



**HEALTH CARE SERVICES
DEPARTMENT
PHARMACEUTICAL POLICY**

USER GUIDE: TR-FPP FRONT-OFFICE

**Signature procedure for the commitment for products
listed in**

Version 1.0

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COMMISSION FOR REIMBURSEMENT OF PHARMACEUTICAL PRODUCTS AND BENEFITS

Instructions for the signature procedure for the commitment for products listed in

1. Foreword

These user instructions explain how to access the application and "sign" commitments.

!!! Currently, the **active dressings** described in the list in the appendix to the 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 and **self-catheterization catheters** described in the list in the appendix to the Royal Decree of 18 April 2017 setting out the conditions under which the compulsory health care and benefits insurance contributes to the cost of self-catheterization at the beneficiary's home are NOT affected by this obligation.

2. Regulatory basis

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 20*bis* of the law on compulsory health care and benefits insurance, coordinated on 14 July 1994.

"**Art. 146.** Within two months of the date of entry into force of this provision, companies must have signed a commitment form for each product listed and sent it to the Commission Secretariat.

After that date, the Commission will propose the automatic removal of products for which the commitment form has not been signed by at least one company."

3. General introduction - access procedure

The interactive application allowing the electronic submission of commitments for reimbursable products included in the list in the appendix to the Royal Decree of 23 November 2021 is available on the INAMI-RIZIV 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

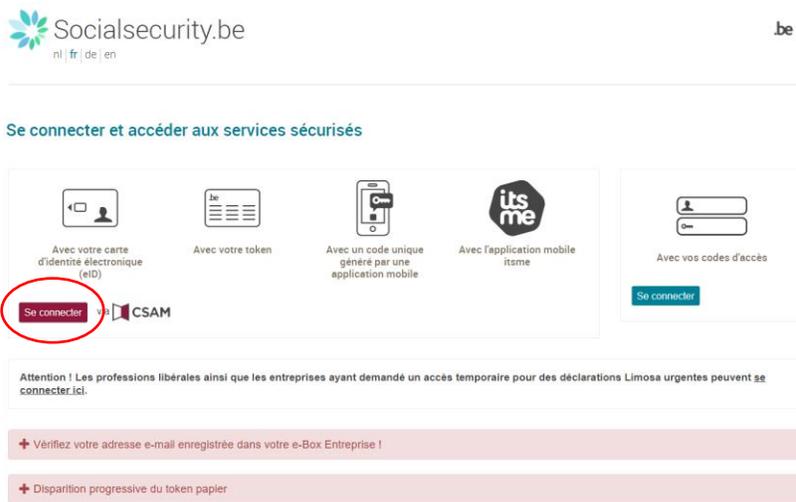
If your company is not included in the list of companies or for any questions about the access procedure, please contact the General Secretariat on 02/739.77.41 or send an email to the following address: crppp-ctfpv@riziv-inami.fgov.be, with secr-farbel@riziv.fgov.be in cc.

The procedure is as follows:

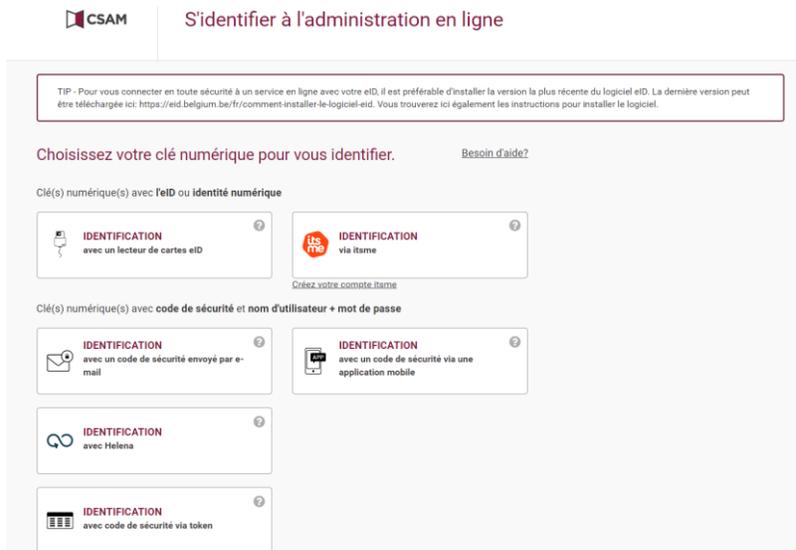
1) Click "Company"



2) Click "Log on"



3) Choose your connection method:



4) The company's home page appears:



TR-FPP AQUILAB



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

You must update and complete your data in the system .

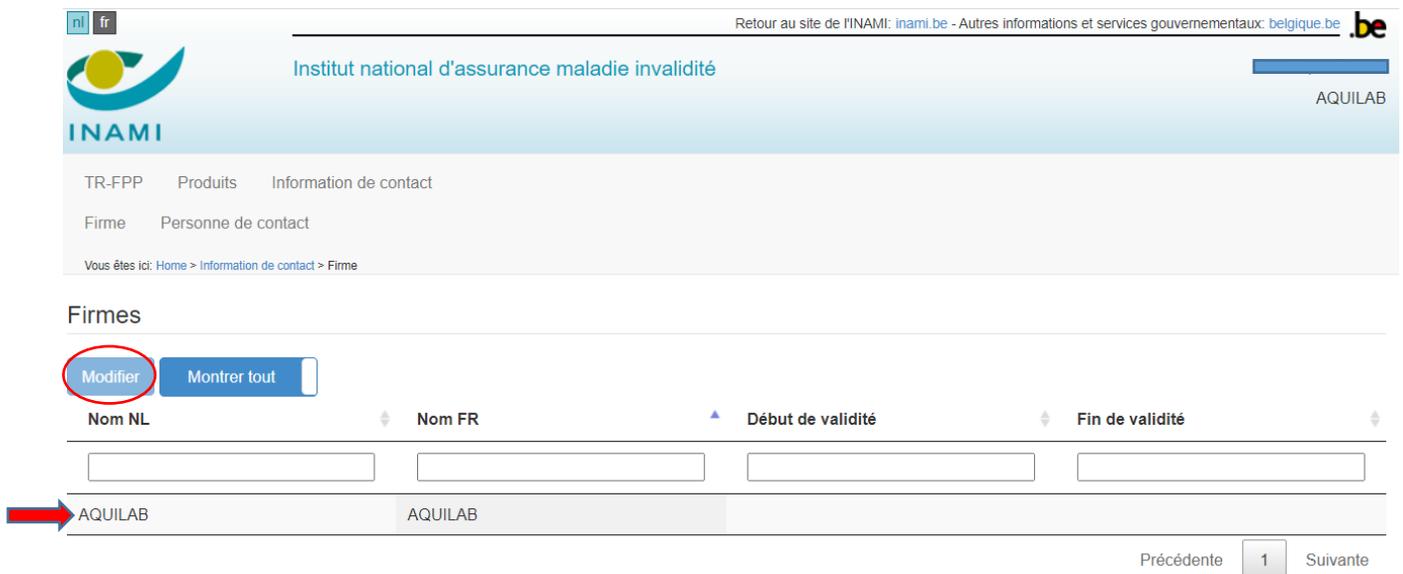
On the home page, select the "contact information" tab



TR-FPP AQUILAB

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.

Modifier firme

Id	<input type="text"/>	Id en Contacts	<input type="text"/>
Numéro CBE(*)	<input checked="" type="checkbox"/>	<input type="text"/>	
Nom NL(*)	<input type="text"/>		
Nom FR(*)	<input type="text"/>		
Nom AL(*)	<input type="text"/>		
Nom abrégé NL(*)	<input type="text"/>		
Nom abrégé FR(*)	<input type="text"/>		
Nom abrégé AL(*)	<input type="text"/>		
Pays(*)	<input type="text"/>	Langue(*)	<input type="text"/>
Début de validité	<input type="text"/>	Fin de validité	<input type="text"/>
Téléphone	<input type="text"/>	Mobile	<input type="text"/>
Email	<input type="text"/>		
Rue	<input type="text"/>		
Numéro	<input type="text"/>	Boite	<input type="text"/>
Bâtiment, étage	<input type="text"/>		
Code postal	<input type="text"/>		
Commune	<input type="text"/>		

Created by	<input type="text"/>	<input type="text"/>
Modified by	<input type="text"/>	<input type="text"/>

Finish by saving

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" tab



TR-FPP AQUILAB

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



Firmes

Nom NL	Nom FR	Début de validité	Fin de validité
AQUILAB	AQUILAB		

Précédente 1 Suivante

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

The screenshot shows the INAMI website interface. At the top, there is a navigation bar with the INAMI logo and the text "Institut national d'assurance maladie invalidité". Below this, there are tabs for "TR-FPP", "Produits", and "Information de contact". The "Information de contact" tab is active, showing "Firme" and "Personne de contact". The "Firme" dropdown menu is set to "AQUILAB". Below the dropdown, there are three buttons: "Ajouter", "Modifier", and "Montrer tout". The "Ajouter" button is circled in red. Below the buttons, there is a table with columns for "Nom", "Début de validité", and "Fin de validité". The table is currently empty. At the bottom right of the table, there are navigation buttons: "Précédente", "1", and "Suivante".

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

The screenshot shows the "Ajouter contact" form. The form contains the following fields: "Nom de famille(*)", "Prénom(*)", "Langue(*)" (dropdown), "Téléphone" and "Mobile" (text inputs), "Email(*)", "Rue", "Numéro" and "Boite" (text inputs), "Bâtiment, étage", "Commune", "Code postal" and "Pays" (dropdown), "Début de validité" and "Fin de validité" (date pickers). At the bottom of the form, there are two buttons: "Sauvegarder" and "Annuler". The "Sauvegarder" button is circled in red, and a red arrow points from the text "Finish by saving" to it.

The following fields are mandatory and must be completed

Surname
First name
Language
Email

The other fields are optional but strongly recommended.

5. Practical recommendations for drafting the commitment

→ One listed product = one commitment

For each reimbursable product included in Part I of the list of reimbursable products in the appendix to the aforementioned Royal Decree, the company responsible for submitting the application (= the applicant) is required to complete, date and sign a commitment.

In the checklists below, you will find the elements that must be included in the commitment.

These instructions do not replace the legal basis.

6. The commitment

Once your company's data has been entered, you must complete and sign a commitment for each product included in the list of reimbursable products in the appendix to the Royal Decree of 23 November 2021.

Select the "Products" menu

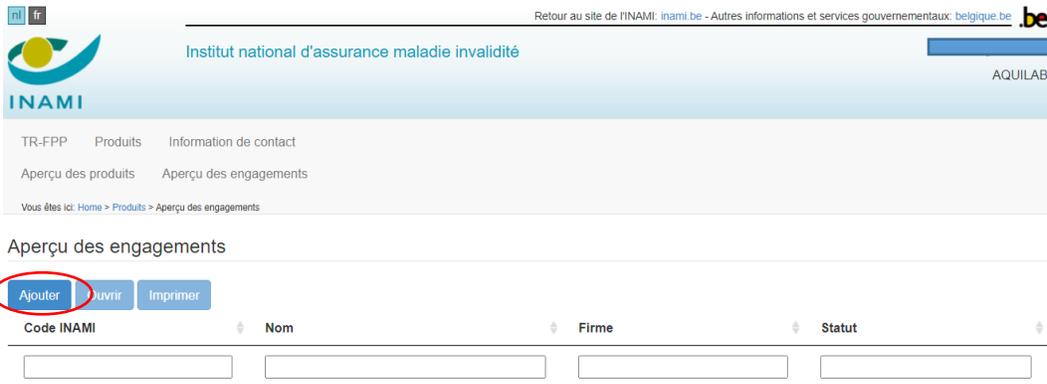


TR-FPP AQUILAB

Then, select the "Commitments overview" menu to add all the products



Then click "Add".



You are then taken to the following environment:

The screenshot shows the INAMI website header with the logo and navigation menu. The main content area is titled 'Type de demande' and contains a form with several fields: 'Code INAMI', 'Dénomination + Nom spécifiant', and 'Statut'. Below the form are tabs for 'Identification', 'Contact', 'Conditionnement', 'Composition', and 'Engagement'. The 'Identification' tab is currently selected.

Click on each tab and complete the data.
If the data is not entered correctly, you will not be able to move to the next tab.

At the end of each step, click "Confirm the content of this section" to move to the next tab.

6.1. The elements required for the commitment

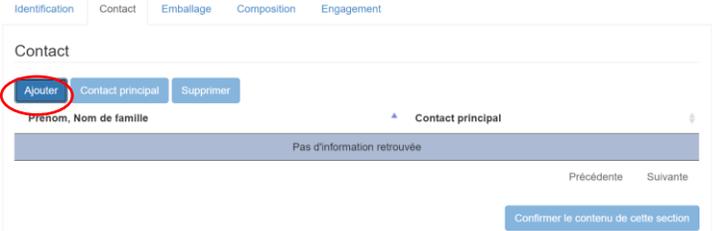
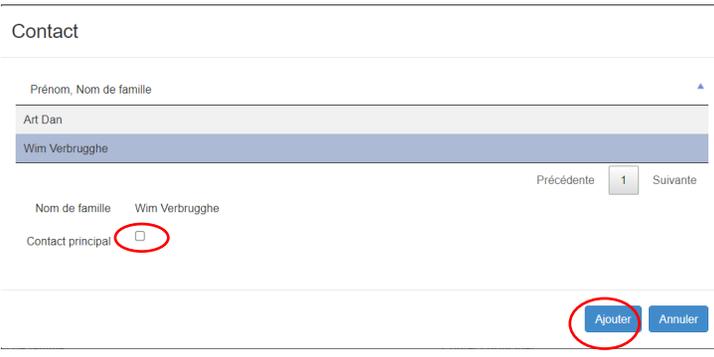
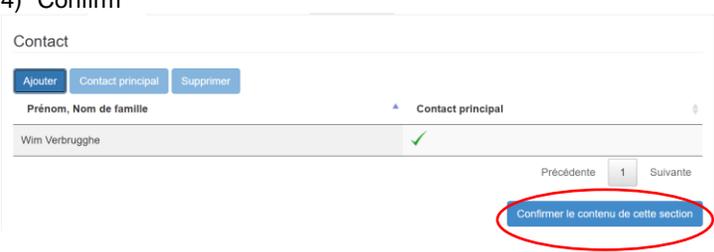
For each tab, the required elements are as follows:

Required elements		Mandatory	Optional	Comments/examples
Identification				
Company				
	Name of the company responsible for the application	X		the company name is displayed automatically = name of the company signing the commitment
	Signature date of the commitment	X		registered automatically once the commitment is duly completed and finalised
Product				
	Category	X		Drop-down menu - click on the appropriate category
	Group	X		Drop down menu - click on the appropriate group
	Name FR and NL	X		= name of the product <i>Example:</i> Paracetamol Melolin PKU Anamix Junior LQ fruits of the forest flavour
	Specifying name		X	= additional specification of the packaging <i>Example:</i> Paracetamol 25g → the specifying name is 25g Melolin 25 x (5x5cm) → specifying name is 25 x (5x5cm) PKU Anamix Junior LQ fruits of the forest flavour 6 x 6 x 125 ml → specifying name is 6 x 6 x 125 ml

		<p>The product's name and specifying name will form the name of the file you create:</p> <div style="border: 1px solid black; padding: 5px;"> <p>Type dossier Engagement Code INAMI MAG/2022/00254</p> <p>Denomination + Nom Melolin 25x(5x5cm) Statut En création spécifiant</p> <p>Identification Contact Conditionnement Composition Documents Engagement</p> <p>Firme</p> <p>Nom(*) AQUILAB</p> <p>Date engagement</p> <p>Produit/Prestation</p> <p>Type/Catégorie/Groupe(*) Produit MAG - préparations magistrales Pansement passif</p> <div style="border: 1px solid red; padding: 2px;"> <p>Dénomination NL(*) Melolin</p> <p>Nom spécifiant NL 25x(5x5cm)</p> <p>Synonymes NL</p> <p>Dénomination FR(*) Melolin</p> <p>Nom spécifiant FR 25x(5x5cm)</p> <p>Synonymes FR</p> </div> </div>						
	Synonyms		X	<p>Only for products for raw materials for magistral preparations.</p> <p><i>Example:</i> Tosylchloramide sodium: synonym = Chloramine</p>				
	Status "orphan"		X					
	Status "imported"		X					
	Self-catheterization reference number		X*	<p>* Only for self-catheterization catheters</p> <p>= number of the company-specific article</p> <p><i>Example:</i></p> <table border="1" style="width: 100%; text-align: center;"> <tr> <td style="width: 30%;">Teleflex Medical</td> <td style="width: 30%;">RÜSCH CARE 20cm NELATON CH08</td> <td style="width: 10%;">8</td> <td style="width: 10%;">850160</td> </tr> </table>	Teleflex Medical	RÜSCH CARE 20cm NELATON CH08	8	850160
Teleflex Medical	RÜSCH CARE 20cm NELATON CH08	8	850160					
	EU Classification	X*		<p>Drop-down menu - click on the appropriate category</p> <p>* Only mandatory for medical devices</p> <p>This classification can be found in:</p> <ul style="list-style-type: none"> - REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices; or - REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices. 				
Liability								
	Name of the company that places the product on the market	X		<p>= company name that will be published next to the product name → may be different from the company that signs the commitment</p> <p>(NB: for raw materials for magistral preparations, the company name is not published)</p>				



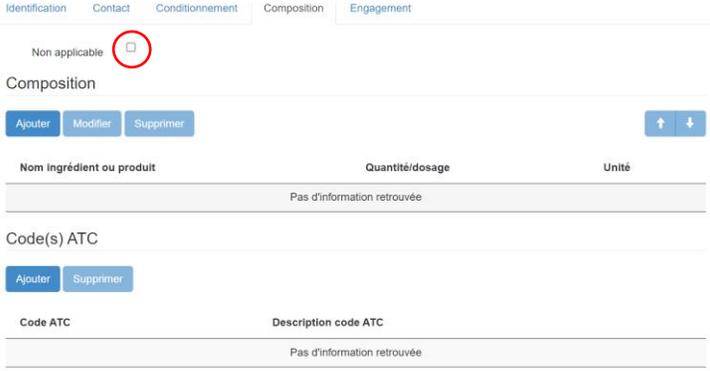
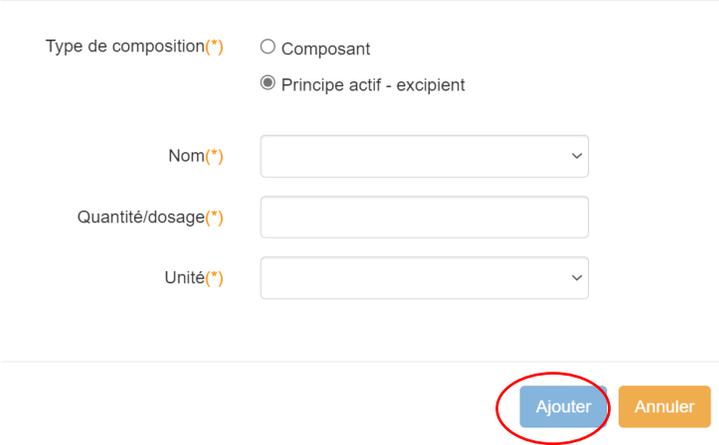
Confirmer le contenu de cette section

Contact	First name and surname of the contact person	X		<p>1) Click "Add"</p>  <p>2) Select the contact person by clicking their name and clicking "Add"</p>  <p>3) Specify whether they are the "Main contact" and click "add"</p>  <p>4) "Confirm"</p> 
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Confirmer le contenu de cette section

Packaging				
Description of the packaging				
	Description NL and FR	X		= full name of the product as it will be published <i>Example:</i> Passive dressings: Melolin 25 x (5cmx5cm) Medical nutrition: PKU Anamix Junior LQ fruits of the forest flavour 6x6x125 ml
Package characteristics				
	Quantity	X		= number of "units" in the package <i>Example:</i> Passive dressings: Melolin 25 x (5cmx5cm) → quantity = 25 Magistrals: Paracetamol 25g package → quantity = 1 Medical nutrition: PKU Anamix Junior LQ fruits of the forest flavour 6x6x125 ml → quantity = 36
Depending on the category of the product, such data is strongly recommended	Pharmaceutical form		X*	Drop-down menu * Only <i>mandatory</i> for products for magistral preparations
	Volume/weight	Unit (Drop-down menu)		X = total quantity (weight or volume) of the product per package <i>Example:</i> Magistrals: Paracetamol 25g package → volume = 25/unit = g Medical devices: ECOBAG bag 3L → volume = 3/unit = L Medical nutrition: PKU Anamix Junior LQ fruits of the forest flavour - packaging 6x6x125 ml → volume = 125/unit = ml
	Dosage	Unit (Drop-down menu)		X = product concentration/dosage <i>Example:</i> Medical devices: MUCOCLEAR 6% 60 x 4 mL hypertonic solution/hypertonische oplossing" → dosage = 6/unit = %.
	Dimensions	Unit (Drop-down menu)		X = size/dimension of the product <i>Example:</i> Passive dressings: Melolin 25 x (5cmx5cm) → dimension 1 = 5/unit 1 = cm --- dimension 2 = 5/unit 2 = cm Dimension <input type="text"/> Unité <input type="text"/> x <input type="text"/> Unité <input type="text"/>
	Density			X Only for products for magistral preparations
 Confirmer le contenu de cette section				

<p>Composition</p>			<p>If "Composition" and "ATC codes" are not applicable: tick "Not applicable" <input type="checkbox"/></p>  <p><i>Example:</i> Medical devices: OMRON Blood Pressure Monitor</p>
	<p>Composition</p>	<p>X</p>	<p>= complete product composition</p> <p>Click "Add" as many times as an product/excipient/active substance needs to be added:</p>  <p>You are then taken to the "Composition" document where you choose the composition type.</p> <p>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 <i>example</i>: MUCOCLEAR = hypertonic solution). The "Product" choice concerns medical devices in particular. Only the "Active substances" for magistral preparations and medical nutrition are predefined and need to be selected from a drop-down menu.</p> <p>After entering each component, click "add".</p> <p>Composition</p> 

				<p><i>Example:</i></p> <p>Dalibour Water:</p> <div data-bbox="852 241 1555 415"> <p>Composition</p> <p>Ajouter Modifier Supprimer Haut Bas</p> <table border="1"> <thead> <tr> <th>Nom ingrédient ou produit</th> <th>Quantité/dosage</th> <th>Unité</th> </tr> </thead> <tbody> <tr> <td>Zinc sulfate</td> <td>2,50</td> <td>g</td> </tr> <tr> <td>Cupre sulfate</td> <td>0,75</td> <td>g</td> </tr> <tr> <td>eau</td> <td>100,00</td> <td>ml</td> </tr> </tbody> </table> </div>	Nom ingrédient ou produit	Quantité/dosage	Unité	Zinc sulfate	2,50	g	Cupre sulfate	0,75	g	eau	100,00	ml
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Zinc sulfate	2,50	g														
Cupre sulfate	0,75	g														
eau	100,00	ml														
	ATC Code	X		<p>The classification to be used is that established by the "WHO Collaborating Centre for Drug Statistics Methodology" in Oslo.</p> <p>Click "Add" as many times as a code needs to be added:</p> <div data-bbox="852 590 1555 703"> <p>Code(s) ATC</p> <p>Ajouter Supprimer</p> <table border="1"> <thead> <tr> <th>Code ATC</th> <th>Description code ATC</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="text-align: center;">Pas d'information retrouvée</td> </tr> </tbody> </table> </div> <p>Search for the required ATC code by entering it. The description will be displayed automatically. Click "Add"</p> <div data-bbox="852 863 1555 1165"> <p>Code ATC</p> <p>Code ATC(*) <input type="text"/></p> <p>Description code ATC <input type="text"/></p> <p style="text-align: right;">Ajouter Annuler</p> </div> <p><i>Example:</i></p> <div data-bbox="852 1241 1555 1354"> <p>Code(s) ATC</p> <table border="1"> <thead> <tr> <th>Code ATC</th> <th>Description code ATC</th> </tr> </thead> <tbody> <tr> <td>S01AX03</td> <td>COMPOSES A BASE DE ZINC</td> </tr> <tr> <td>V03AB20</td> <td>SULFATE DE CUIVRE</td> </tr> </tbody> </table> </div>	Code ATC	Description code ATC	Pas d'information retrouvée		Code ATC	Description code ATC	S01AX03	COMPOSES A BASE DE ZINC	V03AB20	SULFATE DE CUIVRE		
Code ATC	Description code ATC															
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Code ATC	Description code ATC															
S01AX03	COMPOSES A BASE DE ZINC															
V03AB20	SULFATE DE CUIVRE															

6.2. Finalising the commitment

					
Commitment					
Overview of the status of the different sections				<p>Elements missing from the creation of the commitment will be highlighted in red</p> <p><i>Example:</i></p> <p>Aperçu du statut des différentes sections</p> <ul style="list-style-type: none"> - Identification Compléter - Contact Compléter - Emballage Compléter - Composition Compléter 	
Commitment					
	Name of the person signing the commitment	X		Field completed automatically	
	Company name and address	X		Field completed automatically	
	Occupation of the person signing the commitment	X		For example: director - consultant ...	
	3 commitments to be ticked <u>He/she declares:</u> <u>He/she agrees:</u> <u>They know</u>	X		<p>Tick the following 3 statements:</p> <p><input checked="" type="checkbox"/> Elle déclare.</p> <ul style="list-style-type: none"> - qu'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. <p><input checked="" type="checkbox"/> Elle s'engage.</p> <ul style="list-style-type: none"> - 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 conditionnement(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) ; <p><input checked="" type="checkbox"/> Il/ils savent(s).</p> <ul style="list-style-type: none"> - 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. 	
	"SEND"			<p>When the commitment is complete, click "Send"</p> <p><input checked="" type="checkbox"/> Elle déclare.</p> <ul style="list-style-type: none"> - qu'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. <p><input checked="" type="checkbox"/> Elle s'engage.</p> <ul style="list-style-type: none"> - 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 conditionnement(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) ; <p><input checked="" type="checkbox"/> Il/ils savent(s).</p> <ul style="list-style-type: none"> - 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. <p style="text-align: right;"> <input type="button" value="Supprimer"/> <input type="button" value="Imprimer"/> <input checked="" type="button" value="Envoyer"/> </p>	

				If you wish to print or download the commitment template, click "Print" to print the completed commitment template in the format published in the RD.

Note:

If you need to sign a commitment for more than one product in the same group, you can "duplicate" the data by clicking "Duplicate" after selecting the product to be duplicated.

You then modify the particular characteristics of the relevant product.

Aperçu des engagements

Ajouter	Dupliquer	Ouvrir	Imprimer
Code INAMI	Nom	Firme	Statut
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>