

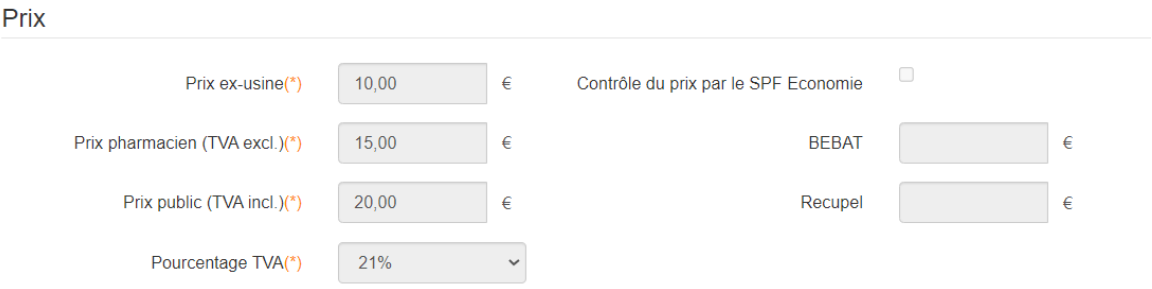



*2. Pricing system*

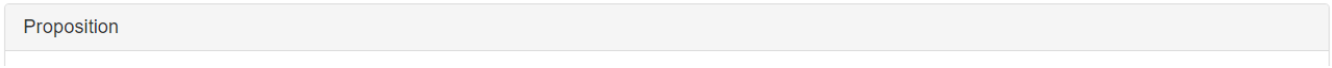
To view the current pricing system, select the relevant line and click "Open".

*3. Price*

The data for the "current" price structure is displayed.



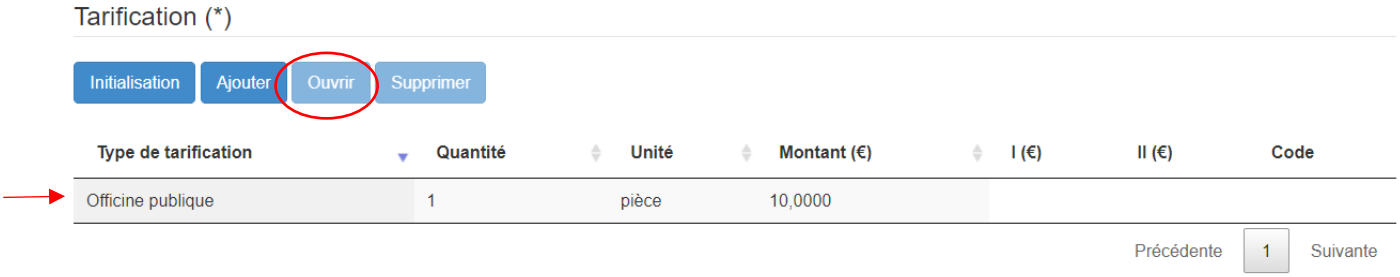
To change the current pricing system/price structure, go to the "Proposal" section




Then specify your **proposed price and pricing system.**
You can change the pricing system according to the proposed new price structure.

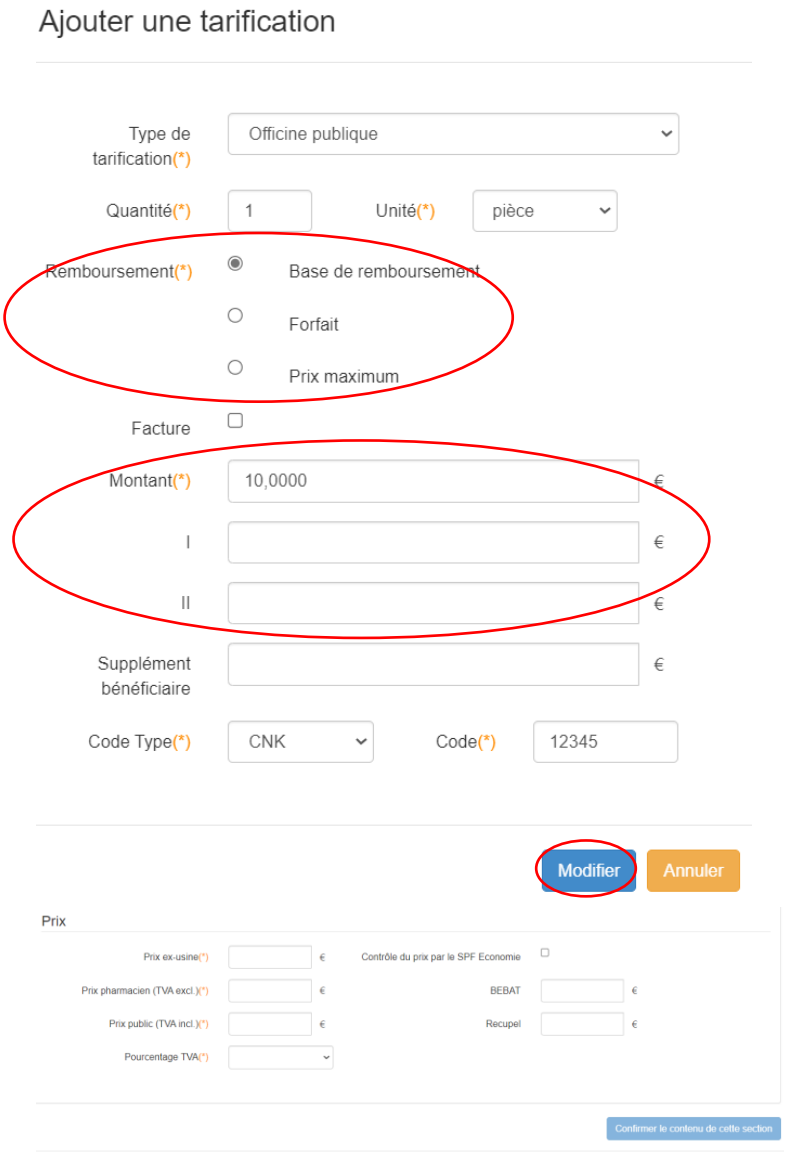
Load the pricing system in the current situation by clicking the "Initialise" button.
You can then change this pricing system.

Select the line to be modified and click the "Open" button.




Modify the fields according to your new proposal and click "Modify".

Since the notification is for a voluntary price reduction, the proposed pricing system change will ONLY affect the amount of the basis of reimbursement/flat rate/maximum price in accordance with the new price structure that must also be proposed.




Once all fields are completed:

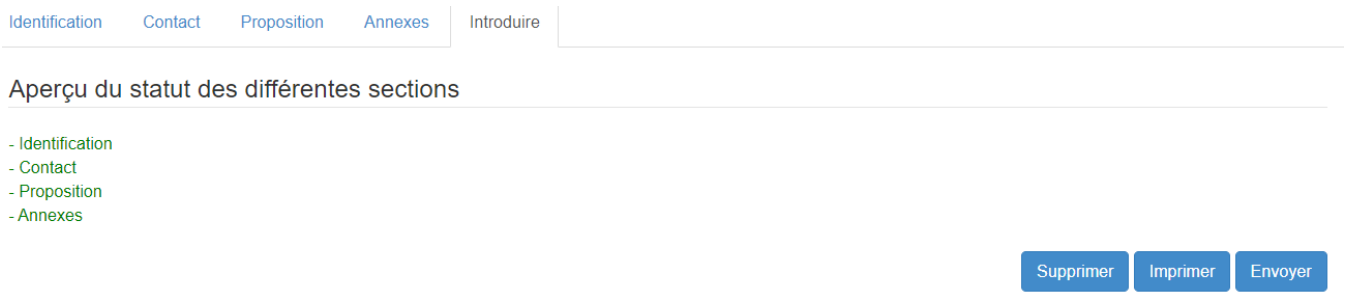
Click → Confirmer le contenu de cette section

### 6.4.4. **Attachments**

In this case, there are no attachments required.

Please go directly to the "Submit" tab.

### 6.4.5. **Submit**




1. This tab gives you an overview of the status of each of the tabs (green = "complete" or red = "to be completed"). Where necessary, fill in any incomplete tabs.

To open an incomplete tab, click "Complete". You can also open the tab by clicking on it.

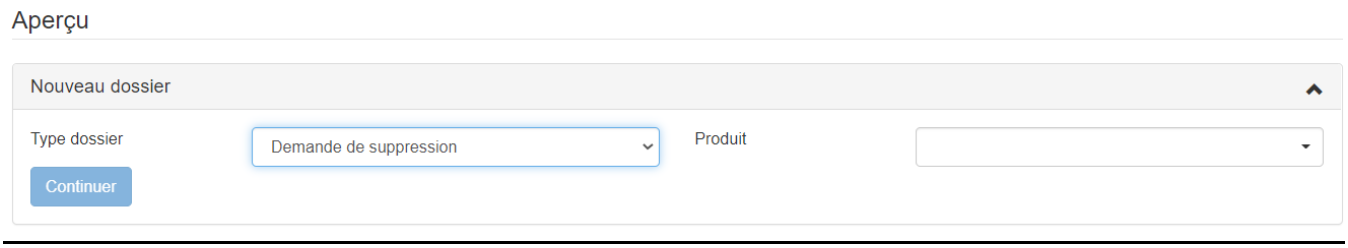
2. To print the application, click "Print". This will generate a pdf containing the different data in the application.

3. Click "Send" to send the application to INAMI-RIZIV. In this case, the application is closed and the application search screen is displayed. Once submitted, the application can still be viewed from the list of current files but cannot be modified.

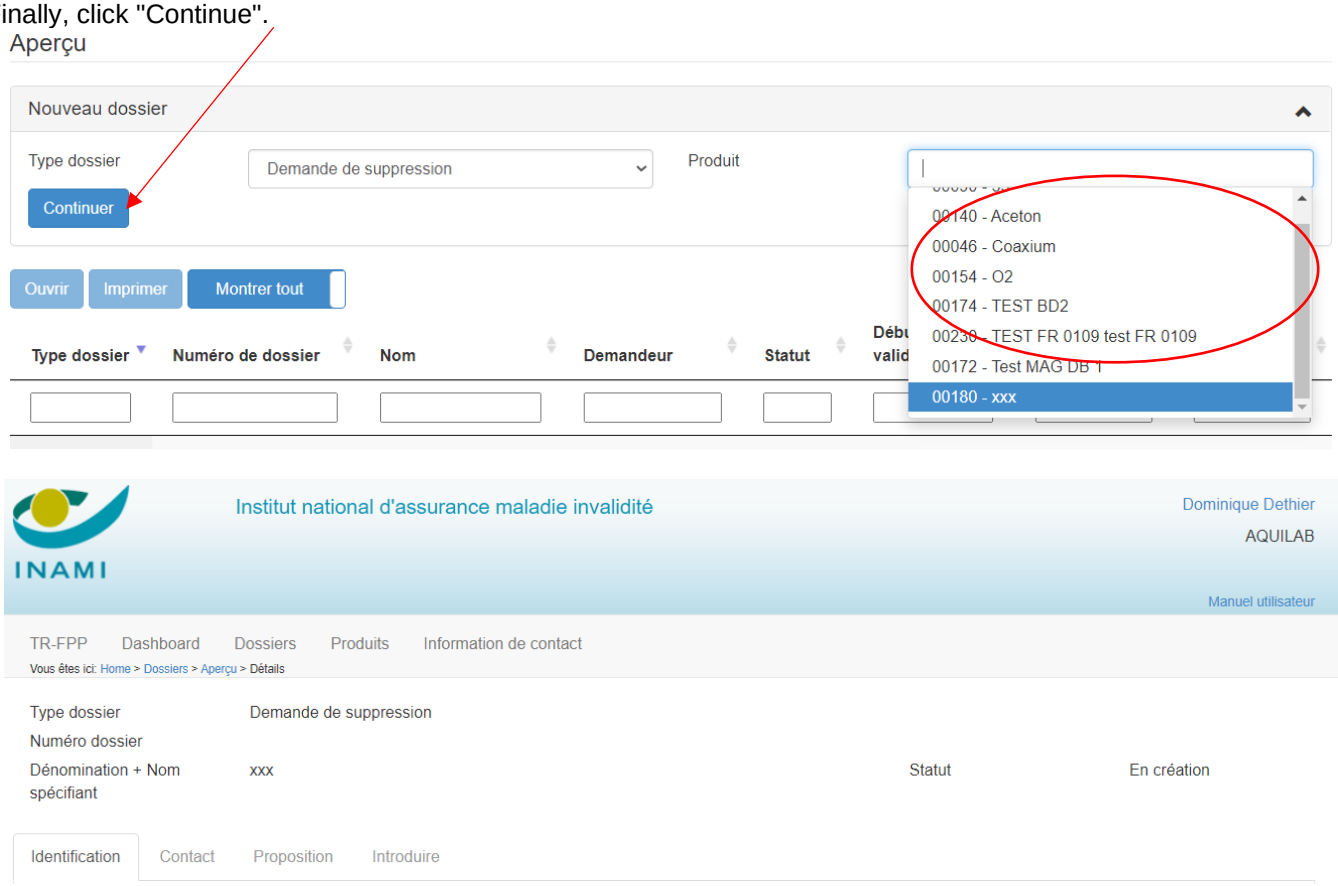
4. If you click "Delete", your application will be deleted.

## 6.5. REMOVAL REQUEST

After selecting the "Removal request" file type, you access the first page as follows:




Since you can only remove a product that is already reimbursable, select the product by clicking the "Product" field.
Select the product for which you want to submit a change request.
Finally, click "Continue".







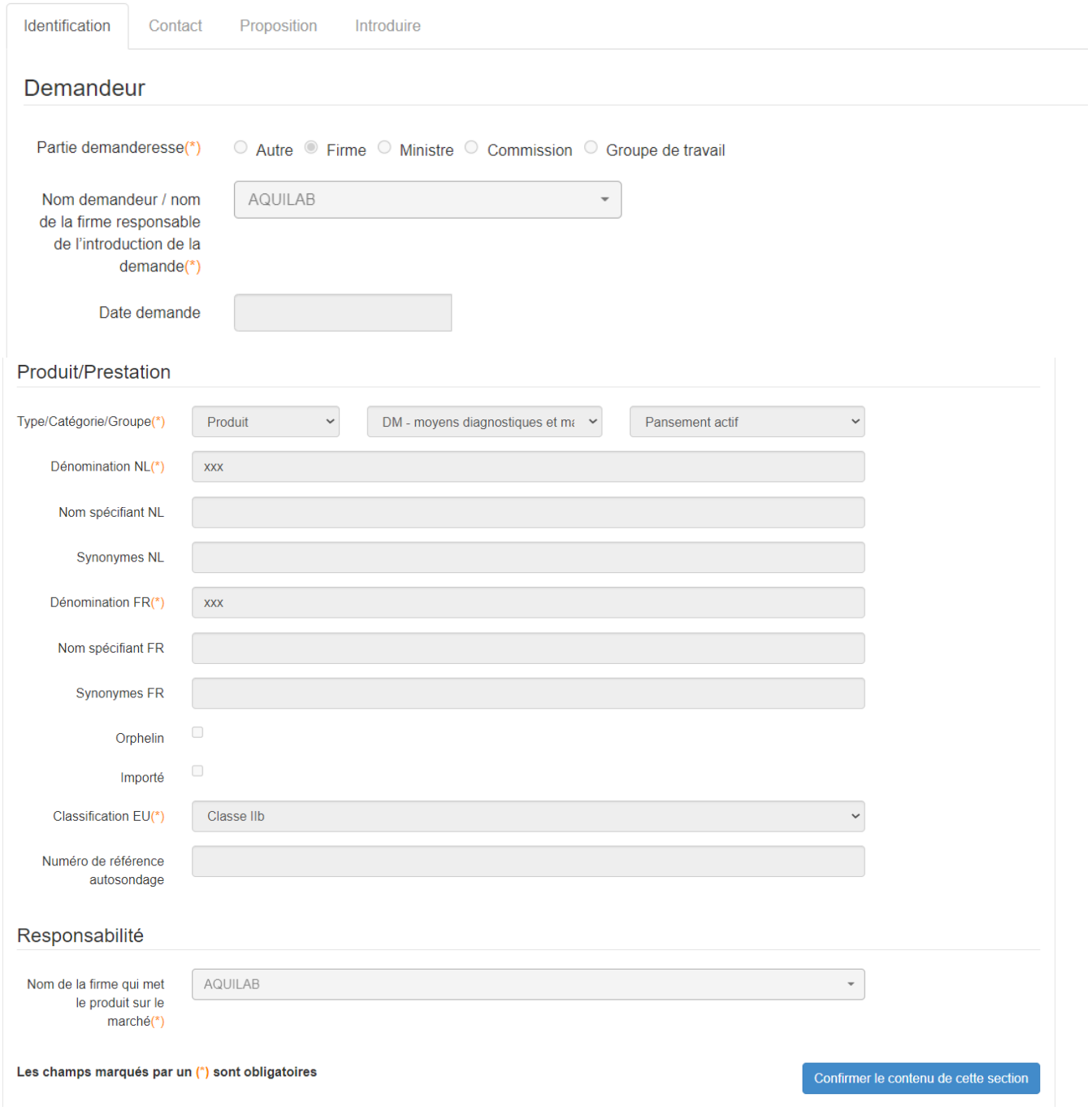
The identification data for the selected product is displayed automatically.
This includes the following data:

- The file type
- The file number: this number is created automatically
- The file status
- The name + the specifying name

These fields cannot be modified.
All this data forms the "header".

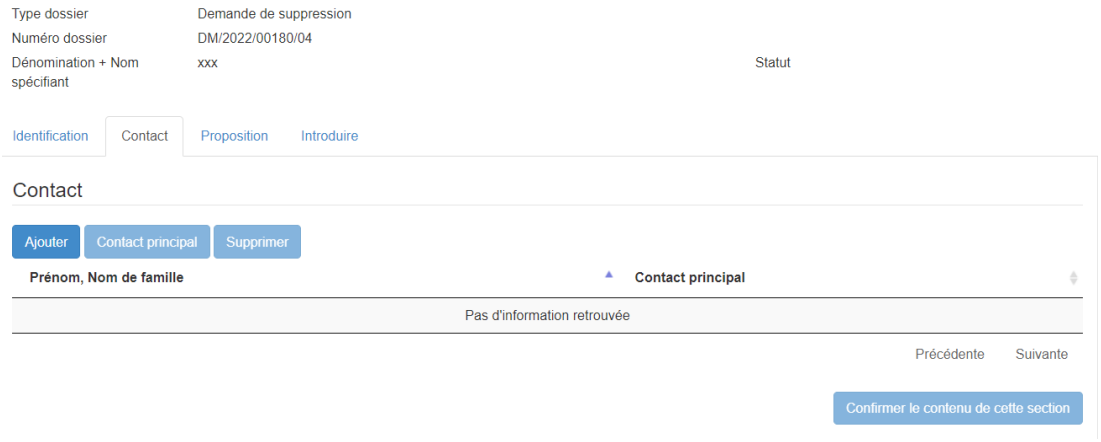
The removal request forms are all structured along the same lines and consist of the following tabs:
- Identification
- Contact
- Proposal
- Submit

### 6.5.1. **Identification**



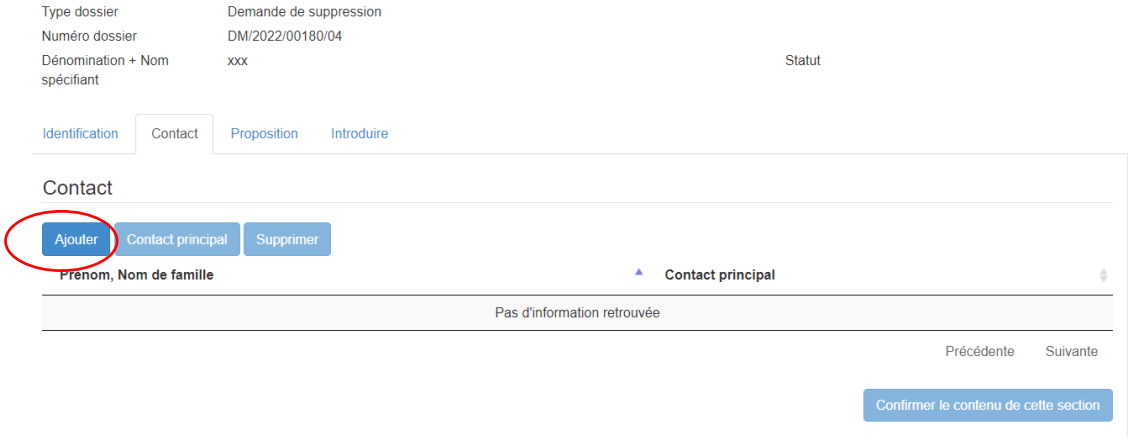

The fields are automatically completed:

### 6.5.2. **Contact**

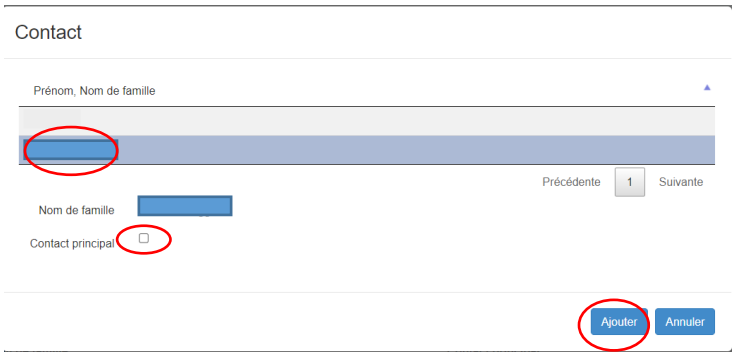



The first name and surname of the contact person(s) must be specified.

1) Click "Add"



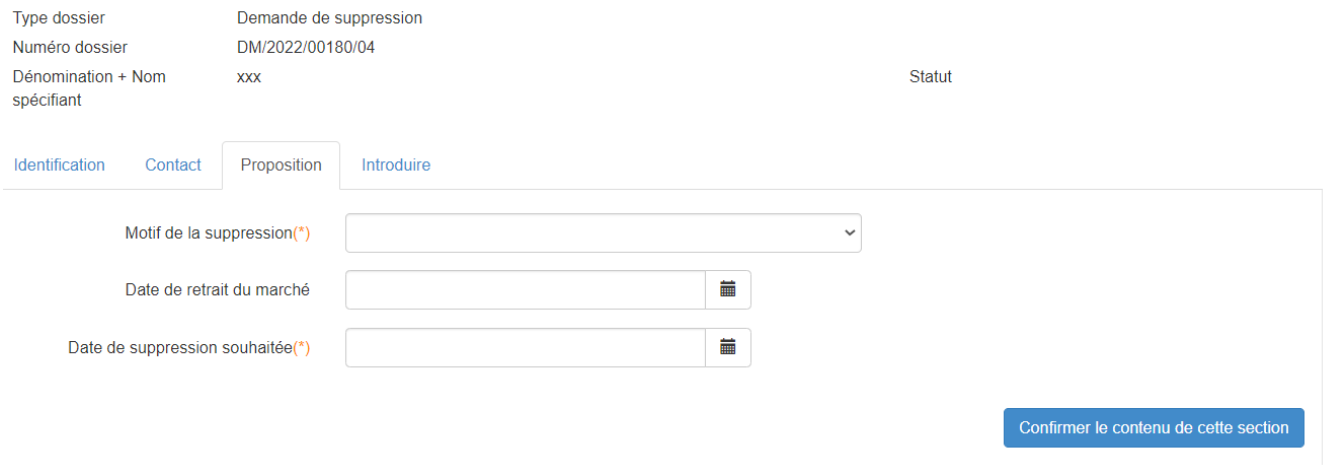

2) Choose the contact person(s) by clicking on their name and specify the primary contact by ticking " Contact principal ☐ " and click "Add".




3) "Confirm"

Once all fields are completed:

### 6.5.3. **Proposal**

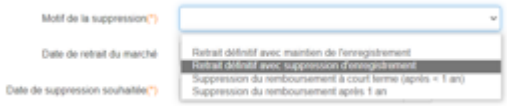



3 fields are displayed:

- Reason for removal
- Date of withdrawal from the market
- Desired removal date

Choose the reason for the removal from the drop-down menu

There are several choices:



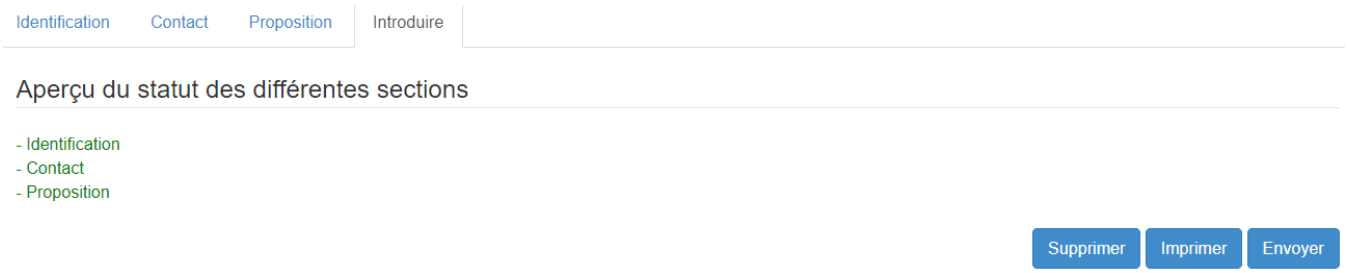

If a reason does not appear in the drop-down menu, please contact the General Secretariat on 02/739.77.41 or send an email to the following address: crppp-ctfpv@riziv-inami.fgov.be, with secr-farbel@riziv.fgov.be in cc.

Specify the withdrawal dates (if the deletion is due to a product withdrawal) and/or the desired deletion date via the calendar available on the right-hand side of the field.

Fields marked with an asterisk (*) are MANDATORY.

Once all fields are completed:

### 6.5.4. **Submit**




1. This tab gives you an overview of the status of each of the tabs (green = "complete" or red = "to be completed"). Where necessary, fill in any incomplete tabs.

To open an incomplete tab, click "Complete". You can also open the tab by clicking on it.

2. To print the application, click "Print". This will generate a pdf containing the different data in the application.

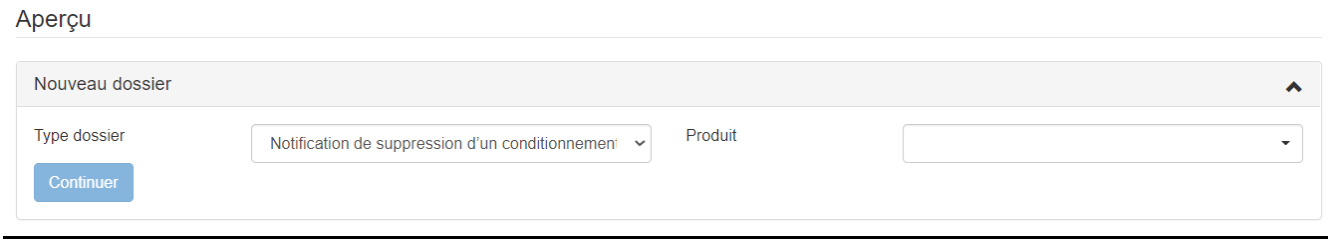
3. Click "Send" to send the application to INAMI-RIZIV. In this case, the application is closed and the application search screen is displayed. Once submitted, the application can still be viewed from the list of current files but cannot be modified.

4. If you click "Delete", your application will be deleted.

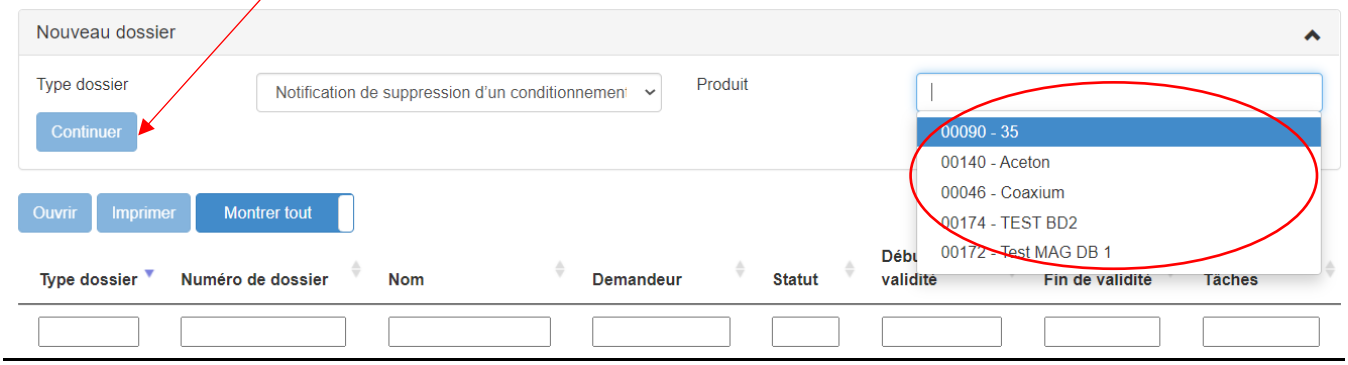
## 6.6. NOTIFICATION OF REMOVAL OF A PACKAGE FOR A RAW MATERIAL FOR MAGISTRAL PREPARATIONS

The removal of one or more packages for a reimbursable raw material may result in an adjustment in the basis of reimbursement for the raw material concerned.

After selecting the "Notification of removal of a package for a raw material for magistral preparations" file type, you access the first page which appears as follows:




Since you can only remove a product that is already reimbursable, select the product by clicking the "Product" field.
Select the product for which you want to submit a change request.
Finally, click "Continue".



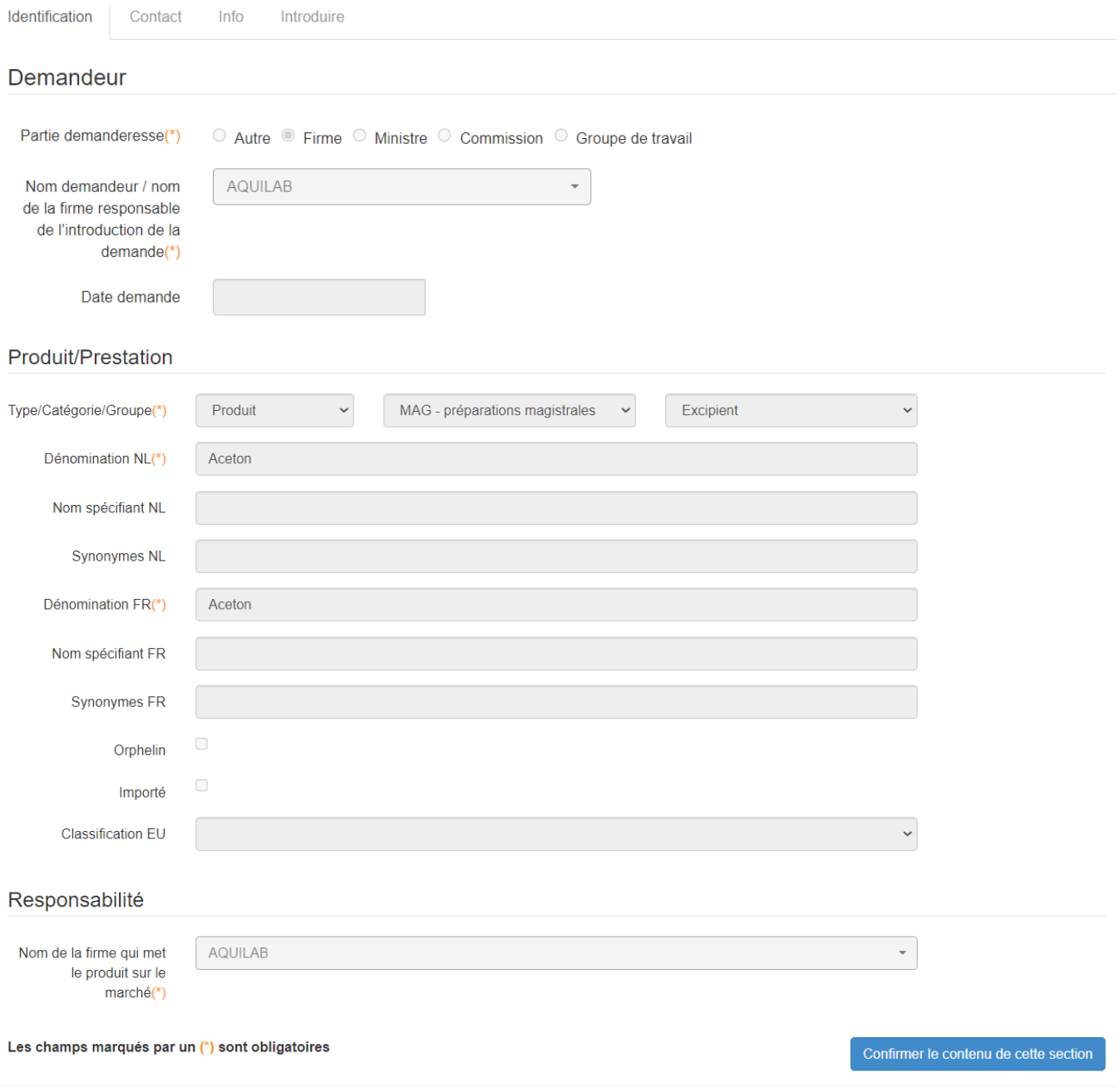
The identification data for the selected product is displayed automatically.
This includes the following data:

- The file type
- The file number: this number is created automatically
- The file status
- The name + the specifying name

These fields cannot be modified.
All this data forms the "header".

The removal request forms are all structured along the same lines and consist of the following tabs:
- Identification
- Contact
- Info
- Submit

### 6.6.1. **Identification**

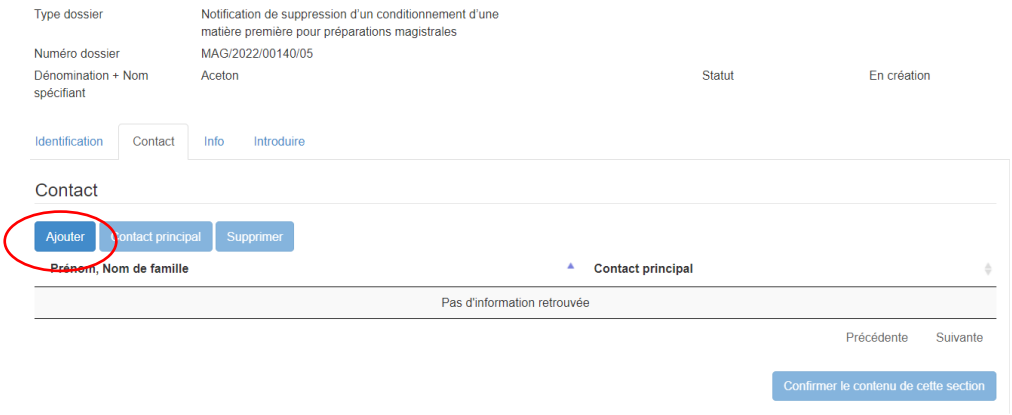



The fields are automatically completed:

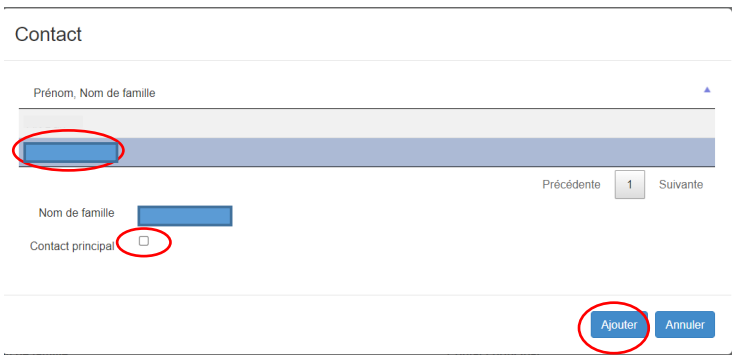
### 6.6.2. **Contact**

The first name and surname of the contact person(s) must be specified.

1) Click "Add"




2) Choose the contact person(s) by clicking on their name and specify the primary contact by ticking " Contact principal ☐ " and click "Add".

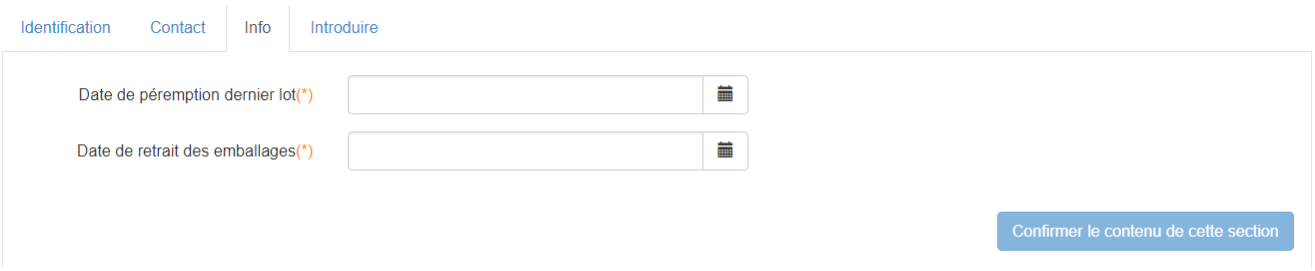



3) "Confirm"

Once all fields are completed:

Click → Confirmer le contenu de cette section

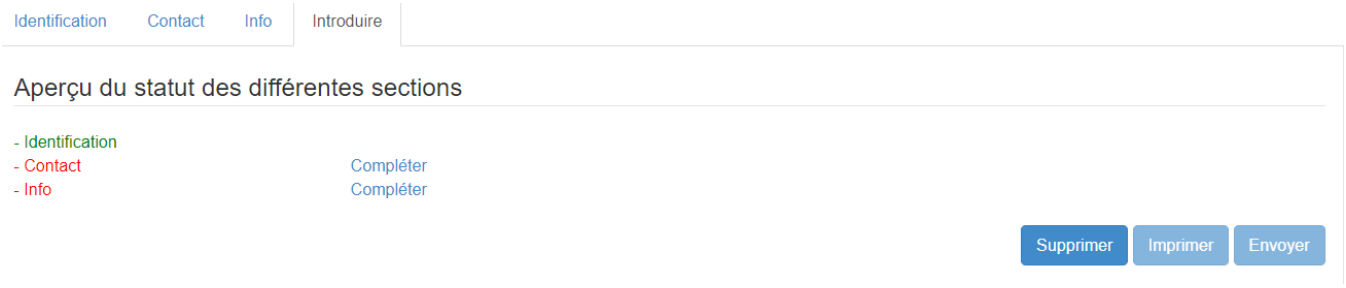
### 6.6.3. **Info**




Complete the 2 required fields.
!!! Remember, this information must be provided 3 months prior to the withdrawal date of the package(s).

Once all fields are completed:

### 6.6.4. **Submit**




---

1. This tab gives you an overview of the status of each of the tabs (green = "complete" or red = "to be completed"). Where necessary, fill in any incomplete tabs.

To open an incomplete tab, click "Complete". You can also open the tab by clicking on it.

2. To print the application, click "Print". This will generate a pdf containing the different data in the application.

3. Click "Send" to send the application to INAMI-RIZIV. In this case, the application is closed and the application search screen is displayed. Once submitted, the application can still be viewed from the list of current files but cannot be modified.

4. If you click "Delete", your application will be deleted.

## 7. Follow-up on the request

**CONSULTATION OF THE DOCUMENTS MADE AVAILABLE BY THE SECRETARIAT OF THE COMMISSION FOR REIMBURSEMENT OF PHARMACEUTICAL PRODUCTS AND BENEFITS (CRPPP) AND ACCESS TO THE DOCUMENTS RELATED TO A FILE FOR WHICH THE PROCEDURE IS ONGOING.**

Since 1 February 2022, the exchange of information between applicants and the CRPPP'S secretariat during a CRPPP procedure took place by registered mail with acknowledgement of receipt or in some cases by email.

From now on, for all files submitted as from 4 October 2022 through the TR-FPP Front-Office, these postal exchanges will be replaced by an electronic exchange using the TR-FPP Front-Office. We call this the "digital processing" of files.

This means that you will receive and be able to consult through the TR-FPP Front-Office:

- Messages from the CRPPP's secretariat with regard to the admissibility or inadmissibility of your file
- Interim / final assessment reports and interim / final recommendations established by the permanent working groups
- Final opinions given by the CRPPP
- Decisions made by the minister
- Possible communication on the suspension or closure of your file, whether the file is being closed at your request or by the administration

This also means that you will need to provide a number of documents to the CRPPP's secretariat through the TR-FPP Front-Office. The following documents need to be provided (depending on the type of file):

- Additional information to be provided in case of an inadmissible or a suspended file
- Response to the interim assessment report
- Response to the interim recommendation

If you encounter a problem in carrying out a task through the TR-FPP Front-Office or in viewing a document that has been made available to you through this system, we kindly ask you to contact the CRPPP's secretariat as soon as possible either by calling 02/739.77.41 or by sending an e-mail to the following address: crppp-ctfpv@riziv-inami.fgov.be, and adding secr-farbel@riziv.fgov.be in Cc
We will do all we can to help you as quickly as possible.

For files submitted prior to 4 October 2022, the exchange of information between the applicants and the CRPPP's secretariat will continue as it started, until the end of the procedure, unless the CRPPP's secretariat informs you that the file is subject to a "digital processing" (in that case, the exchange of information between the applicant and the CRPPP's secretariat will take place through the TR-FPP Front-Office as from the date on which you have been informed that the file had been "digitally processed").

Files submitted in paper format to the CRPPP's secretariat from 4 October 2022 onwards will be subject to "non-digital" processing, in which the exchange of information between applicants and the CRPPP's secretariat will take place by registered mail with acknowledgement of receipt, until the end of the procedure.

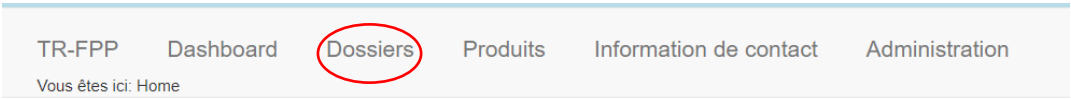
With regard to the file's digital processing, each time a new document is made available to you through the TR-FPP Front-Office within the scope of an ongoing CRPPP procedure and each time you have to perform a new task within the scope of a CRPPP procedure, each person that has been identified as "TR-FPP contact person" in the file in question will be informed by e-mail that a new document is available.
This email is from crppp-ctfpv@riziv-inami.fgov.be and contains the following subject line: "Update of your TR-FPP request".

You will be able to view the documents made available by the CRPPP's secretariat for a file for which the procedure is ongoing and to perform the tasks through the list of your files in progress by following the procedure detailed below:

## 7.1. SEARCHING FOR AN APPLICATION FILE AND RELATED TASKS

### *7.1.1. Searching for a file*

Once you have logged in and clicked on the menu "Dossiers", the list of files currently open for your company appears in the lower part of the screen.

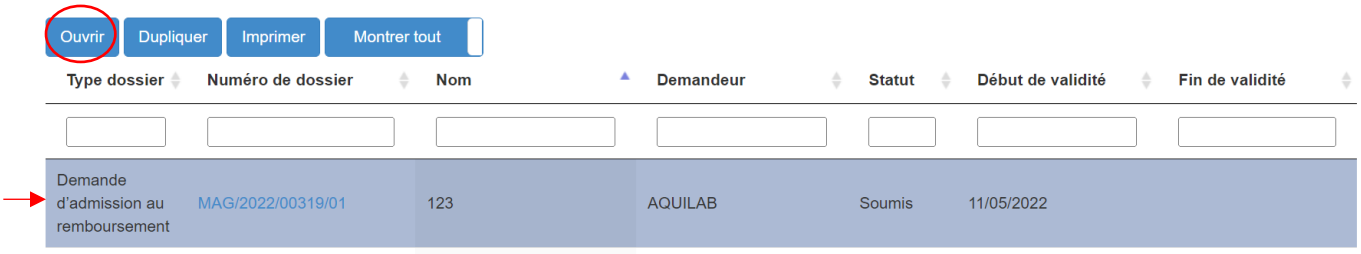



By filling in one or more search criteria (file number, name, type of file), you can limit the amount of information displayed in the grid to those that match your search criteria.

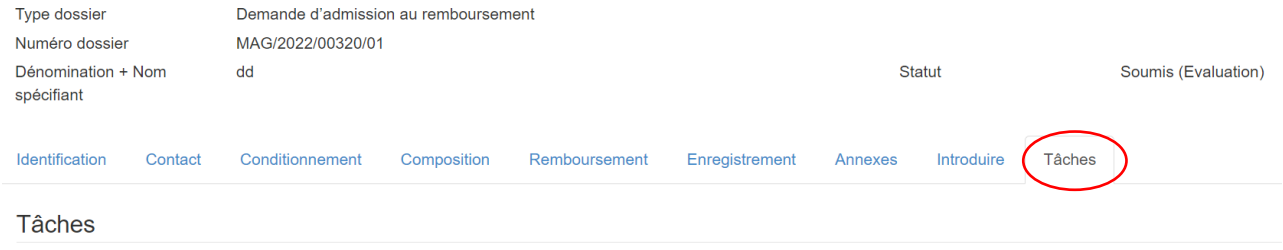
### *7.1.2. Viewing a file and related tasks*

1. Once you have logged in and opened the menu "DOSSIERS", click on the row matching the file you want to view from the list of files in progress. The selected row in the grid appears in a different colour.

Click on the button "Ouvrir" to display the details of the request.



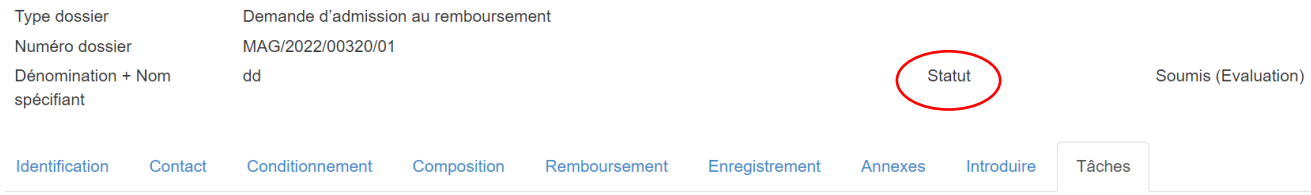

The documents available to you through the TR-FPP Front-Office within the scope of an ongoing CRPPP procedure and the tasks you need to perform, can be found in the tab "Tâches".




Note: Since the application has already been sent to INAMI-RIZIV, the information in all the tabs other than the tab "Tâches" can only be viewed and cannot be modified (except for the tab "Contact" which can always be modified).

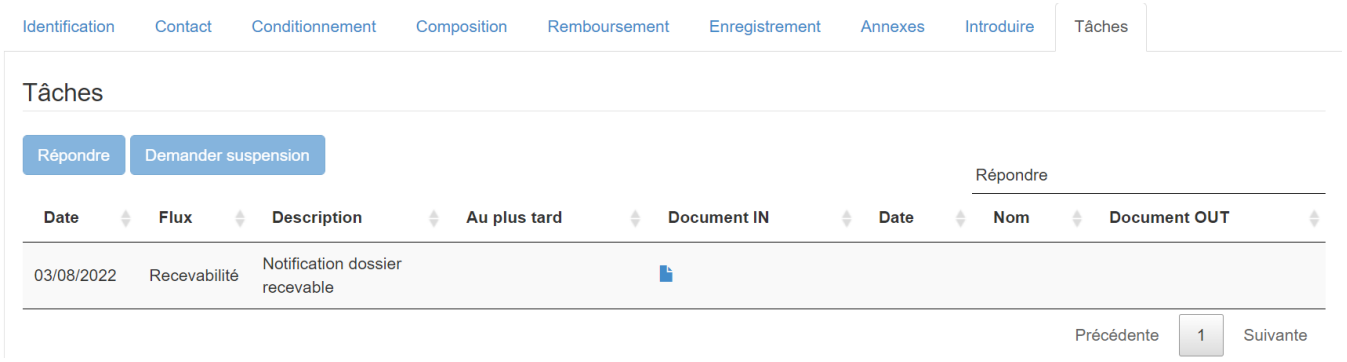
### *7.1.3. Status of a file*

You will see the status of an application file in the application details under "Statut".



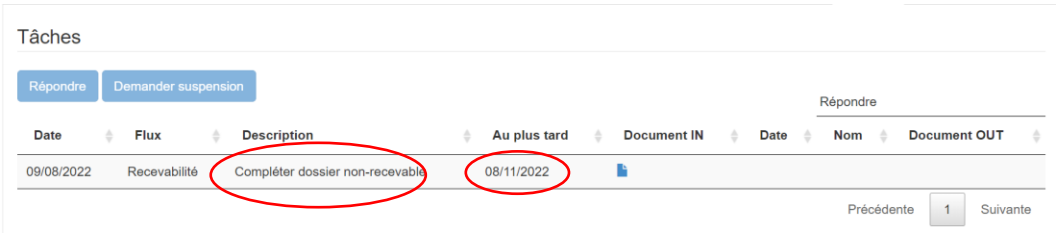

## 7.2. ADMISSIBILITY and INADMISSIBILITY FLOW

- In case of admissibility, you will receive a "notification dossier recevable".




You can view this notification by clicking on the icon in the column "Document IN".

- In case of inadmissibility, you will see a task "compléter dossier non-recevable" as well as the date by which this task must be completed.

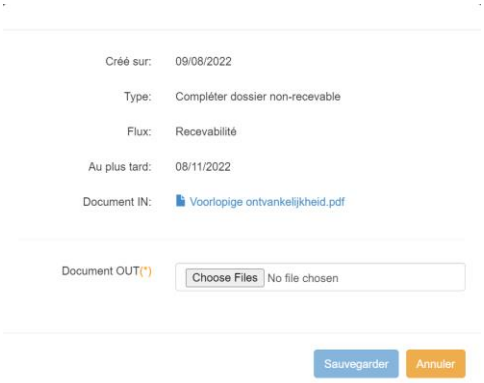



By clicking on the icon in the column "Document IN", you will be able to view (and download if you want to) the letter from the CRPPP's secretariat informing you of the inadmissibility of your file and of the missing information that must be provided to make the file admissible.

The inadmissibility may be due to missing documents or errors made when completing the various tabs.

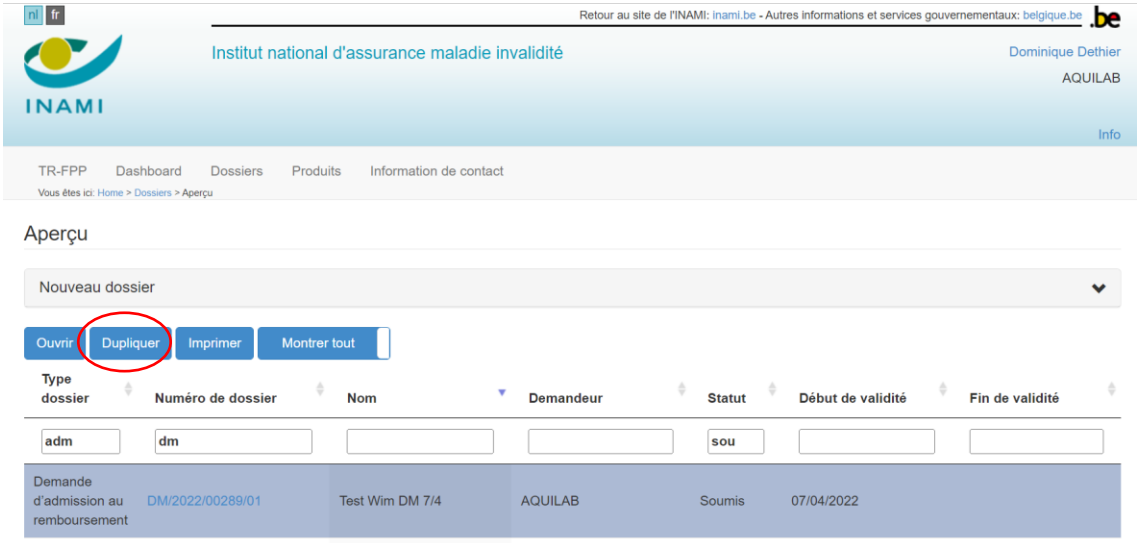
To send the missing information to the CRPPP's secretariat, you must first click on the task you wish to perform to select it. Once selected, the task row appears in blue:

Click on "Répondre". A new window will open:




To perform the task, you will need to download the document(s) that further complete(s) the file. To do this, click on "Choose File", choose the document(s) to be downloaded and finally, click on "Sauvegarder".
For added convenience, it would be better if the documents to be downloaded are kept in the same folder.
Note: you can only download one document at a time.

If the inadmissibility is due to an error in a tab, resubmit a duly completed file.
To do this and to proceed more quickly, return to the homepage, select the file in question and click on "Dupliquer".




Your file will receive a new number and the name will be followed by the word 'copy'.

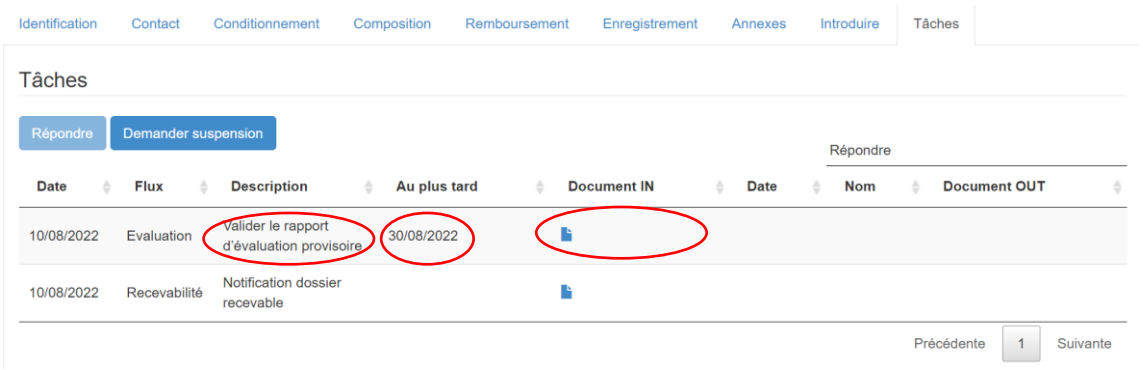
You can then make the necessary changes/corrections in this "new" file (for example, removing the word 'copy' from the name).

## 7.3. ASSESSMENT FLOW

- Depending on whether or not the procedure that a file follows includes an assessment report, you will receive an interim assessment report to which you will have to respond.

- In the case of an administrative file requesting eligibility for reimbursement, this assessment will immediately be final and will be sent to you at the same time as the interim recommendation (next flow).

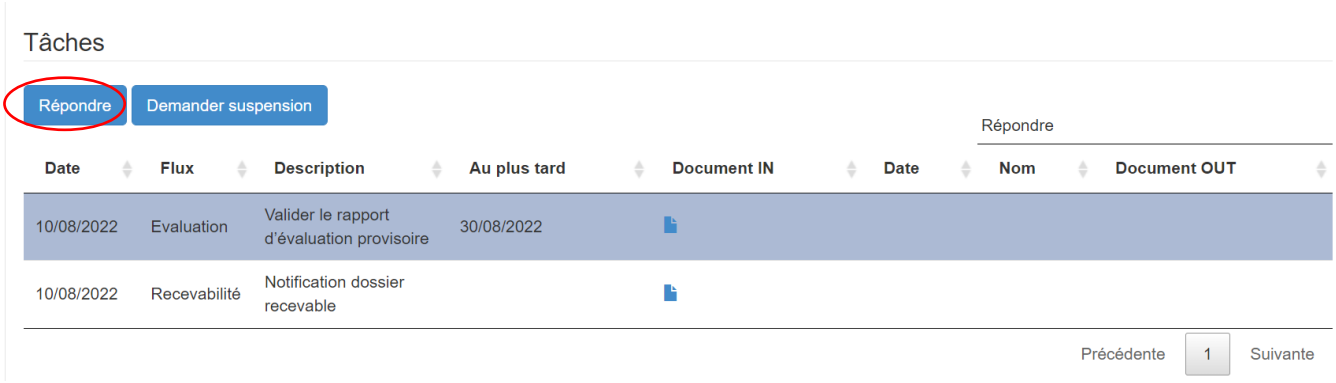
The interim assessment report will be sent to you through the tasks ["Tâches"] related to the file in question, more specifically through the task "Valider le rapport d'évaluation provisoire" :



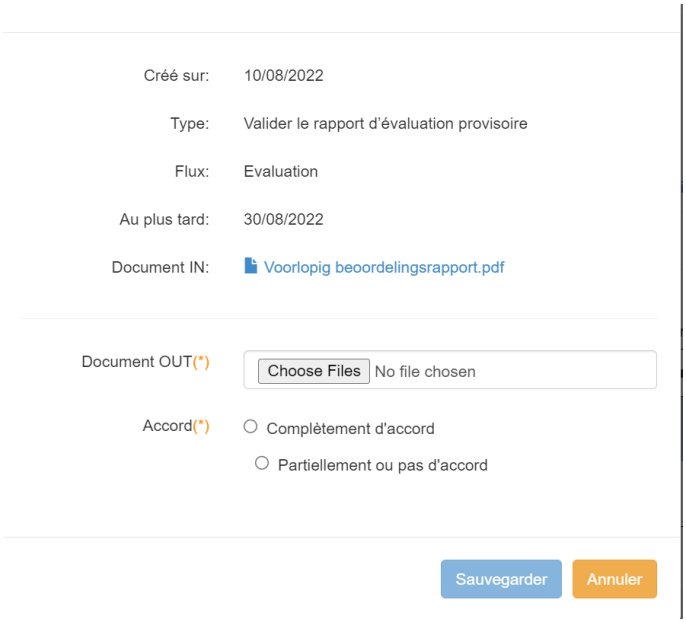

By clicking on the icon in the column "Document IN", you will be able to read (and download if you want to) the interim assessment report.

On the corresponding row, you will also see the deadline by which your response must reach the CRPPP's secretariat.

To send your response to the interim assessment report to the CRPPP's secretariat, you will first need to click on the task you wish to perform to select it. Once selected, the task row appears in blue:



Click on "Répondre". A new window will open:



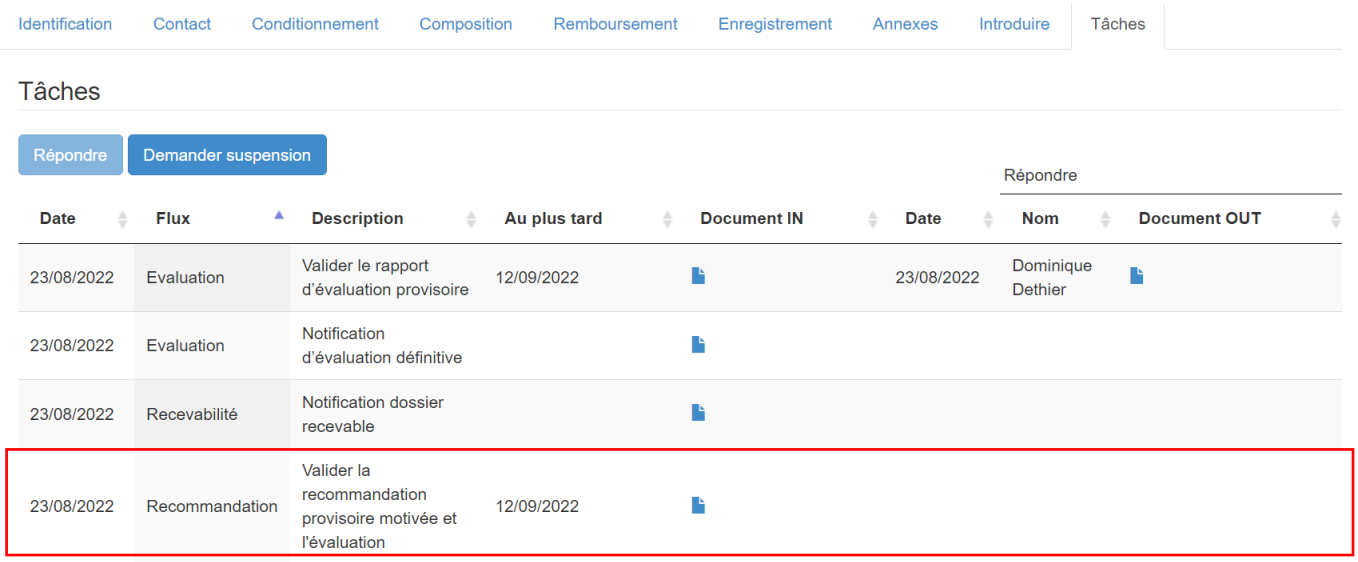

To reply:

- tick whether you fully agree ["Complètement d'accord"], partly agree or do not agree ["Partiellement ou pas d'accord"] with the interim assessment report;
- download the document(s) that further complete(s) the file. To do this, click on "Choose File", choose the document(s) to be downloaded and finally, click on "Sauvegarder".
  For added convenience, it would be better if the documents to be downloaded are kept in the same folder.

You will then receive the final assessment report for which you will notice that no response is required (neither a date in the column "Au plus tard" nor a mandatory response):

## 7.4. RECOMMENDATION FLOW

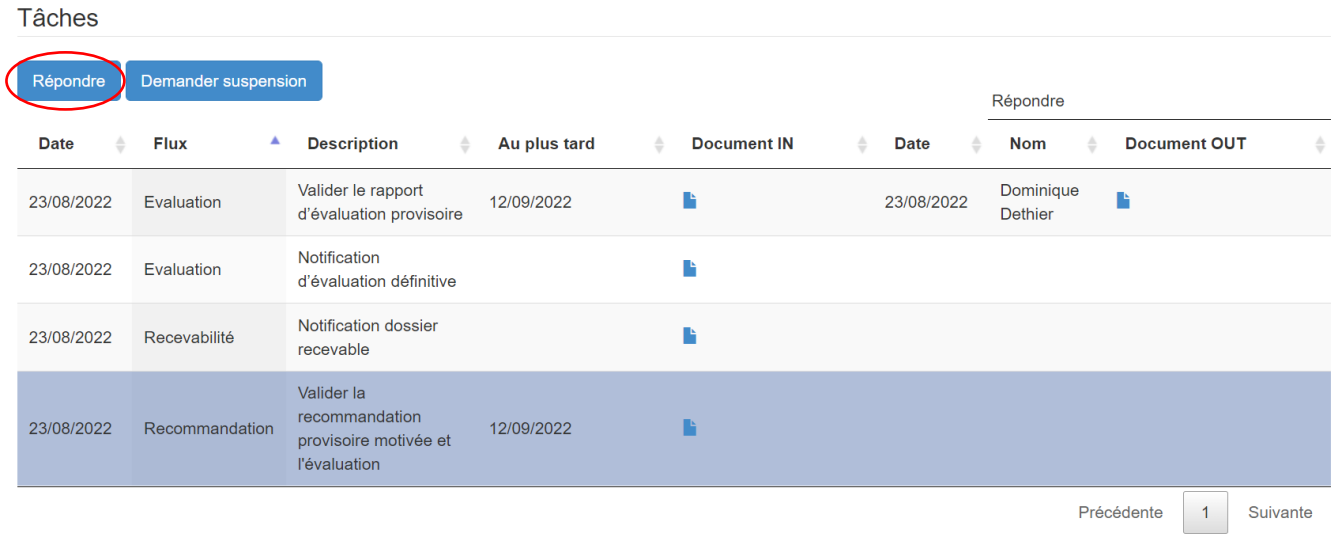
The interim recommendation will be sent to you through the tasks ["Tâches"] related to the file in question, more specifically through the task "Valider le rapport d'évaluation provisoire" :



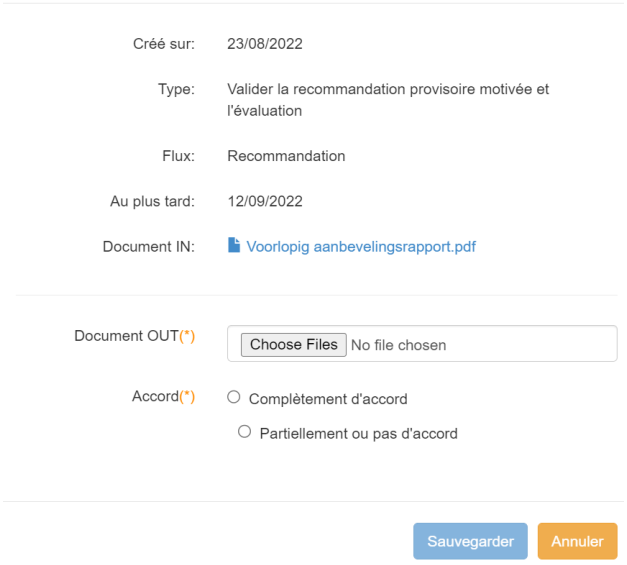

By clicking on the icon in the column "Document IN", you will be able to read (and download if you want to) the interim assessment report.

On the corresponding row, you will also see the deadline by which your response must reach the CRPPP's secretariat.

To send your response to the interim recommendation to the CRPPP's secretariat, you will first need to click on the task you wish to perform to select it. Once selected, the task row appears in blue:




Click on "Répondre". A new window will open:



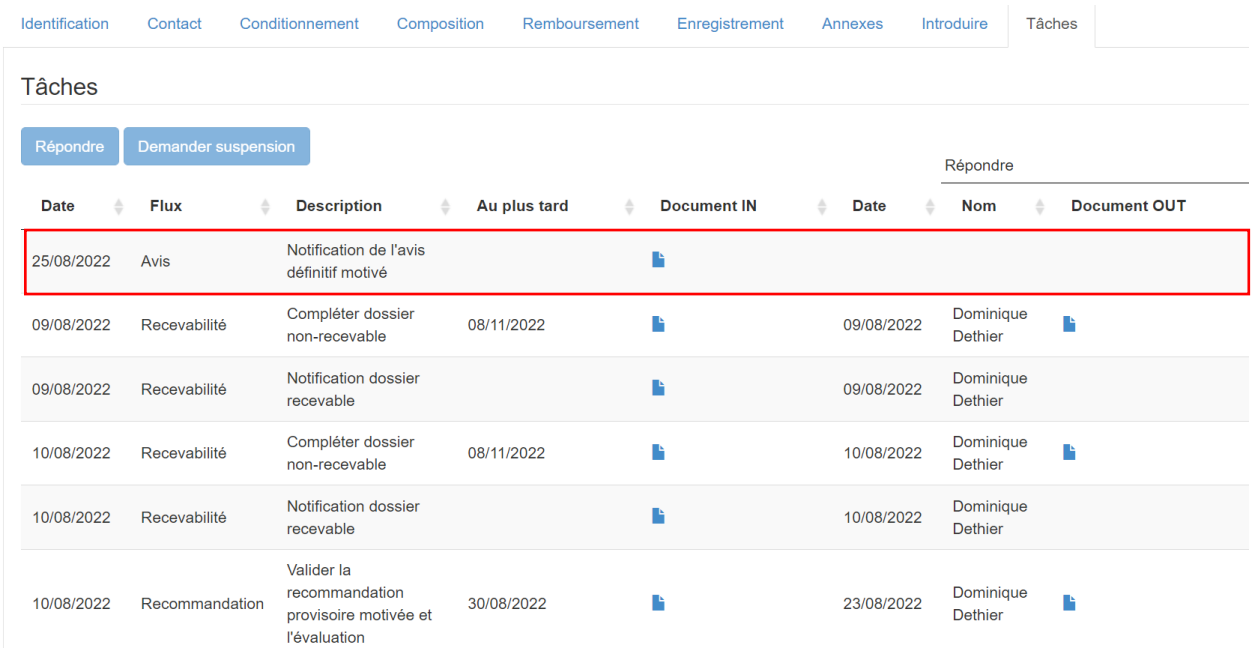

To reply:

- tick whether you fully agree ["Complètement d'accord"], partly agree or do not agree ["Partiellement ou pas d'accord"] with the interim recommendation;
- download the document(s) that further complete(s) the file. To do this, click on "Choose File", choose the document(s) to be downloaded and finally, click on "Sauvegarder".
  For added convenience, it would be better if the documents to be downloaded are kept in the same folder.

You will then receive the final recommendation for which you will notice that no response is required (neither a date in the column "Au plus tard" nor a mandatory response):

## 7.5. OPINION FLOW

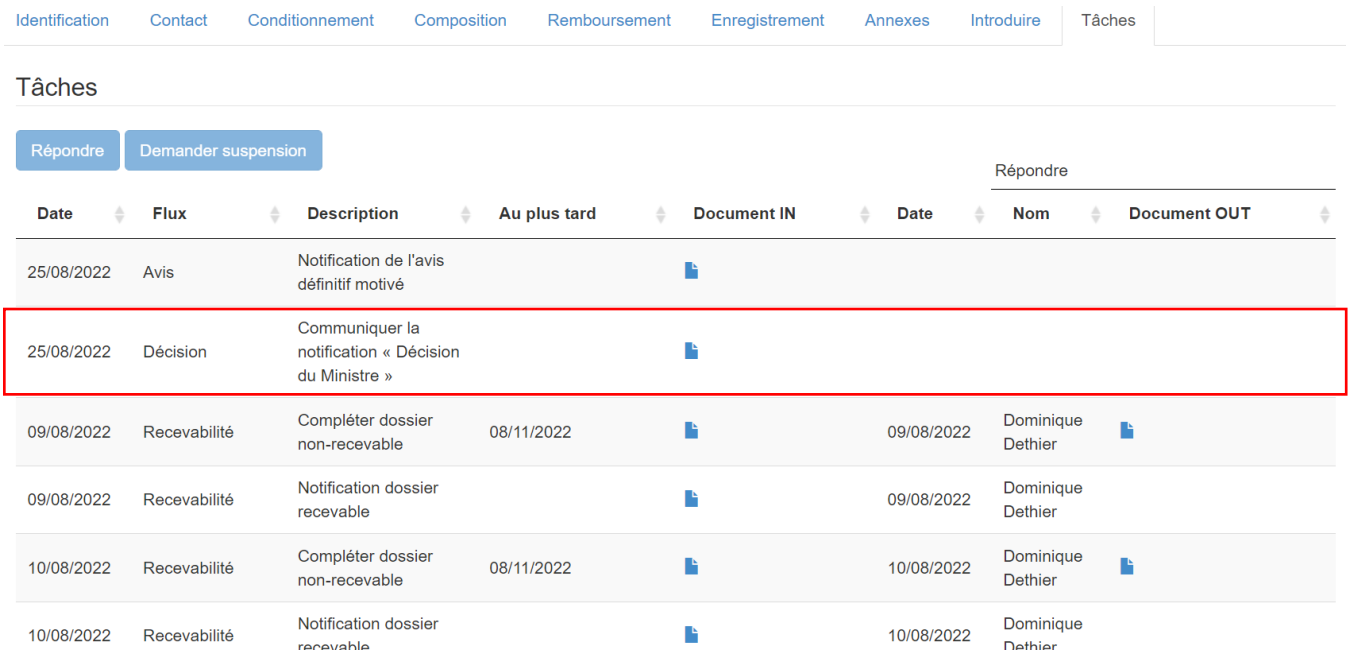
The opinion will be sent to you through the tasks ["Tâches"] related to the file in question, more specifically through the task "Notification de l'avis définitif motivé":



By clicking on the icon in the column "Document IN", you will be able to read the opinion given (and download it if you want to).

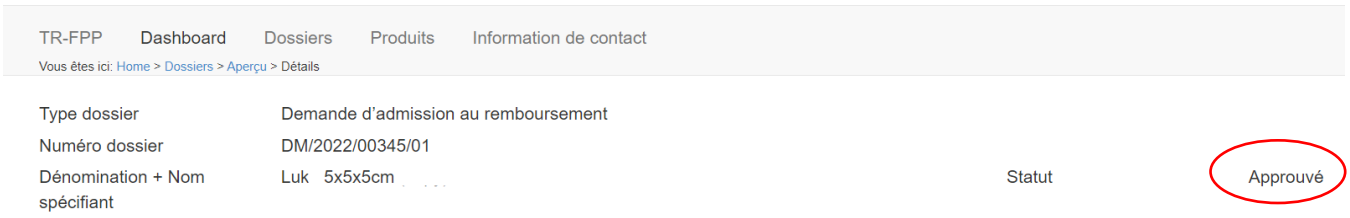
## 7.6. MINISTER'S DECISION FLOW

The Minister's decision will be sent to you through the tasks ["Tâches"] related to the file in question, more specifically through the task "Communication de la décision du Ministre" :




The file will then appear under the status "Approuvé" if the Minister approves it.

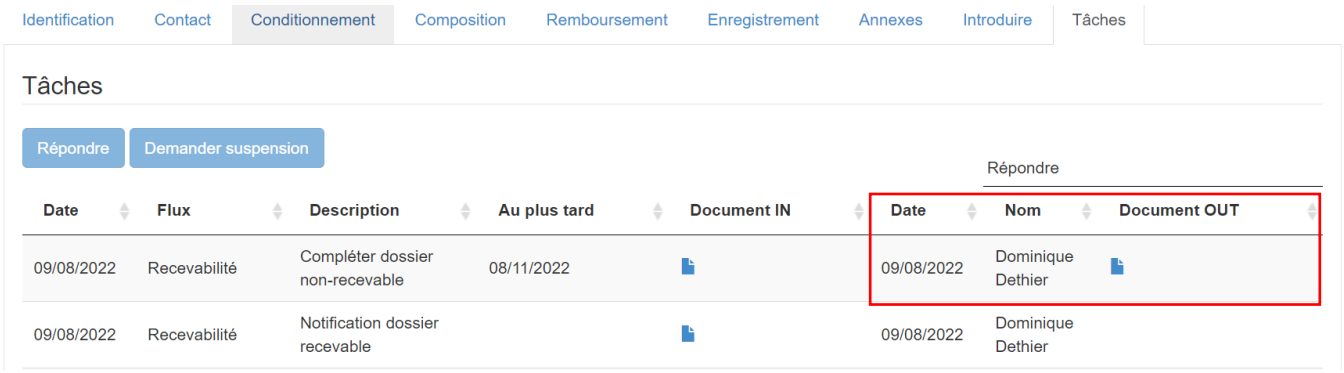
If the Minister issues a refusal, the file will receive the status "Refusé".



## 7.7. SPECIFICATIONS

### *7.7.1. File manager*

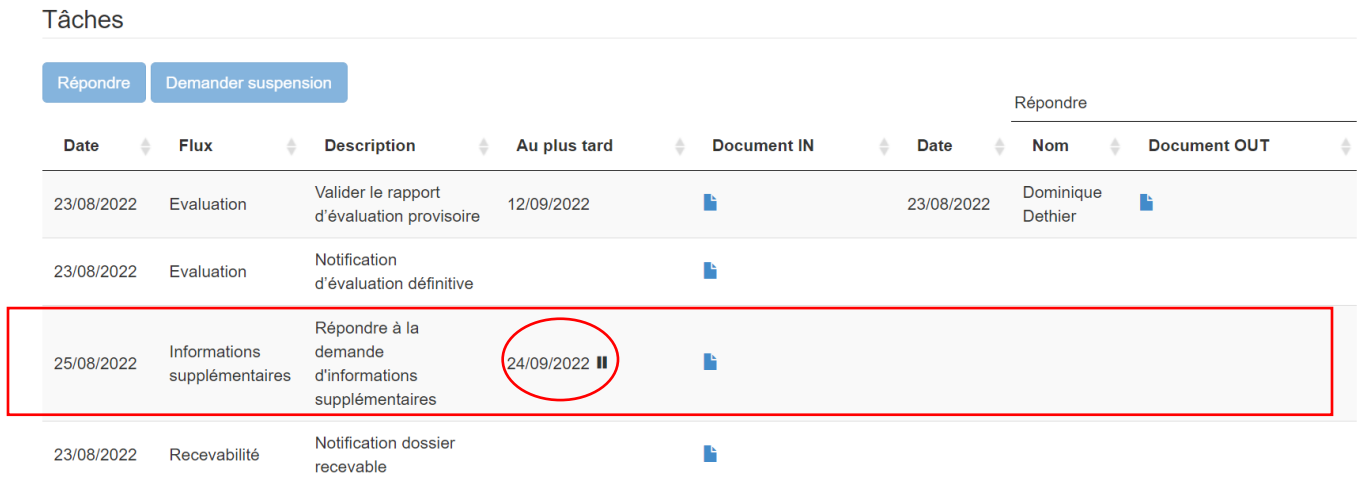
You will notice in the tasks that the date and name of the person who performed the task and the uploaded documents (documents OUT) are visible in the columns under "Document OUT".



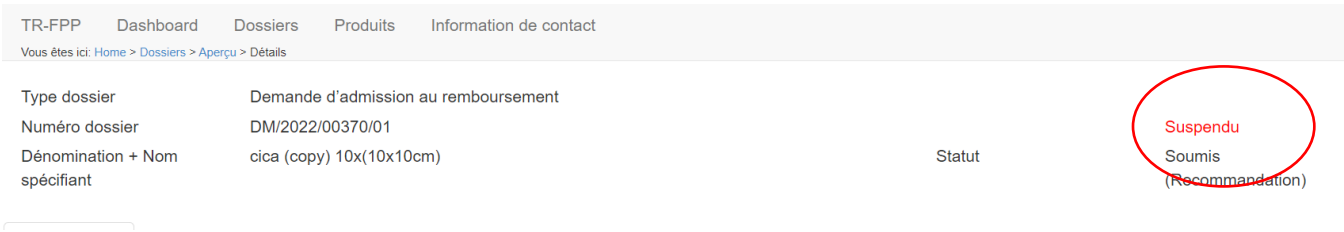

### *7.7.2. Implementation of Article 23 of the Royal Decree of 23 November 2021: request for additional information*

This function does not appear in your application but can be generated by the file manager.

A new task will then appear in the tab "Tâches" under the description "répondre à la demande d'informations supplémentaires" :



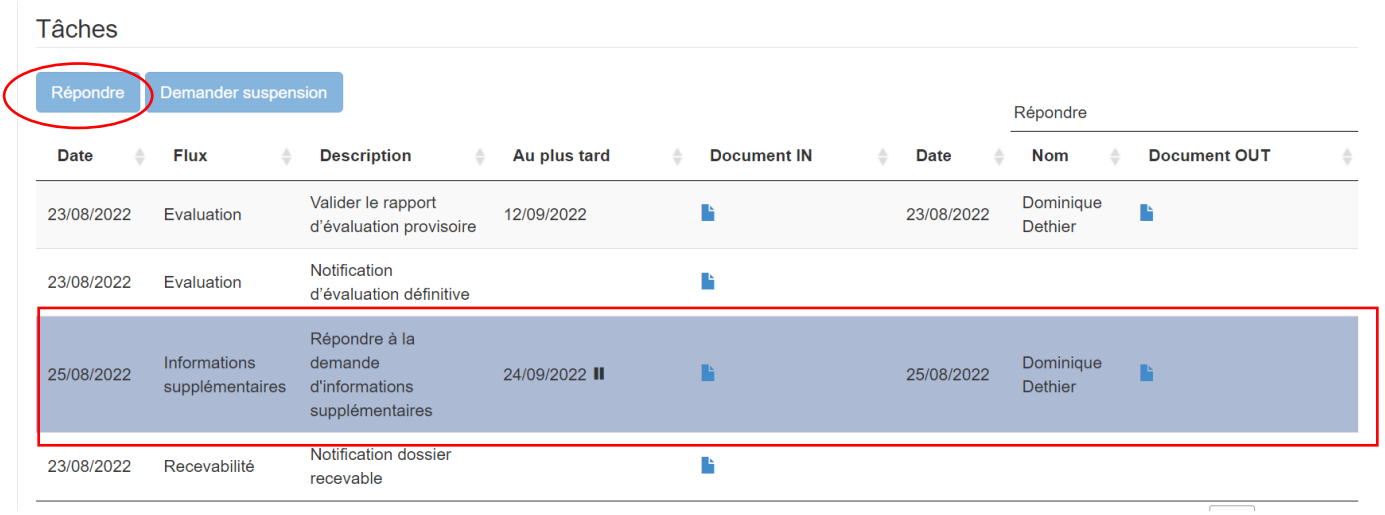

You will see in the application details that the status of the application file has been modified under "Statut"



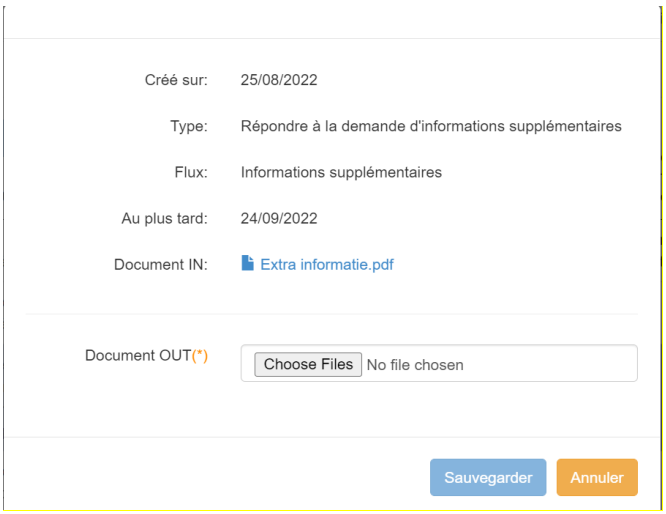
By clicking on the icon in the column "Document IN", you will be able to read (and download if you want to) the letter from the CRPPP's secretariat informing you of the request for additional information as well as of the deadline for completing this task.

The sign ⏸ means that the deadlines are suspended.

To send the requested information to the CRPPP's secretariat, you must first click on the task you wish to perform to select it. Once selected, the task row appears in bleu :



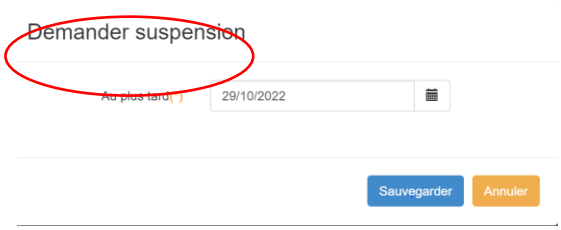

Click on "Répondre". A new window will open:




To reply, download the document(s) that provide(s) additional information. To do this, click on "Choose File", choose the document(s) to be downloaded and finally, click on "Sauvegarder".
For added convenience, it would be better if the documents to be downloaded are kept in the same folder.

### *7.7.3. Request to extend the deadline during the procedure*

If stated in the regulations, you may request an extension of the deadline




This suspension may not exceed 60 days.

The new date will then be displayed in the tab "Tâches" - column "Au plus tard"

| Date | Flux | Description | Au plus tard | Document IN | Date | Nom | Document OUT |
|---|---|---|---|---|---|---|---|
| 10/08/2022 | Evaluation | Valider le rapport d'évaluation provisoire | 01/09/2022 | | | | |

Meanwhile, the status of the file will also be modified

| | | | |
|---|---|---|---|
| Type dossier | Demande d'admission au remboursement | | |
| Numéro dossier | DM/2022/00359/01 | | Suspendu |
| Dénomination + Nom spécifiant | cica 10x(10x10cm) | Statut | Soumis (Evaluation) |