Application for Import Confirmation Operation Manual (Application Functions)

Rev.1.10

Table of Contents

2.1 OVERVIEW OF APPLICATION FUNCTIONS 1
2.1.1 Overview *1*
2.1.2 User Type and Role *2*
2.2 IMPORT CONFIRMATION APPLICATION 3
2.2.1 Import for Personal Use *3*
2.2.2 Import for Treatment, etc. by Doctors, etc. *15*
2.2.3 Import for Trials and Research *31*
2.3 BULK APPLICATION 45
2.3.1 Register the Bulk Application Information *45*
2.3.2 Data Specifications of Bulk Application Files *51*
2.4 REFER TO THE STATUS 65
2.4.1 Search Import Confirmation Applications *65*
2.4.2 View Import Confirmation Applications *68*
2.4.3 Edit or Withdraw an Import Confirmation Application *71*
2.4.4 Approve Application by Agent *75*
2.4.5 Download a Yunyu Kakunin-sho/Import Certificate *77*
2.4.6 Download Application Status List *80*
2.4.7 Duplicate Import Confirmation Application *83*

2.1 Overview of Application Functions

2.1.1 Overview

This chapter describes the operation procedures of the "Application Functions" in the Application for Import Confirmation.

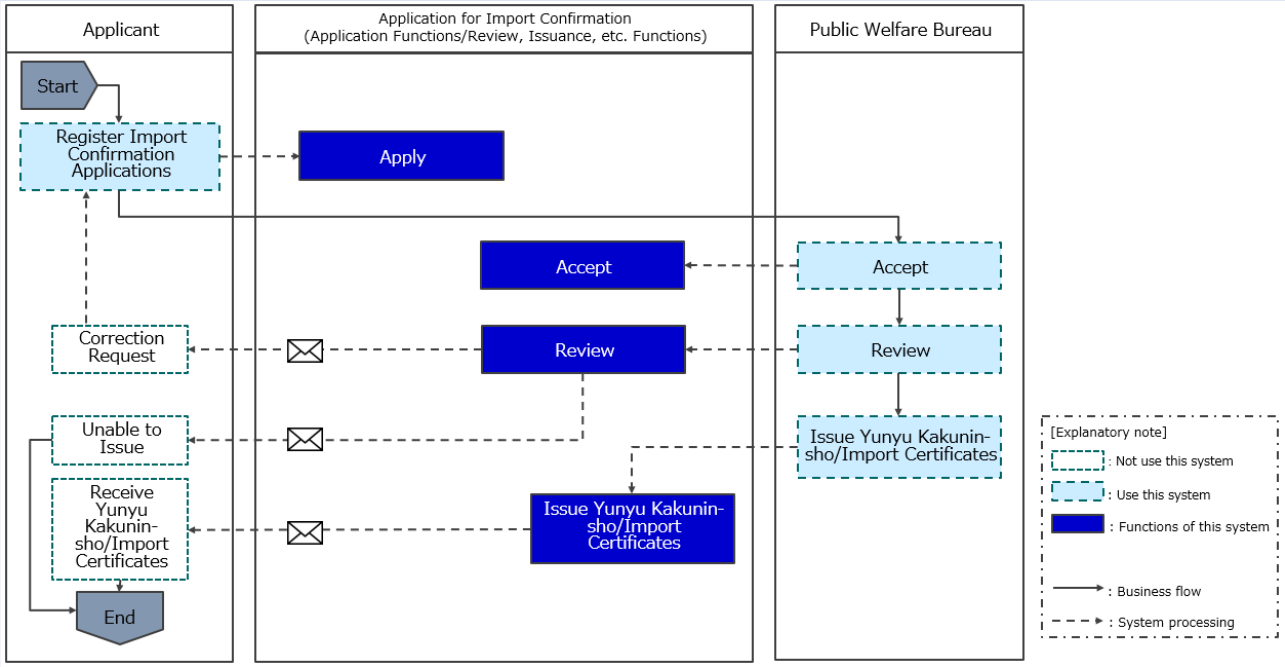
● Application Functions

The "Application Functions" offer functions such as Import Confirmation Application and Refer to the Status.

Function Name		Description
Import Confirmation Application		Offers a function to apply for import confirmation depending on the application type: "Import for Personal Use," "Import for Treatment, etc. by Doctors, etc.," and "Import for Trials and Research."
	Bulk Application	Offers a function to register bulk application information.
Refer to the Status		Offers functions to search, view, edit, and cancel import confirmation applications, approve applications by agents, download application status lists, download import confirmation applications, and duplicate for import confirmation.

● Flow from Application to Receipt of Import Confirmation Certificate

The flow from application to receipt of an import confirmation certificate in the "Application Functions" is as follows:



2.1.2 User Type and Role

Users of the “Application Functions” are as follows. Each user role is described.

User Type	Account Type	Role
Applicant	Healthcare Professional	Applies for import confirmation depending on the application type: “Import for Personal Use,” “Import for Treatment, etc. by Doctors, etc.,” and “Import for Trials and Research.” Uses the Refer to the Status function after application.
	Personal	
	Corporate	
Agent		Uses the same functions as those of an applicant as an application agent.

2.2 Import Confirmation Application

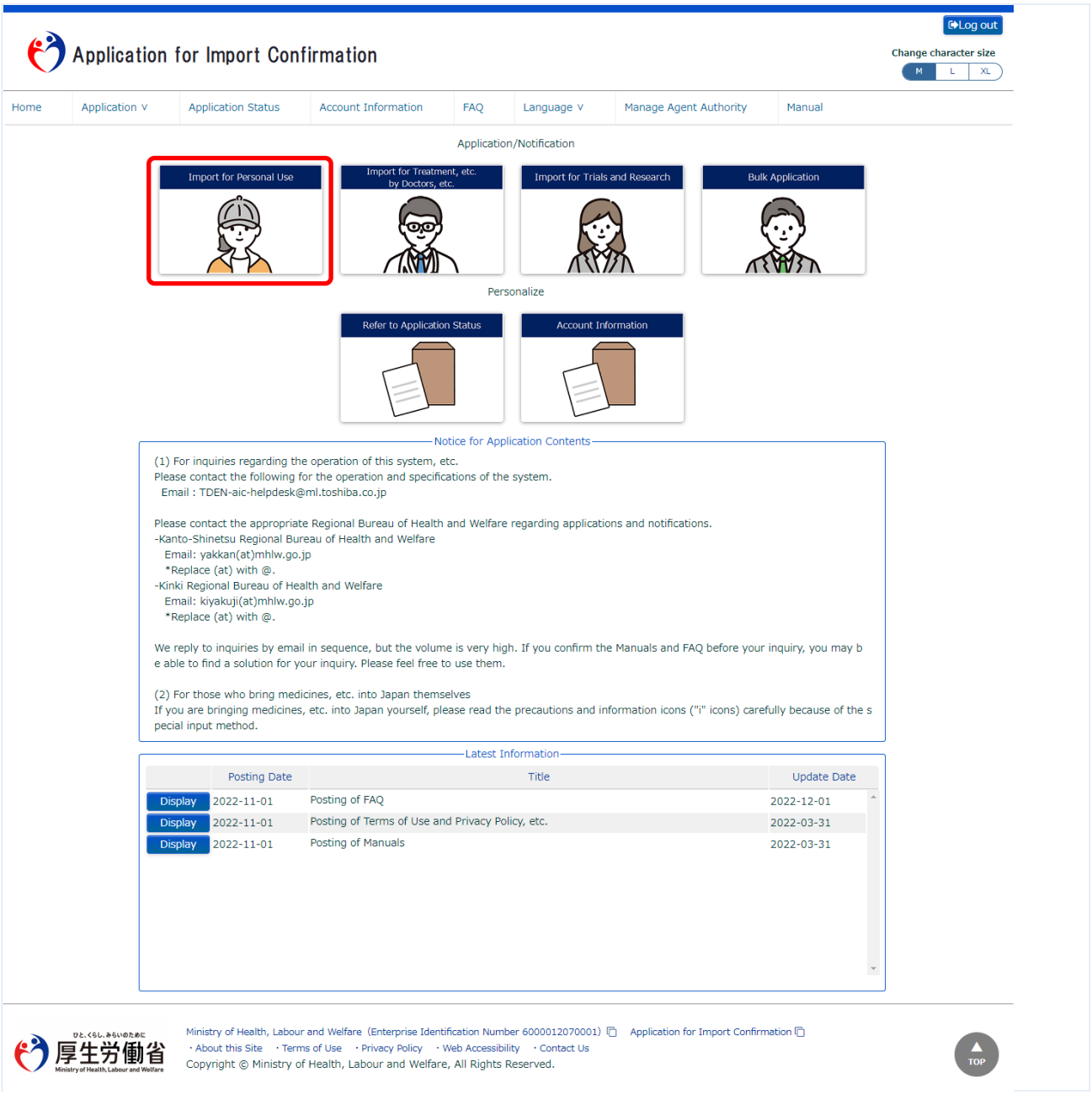
2.2.1 Import for Personal Use

This is a function for an applicant to submit an import confirmation application to import for personal use.

(1) Open the screen to apply for import confirmation

Click “Import for Personal Use” on the Home screen.

<Home Screen/Applicant>



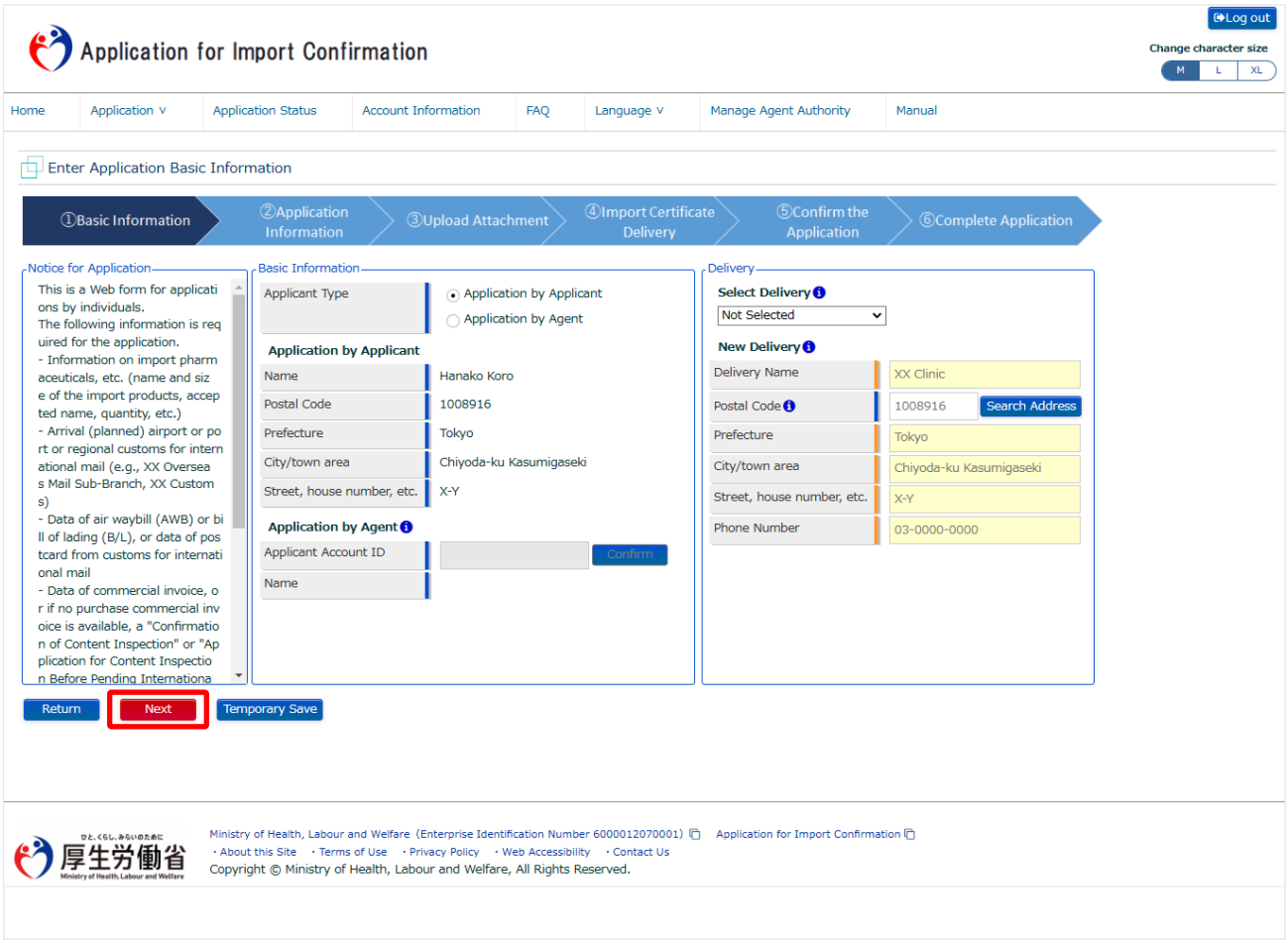
(2) Enter application basic information

The screen to enter application basic information is displayed.

The orange fields are required items, so make sure to enter them.

*Please consult with the Kanto Shinetsu or Kinki Health and Welfare Bureau that has jurisdiction over your application if you have any questions about the contents (what information should be included) or optional items (which items should be selected).

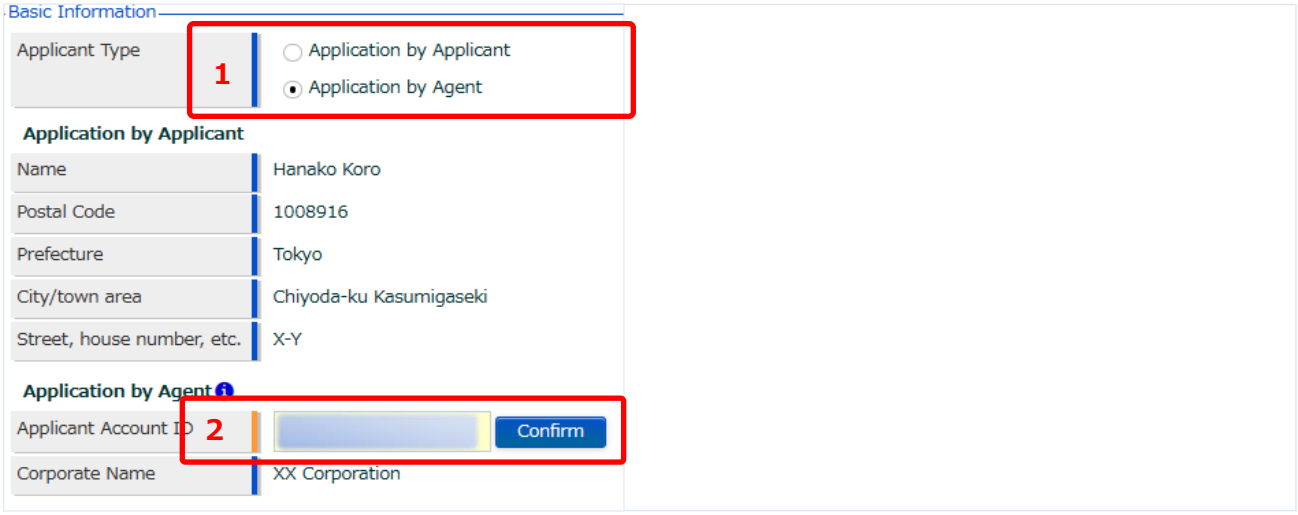
<Enter Application Basic Information>



[Basic Information]

1. If the application is to be made by the applicant himself/herself, please confirm that “Application by Applicant” is selected.

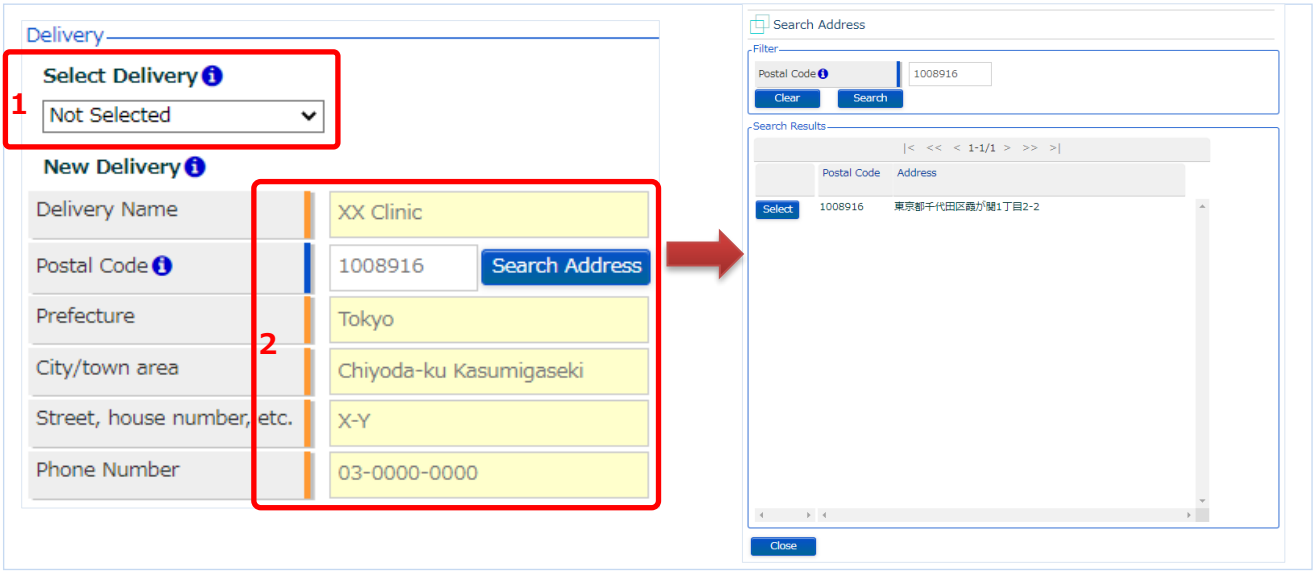
2. Select “Application by Agent” if an agent will apply, enter “Applicant Account ID” in the Application by Agent section, and click “Confirm.”



[Delivery]

1. In the "Select Delivery" field, select a registered destination from the pull-down menu. (If you wish to increase the number of options, please add more addresses by changing your account information.)
2. If there is no delivery destination in the pull-down, enter a delivery destination in “New Delivery.”

When you enter a postal code (without a hyphen) and click “Search Address,” the Search Address dialog is displayed. Click “Select” to select a postal code and an address.



Enter data and click “Next.”

To temporarily save, click “Temporary Save.” The contents in the process of entry will be saved with the correspondence status "Have not applied." To resume the application, select the "Refer to Application Status" button on the Home screen, select the details button for the temporarily saved application, and enter the missing information using the "Revise and reapply" button.

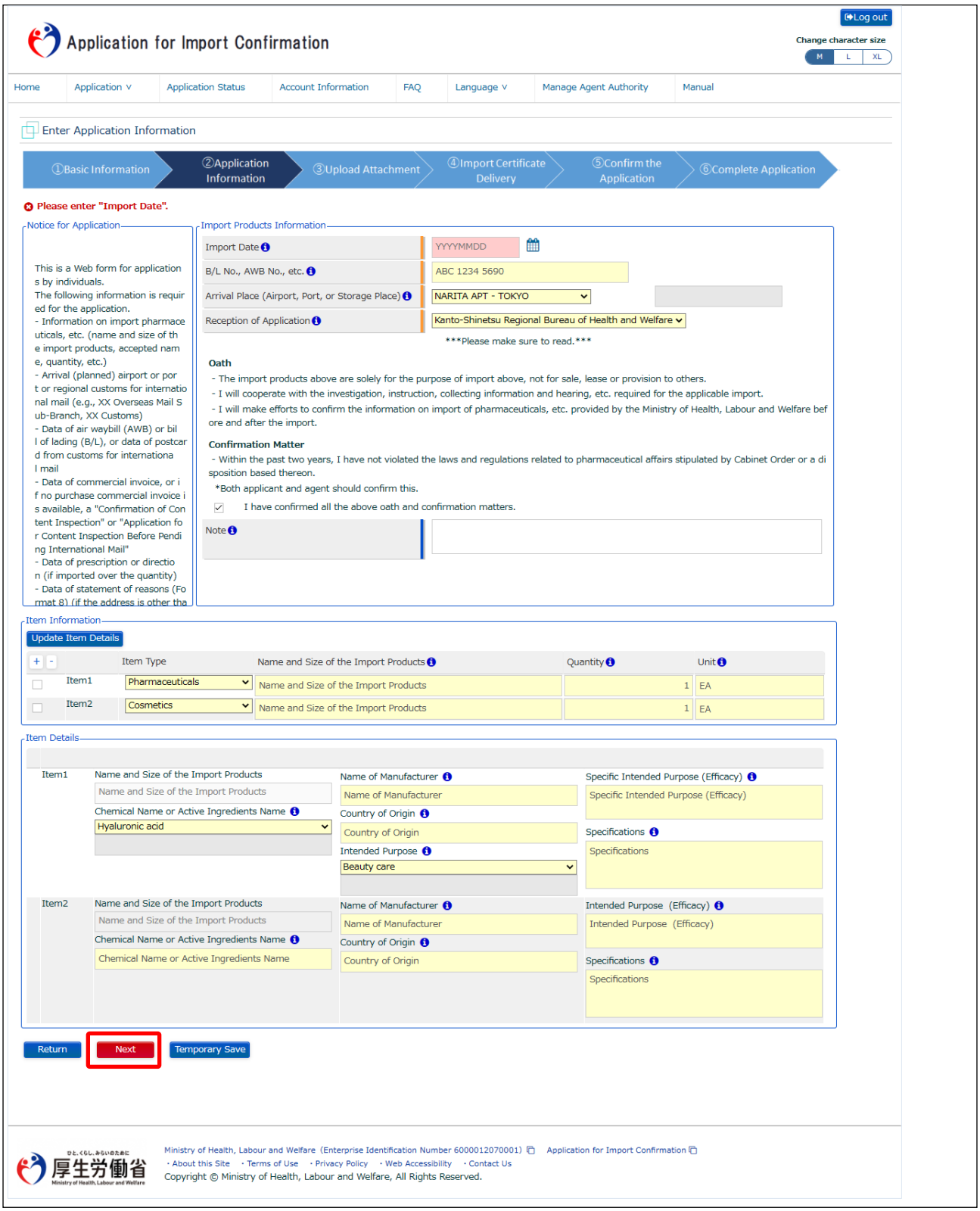
Click “Return” to go back to the Home screen.

(3) Enter application information

The screen to enter application information is displayed.

Enter data according to the information icons and click “Next.”

<Enter Application Information/Import for Personal Use>

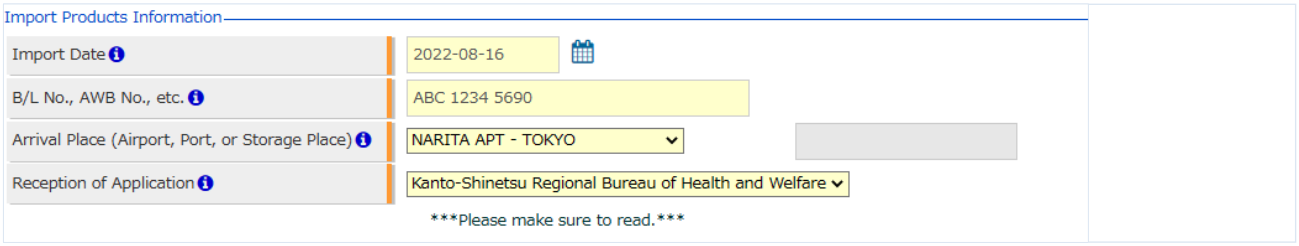


[Import Products Information]

Enter the arrival date of the import products in Japan in “Import Date.” If you have not yet arrived in Japan, please enter the expected date of arrival.

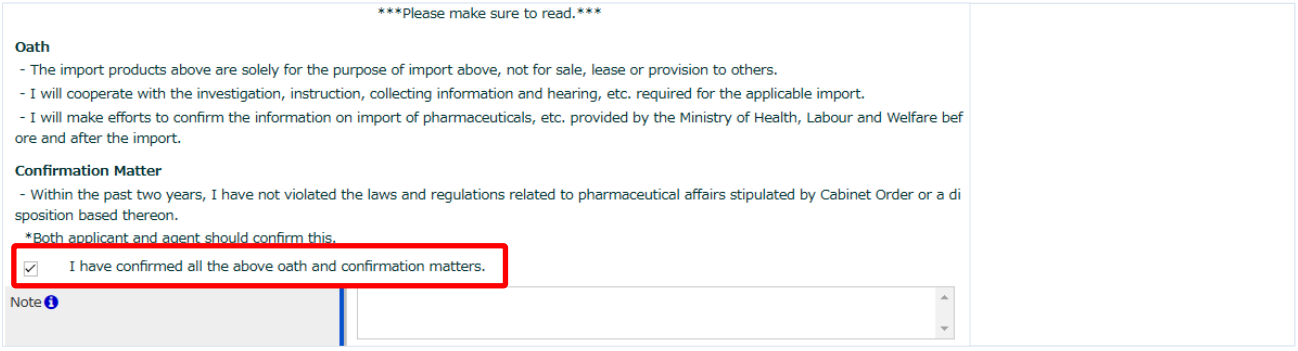
Enter the Air Waybill (AWB) No. or Bill of Lading (B/L) No. in “B/L No., AWB No., etc.” Enter the Notice No. (12 digits) of the postcard from customs if you received one.

Select the arrival place, etc. from the “Arrival Place (Airport, Port, or Storage Place)” pull-down. If you selected Other, enter in “Other.” Enter a part of the name of the airport or other facility in the input field to see the candidates. Select “Reception of Application” from the pull-down.



Confirm the contents of the Oath and the Confirmation Matter and check the box, “I have confirmed all the above oath and confirmation matters.”

Enter a supplementary note, etc. for the application in “Note” if any.



[Item Information]

Select “Item Type” from the pull-down.

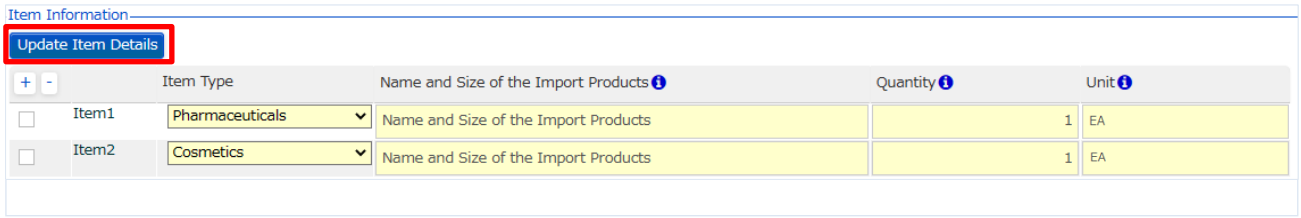
Enter the name and the quantity per unit described in the invoice in “Name and Size of the Import Products.”

Enter the quantity described in the invoice in “Quantity.”

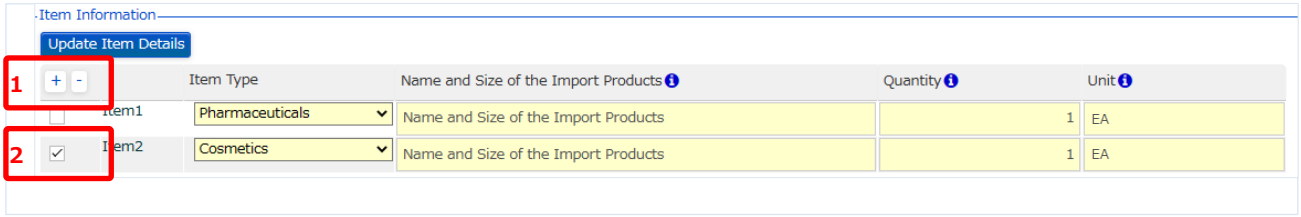
Enter the unit of quantity such as 'tablets', 'pills', 'EA' in “Unit.”

When entry is completed, click “Update Item Details.” The entry in Item Information will be updated in the Item Details, so please continue to enter the Item Details.

If you edited Item Information after updating Item Details, click “Update Item Details” again. The edited data will be updated in the Item Details.



1. To add rows, click "+."
2. To delete rows, check the rows to delete and click "-" at 1.



[Item Details]

If the item type for "Chemical Name or Active Ingredients Name" is pharmaceuticals, select it from the pull-down list. If you selected Other from the pull-down list, enter the accepted name, etc. in "Other." If the item type is other than pharmaceuticals, enter the accepted name, etc.

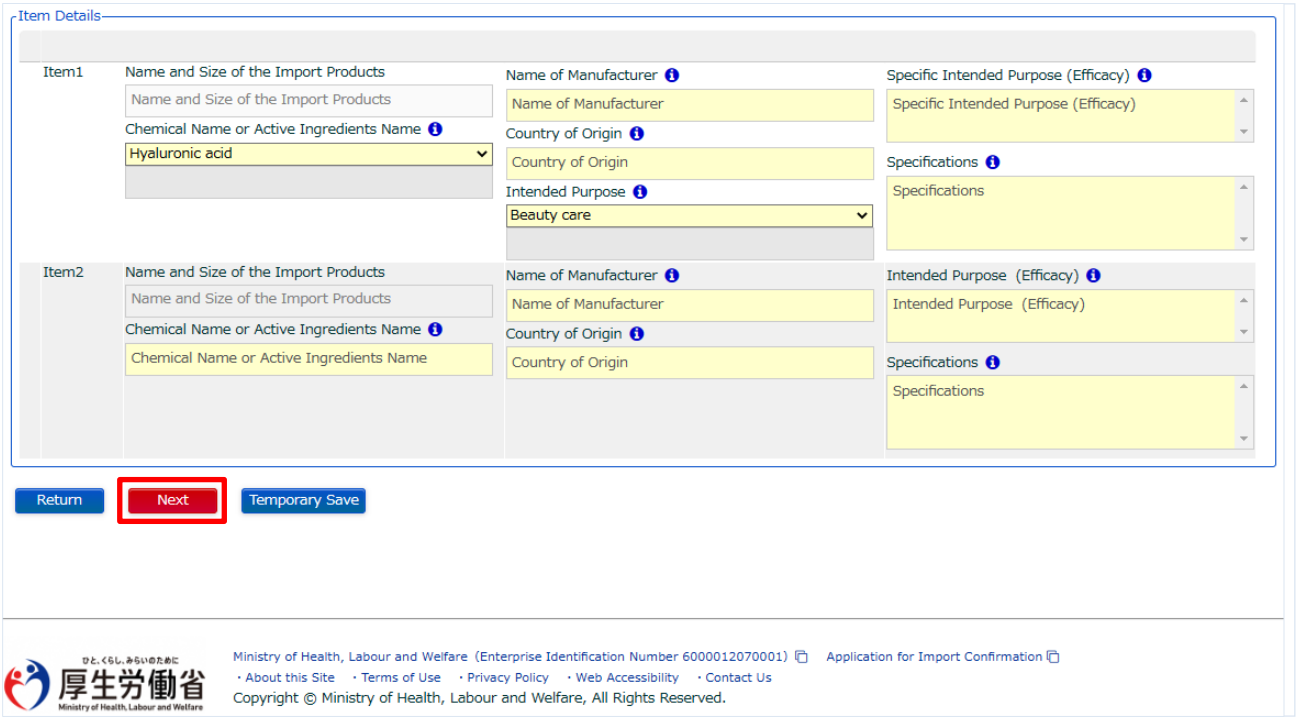
Enter the name of the manufacturer of the import products in "Name of Manufacturer."

Enter a country of origin of the import products in "Country of Origin." Enter part of the country name to see candidate country names and select one.

For pharmaceuticals, select the intended purpose of the import products from the "Intended Purpose" pull-down list. If you selected Other, briefly enter an intended purpose within 20 characters.

Enter a specific purpose of use, general efficacy, etc. of the import products in "Specific Intended Purpose (Efficacy)" for pharmaceuticals and enter it in "Intended Purpose (Efficacy)" for non-pharmaceuticals.

Enter the dosage form, etc. for pharmaceuticals, a summary of rationale and structure, etc. for medical devices, and characteristics of the product for regenerative medicine products in "Specifications."



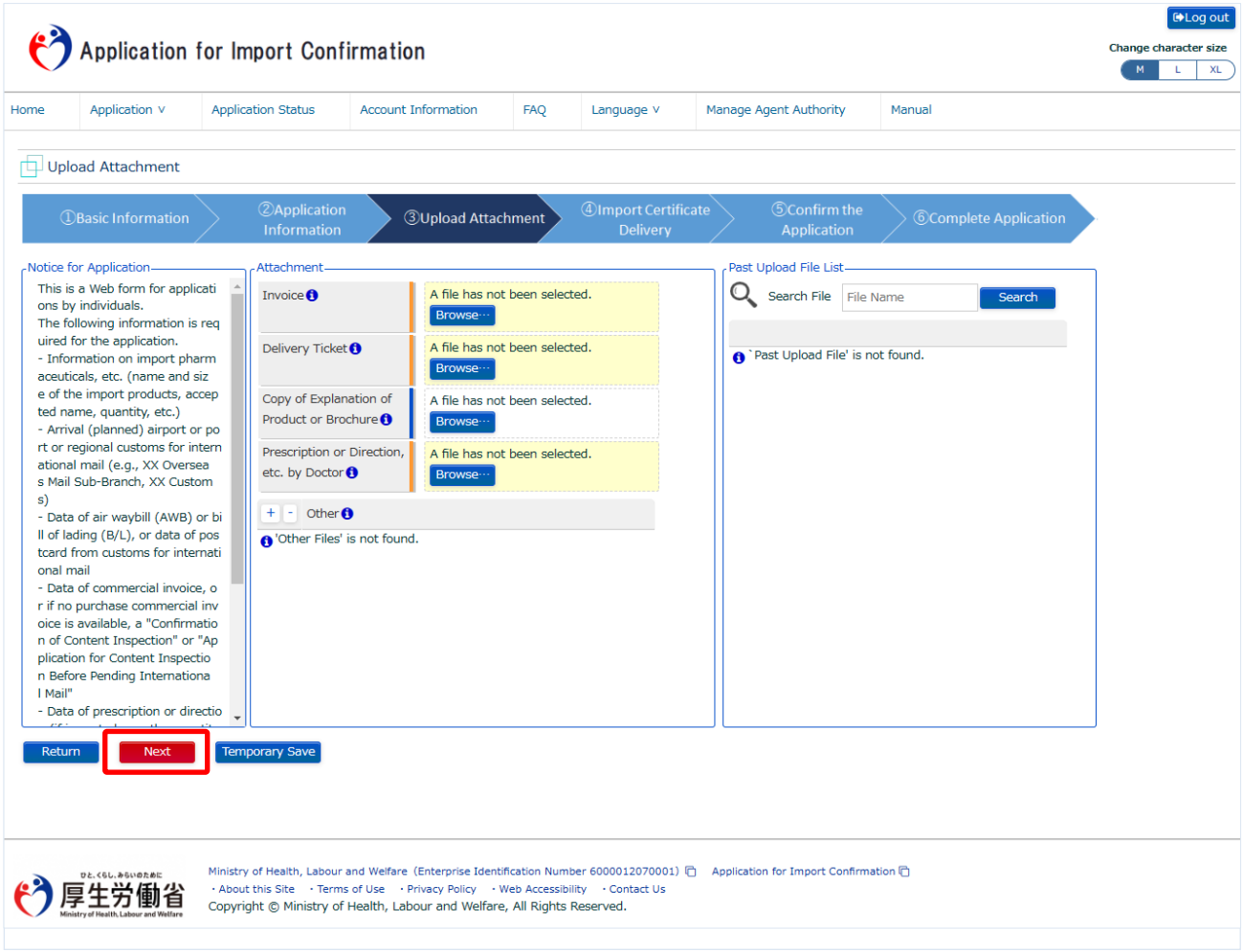
When entry is completed, click “Next.”

(4) Upload attachments

The screen to upload attachments is displayed.

In principle, the fields in orange are required and should be filled in according to the instructions provided by the information icons.

<Upload Attachment/Import for Personal Use>



[Attachments]

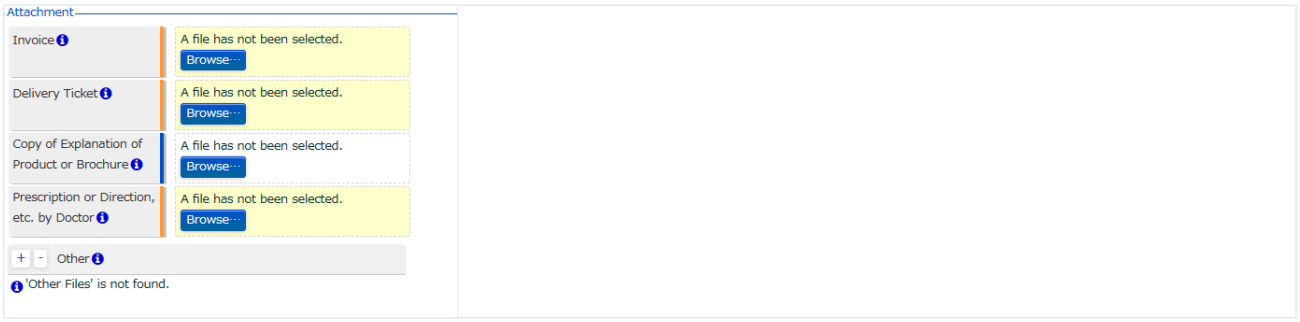
Attach the invoice in “Invoice.” If you do not have an invoice, please attach a "Content Inspection Confirmation" (for international cargo: customs broker) or a "Pending International Mail Item Inspection Form" (for international mail: customs) as an alternative document. If you are bringing medicines, etc. into Japan yourself, please attach a copy of your e-ticket or itinerary showing your name, flight number, and airport of arrival.

Attach the Air Waybill (AWB) or Bill of Lading (B/L) in “Delivery Ticket.” Attach the “Notice from Customs Clearance Procedure for Postal Matter from Abroad” for international mail.

Copies of product explanations or brochures of distributors, etc. can be attached in “Copy of Explanation of Product or Brochure” as additional material.

Make sure to attach a prescription or direction, etc. by a doctor in “Prescription or Direction, etc. by Doctor.”

If you upload files other than the above, attach them in “Other.” To add rows, click “+.” To delete rows, check the rows to delete and click “-.”

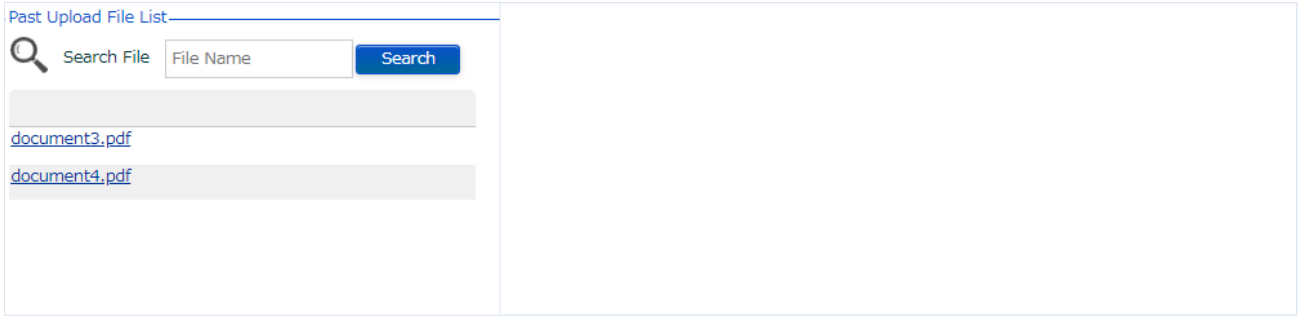


*The file formats that can be uploaded are as follows. The maximum upload size is 100 MB.

- Image files (jpeg, jpg, png)
- Office files (doc, docx, xls, xlsx)
- PDF files (pdf)
- Zipped files (zip) *Files cannot be attached if there are subfolders in the ZIP file

[Past Upload File List]

To reattach files from the Past Upload File List, select the files.
To search files from the Past Upload File List, enter a keyword in “Search File” and click “Search.”
However, "Invoice," "Delivery Ticket," and "Prescription or Direction, etc. by Doctor" are not displayed in the list because they cannot be used interchangeably.



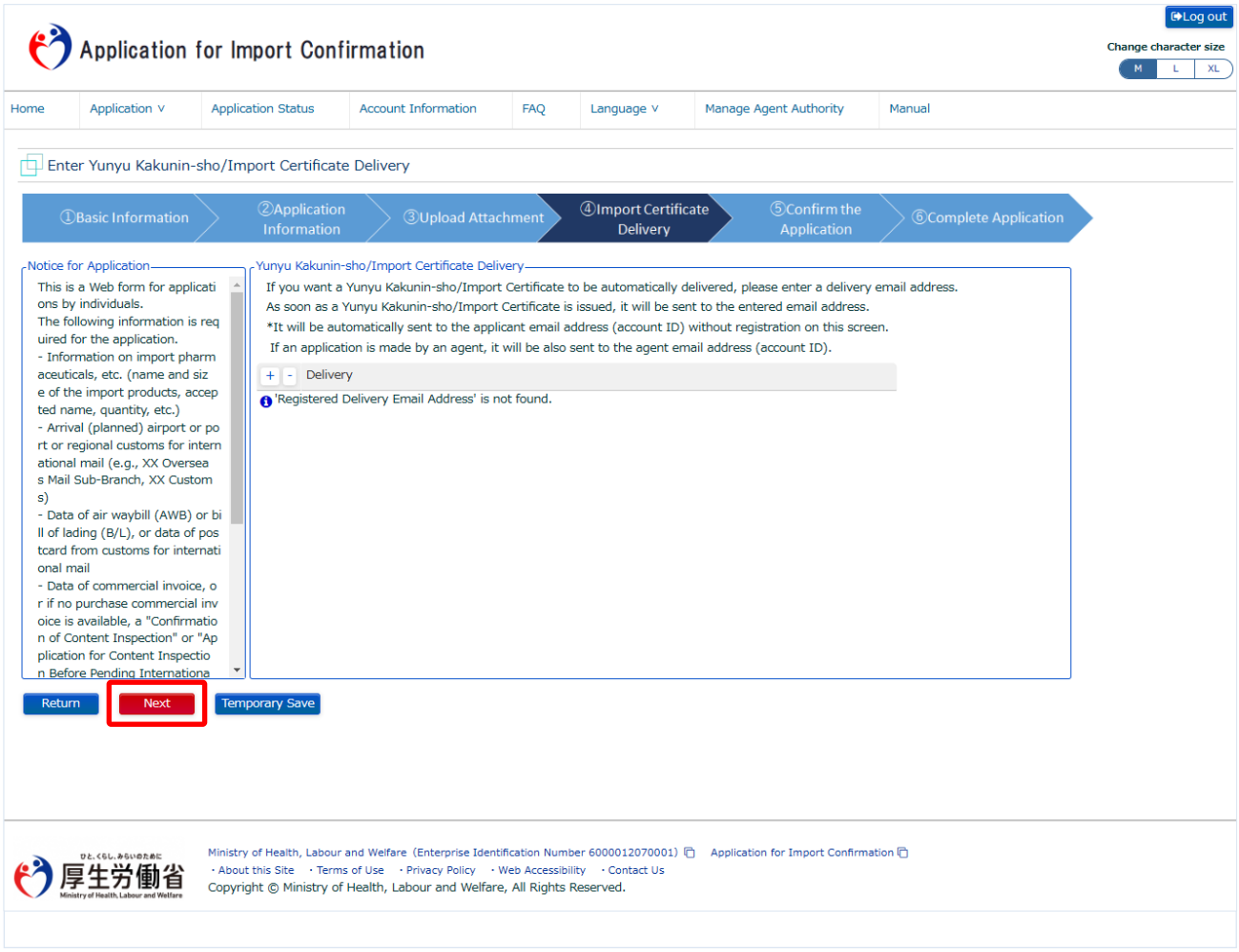
When entry is completed, click “Next.”

(5) Enter a delivery address for a Yunyu Kakunin-sho/Import Certificate

The screen to enter a delivery address for a Yunyu Kakunin-sho/Import Certificate is displayed.
If you want the import confirmation certificate to be sent to an address other than the one you registered when you created your account, please enter the email address to which it should be sent in “Delivery.”
As soon as a Yunyu Kakunin-sho/Import Certificate is issued, it will be sent to the entered email address.
*It will be automatically sent to the applicant email address (account ID) without registration on this screen.
If an application is made by an agent, it will also be sent to the agent email address (account ID). An example for “Delivery” is an email address of the customs broker handling the applicable import products.

To add rows, click “+.” To delete rows, check the rows to delete and click “-.”

<Enter Yunyu Kakunin-sho/Import Certificate Delivery Address>



When entry is completed, click “Next.”

(6) After confirming the application, register

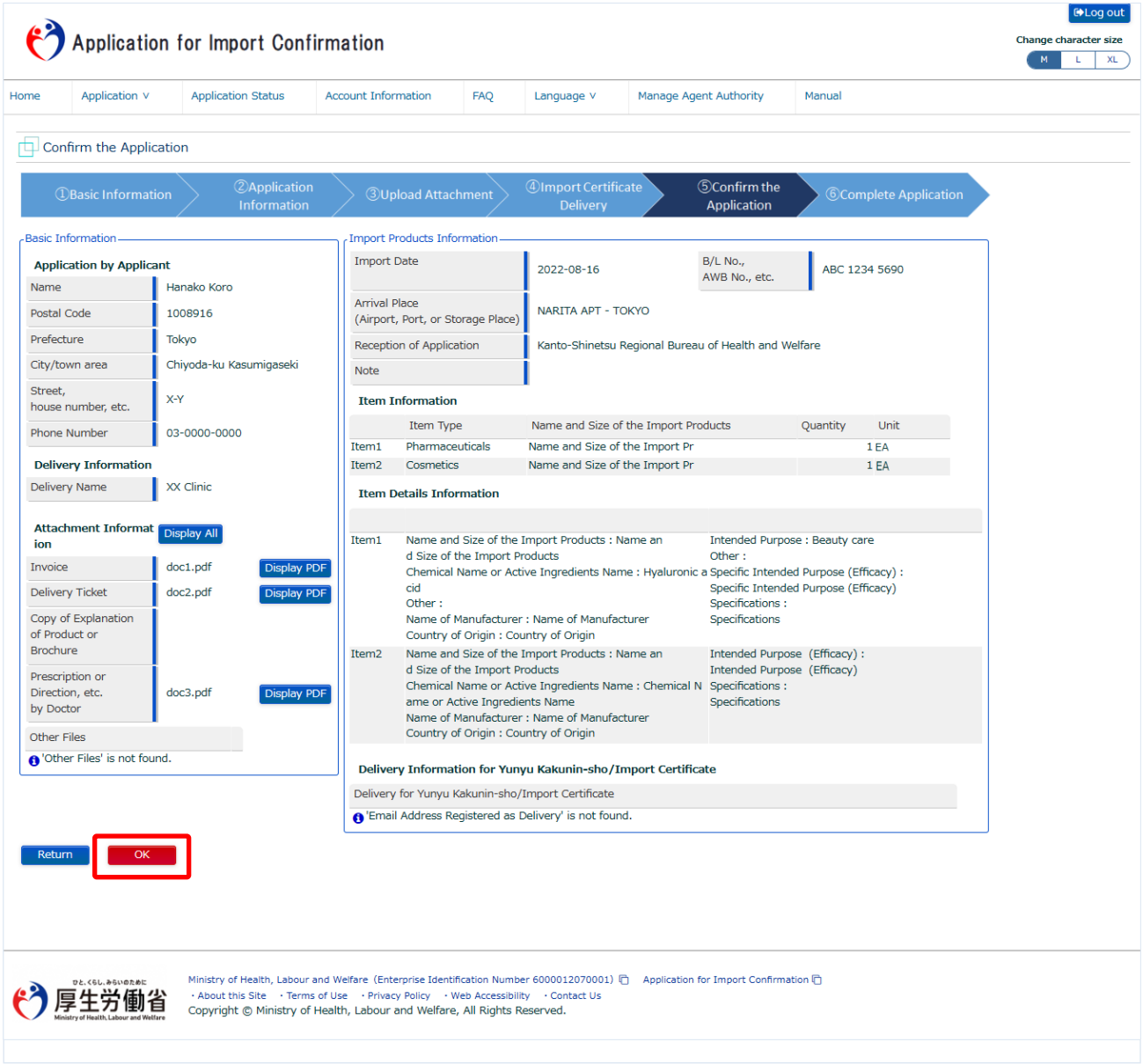
The screen to confirm the application is displayed.

To refer to the information of attachments, click “Display All” or “Display PDF.”

*If all files are not displayed in a different tab after clicking “Display All,” change the pop-up block settings of the browser and set this site to be exempt from pop-up blocking. Please refer to page 8 of the Application for Import Confirmation Operation Manual (Common Functions) for details on how to set your browser's pop-up blocker to exempt sites from pop-up blocking.

Confirm the application and click “OK.”

<Confirm the Application/Import for Personal Use>

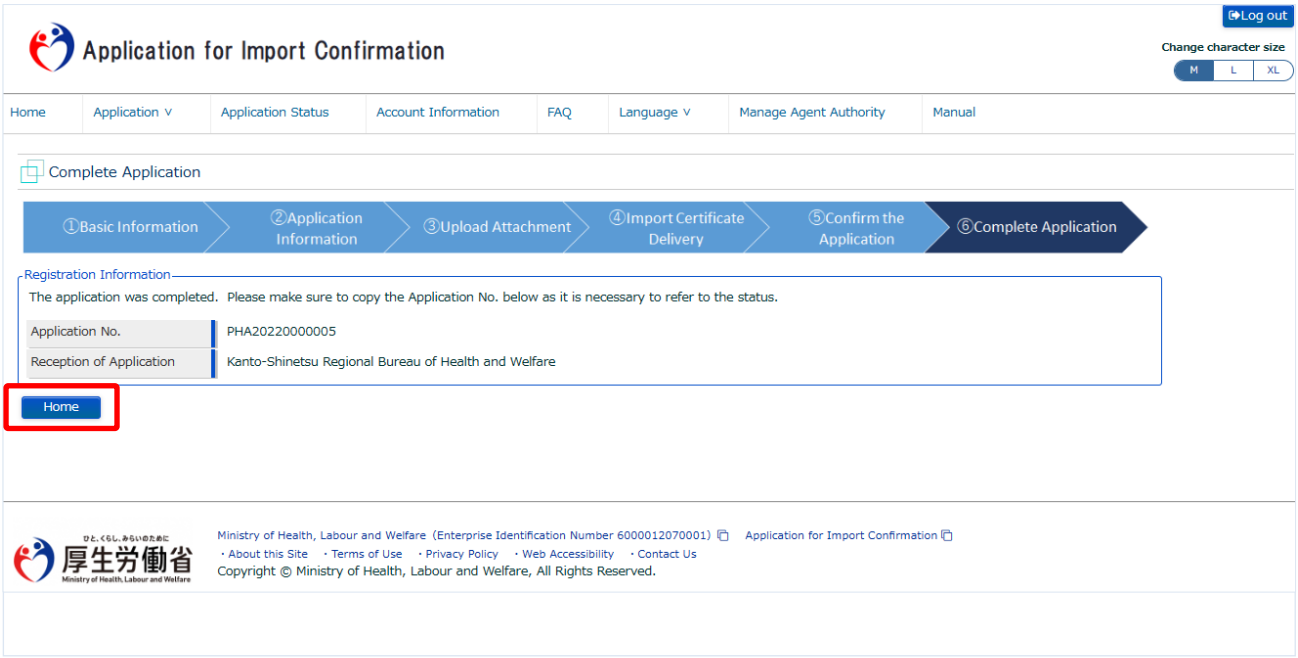


(7) Confirm completion of the application

When the application is complete, it transits to the Complete Application screen. Make sure to copy the displayed Application No.

Click “Home” to go back to the Home screen.

<Complete Application>



2.2.2 Import for Treatment, etc. by Doctors, etc.

This is a function to submit an import confirmation application to import for treatment, etc. by doctors, etc.

(1) Open the screen to apply for import confirmation

Click “Import for Treatment, etc. by Doctors, etc.” on the Home screen.

<Home Screen/Applicant>

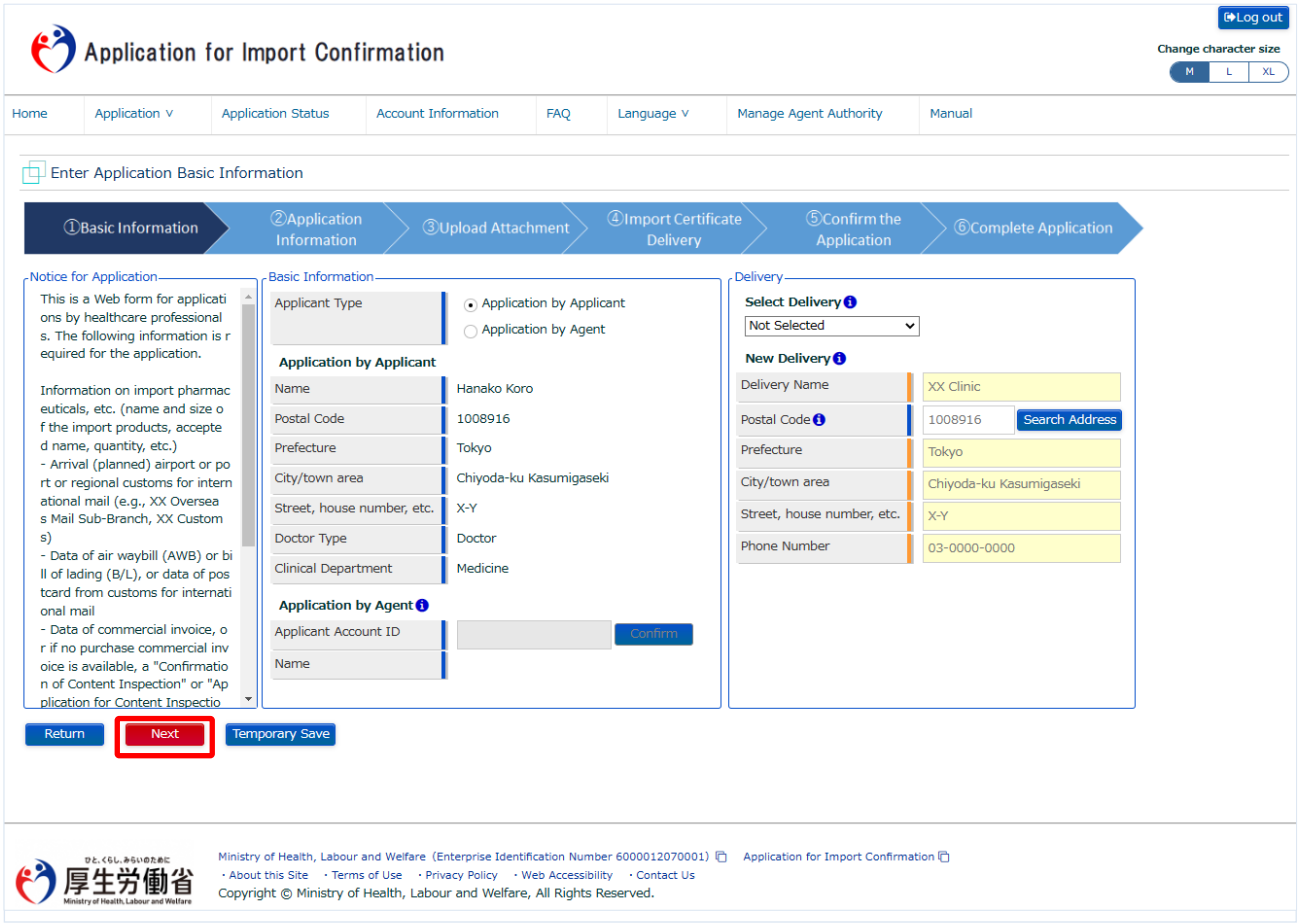


(2) Enter the application basic information

The screen to enter the application basic information is displayed.
The orange fields are required items, so make sure to enter them.

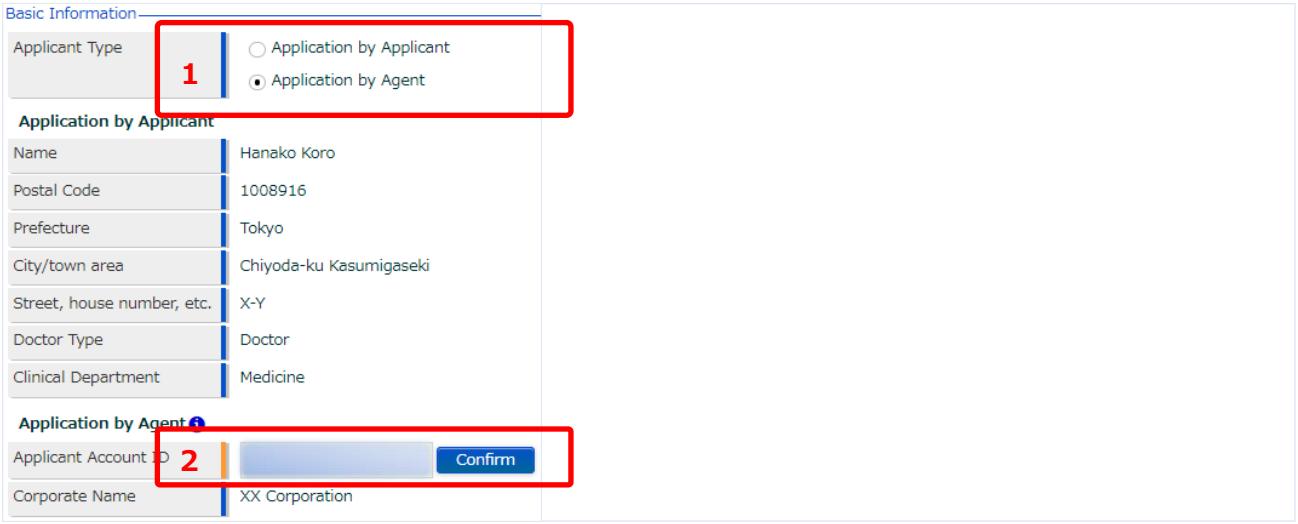
*Please consult with the Kanto Shinetsu or Kinki Health and Welfare Bureau that has jurisdiction over your application if you have any questions about the contents (what information should be included) or optional items (which items should be selected).

<Enter Application Basic Information>



[Basic Information]

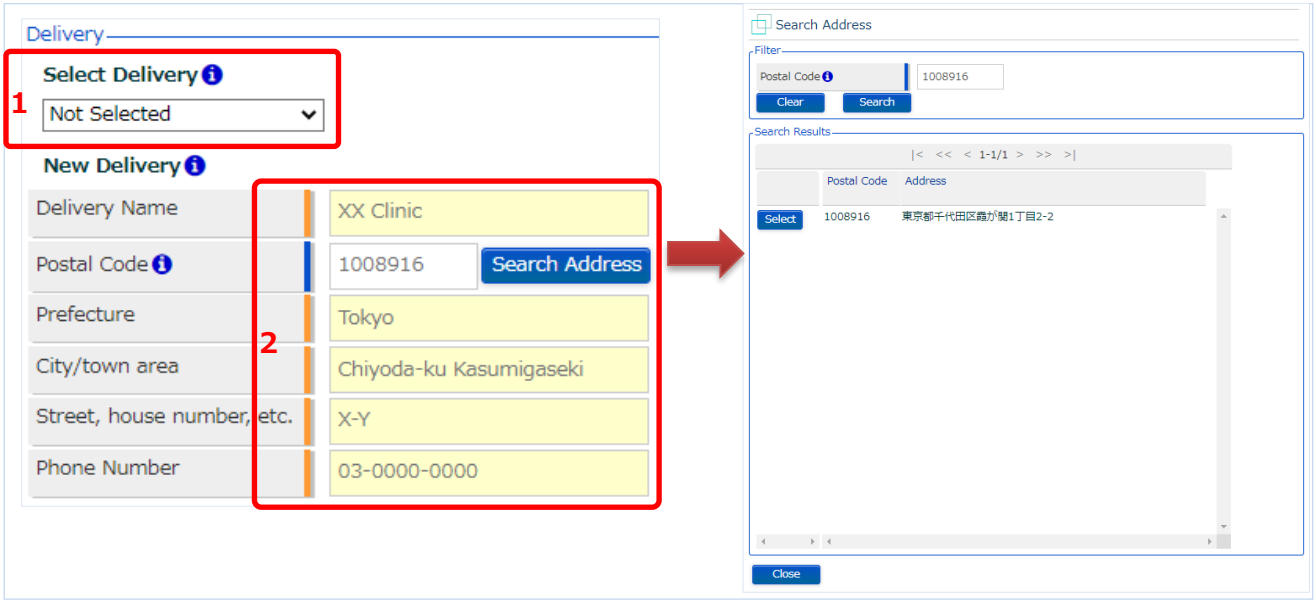
1. If the application is to be made by the applicant himself/herself, please confirm that “Application by Applicant” is selected.
2. Select “Application by Agent” if an agent will apply, enter “Applicant Account ID” in the Application by Agent section, and click “Confirm.”



[Delivery]

1. In the "Select Delivery" field, select a registered destination from the pull-down menu. (If you wish to increase the number of options, please add more addresses by changing your account information.)
2. If there is not a delivery destination in the pull-down, enter a delivery destination in "New Delivery."

When you enter a postal code (without a hyphen) and click "Search Address," the Search Address dialog is displayed. Click "Select" to select a postal code and an address.



Enter data and click "Next."

To temporarily save, click "Temporary Save." The contents in the process of entry will be saved with the correspondence status "Have not applied." To resume the application, select the "Refer to Application Status" button on the Home screen, select the details button for the temporarily saved application, and enter the missing information using the "Revise and reapply" button.

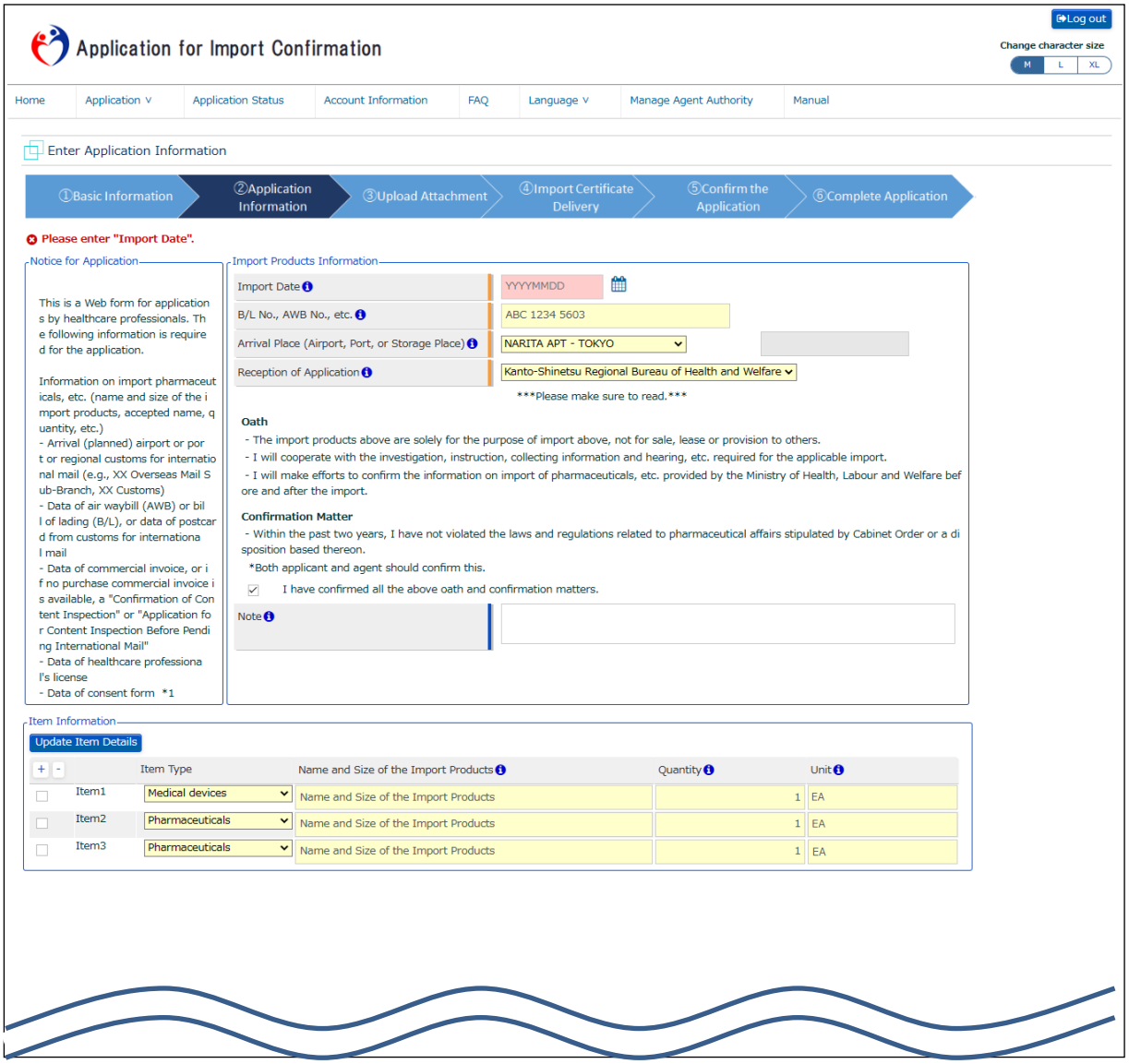
Click "Return" to go back to the Home screen.

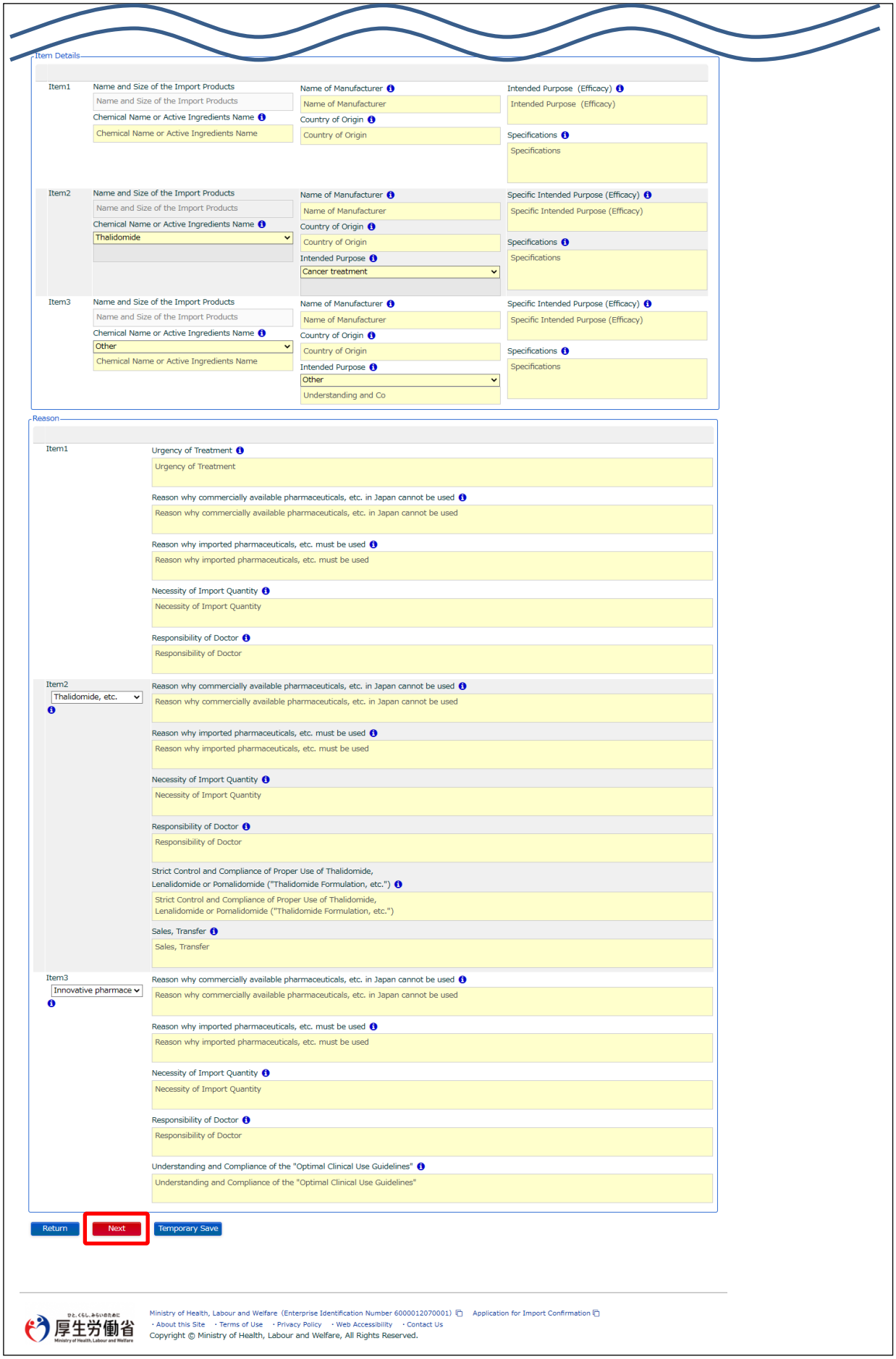
(3) Enter the application information

The screen to enter the application information is displayed.

Enter data according to the information icons and click “Next.”

<Enter Application Information/Import for Treatment, etc. by Doctors, etc.>



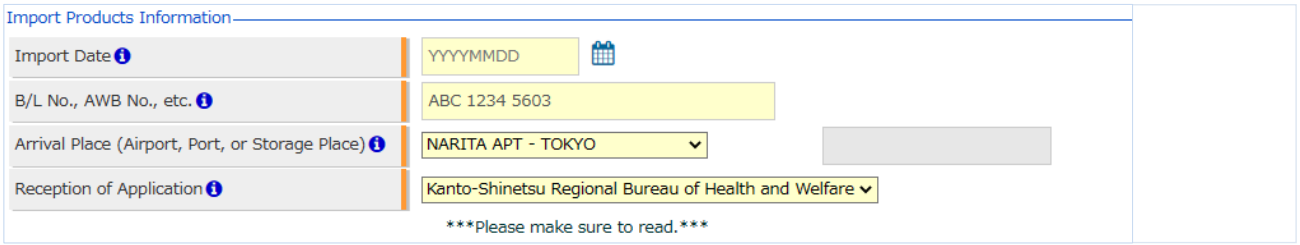

Item Details
Item1
Name and Size of the Import Products
Name and Size of the Import Products
Chemical Name or Active Ingredients Name
Chemical Name or Active Ingredients Name
Name of Manufacturer
Name of Manufacturer
Country of Origin
Country of Origin
Intended Purpose (Efficacy)
Intended Purpose (Efficacy)
Specifications
Specifications
Item2
Name and Size of the Import Products
Name and Size of the Import Products
Chemical Name or Active Ingredients Name
Thalidomide
Name of Manufacturer
Name of Manufacturer
Country of Origin
Country of Origin
Intended Purpose
Cancer treatment
Specific Intended Purpose (Efficacy)
Specific Intended Purpose (Efficacy)
Specifications
Specifications
Item3
Name and Size of the Import Products
Name and Size of the Import Products
Chemical Name or Active Ingredients Name
Other
Chemical Name or Active Ingredients Name
Name of Manufacturer
Name of Manufacturer
Country of Origin
Country of Origin
Intended Purpose
Other
Understanding and Co
Specific Intended Purpose (Efficacy)
Specific Intended Purpose (Efficacy)
Specifications
Specifications
Reason
Item1
Urgency of Treatment
Urgency of Treatment
Reason why commercially available pharmaceuticals, etc. in Japan cannot be used
Reason why commercially available pharmaceuticals, etc. in Japan cannot be used
Reason why imported pharmaceuticals, etc. must be used
Reason why imported pharmaceuticals, etc. must be used
Necessity of Import Quantity
Necessity of Import Quantity
Responsibility of Doctor
Responsibility of Doctor
Item2
Thalidomide, etc.
Reason why commercially available pharmaceuticals, etc. in Japan cannot be used
Reason why commercially available pharmaceuticals, etc. in Japan cannot be used
Reason why imported pharmaceuticals, etc. must be used
Reason why imported pharmaceuticals, etc. must be used
Necessity of Import Quantity
Necessity of Import Quantity
Responsibility of Doctor
Responsibility of Doctor
Strict Control and Compliance of Proper Use of Thalidomide, Lenalidomide or Pomalidomide ("Thalidomide Formulation, etc.")
Strict Control and Compliance of Proper Use of Thalidomide, Lenalidomide or Pomalidomide ("Thalidomide Formulation, etc.")
Sales, Transfer
Sales, Transfer
Item3
Innovative pharmace
Reason why commercially available pharmaceuticals, etc. in Japan cannot be used
Reason why commercially available pharmaceuticals, etc. in Japan cannot be used
Reason why imported pharmaceuticals, etc. must be used
Reason why imported pharmaceuticals, etc. must be used
Necessity of Import Quantity
Necessity of Import Quantity
Responsibility of Doctor
Responsibility of Doctor
Understanding and Compliance of the "Optimal Clinical Use Guidelines"
Understanding and Compliance of the "Optimal Clinical Use Guidelines"
Return
Next
Temporary Save
Ministry of Health, Labour and Welfare (Enterprise Identification Number 6000012070001)
Application for Import Confirmation
About this Site
Terms of Use
Privacy Policy
Web Accessibility
Contact Us
Copyright © Ministry of Health, Labour and Welfare, All Rights Reserved.

[Import Products Information]

Enter the arrival date of the import products in Japan in “Import Date.” If you have not yet arrived in Japan, please enter the expected date of arrival.

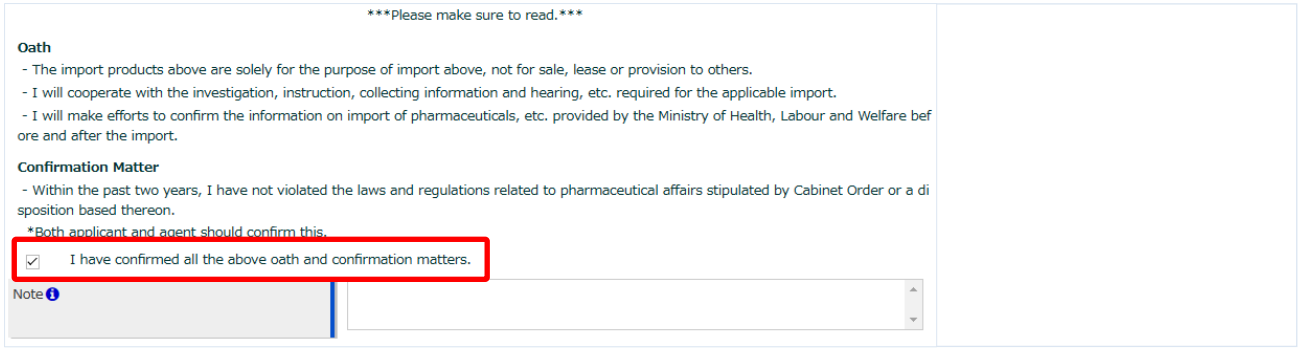
Enter the Air Waybill (AWB) No. or Bill of Lading (B/L) No. in “B/L No., AWB No., etc.” Enter the Notice No. (12 digits) of the postcard from customs if you received one.

Select the arrival place, etc. from the “Arrival Place (Airport, Port, or Storage Place)” pull-down. If you selected Other, enter in “Other.” Enter a part of the name of the airport or other facility in the input field to see the candidates. Select “Reception of Application” from the pull-down.



Confirm the contents of the Oath and the Confirmation Matter and check the box, “I have confirmed all the above oath and confirmation matters.”

Enter a supplementary note, etc. for the application in “Note” if any.



[Item Information]

Select “Item Type” from the pull-down.

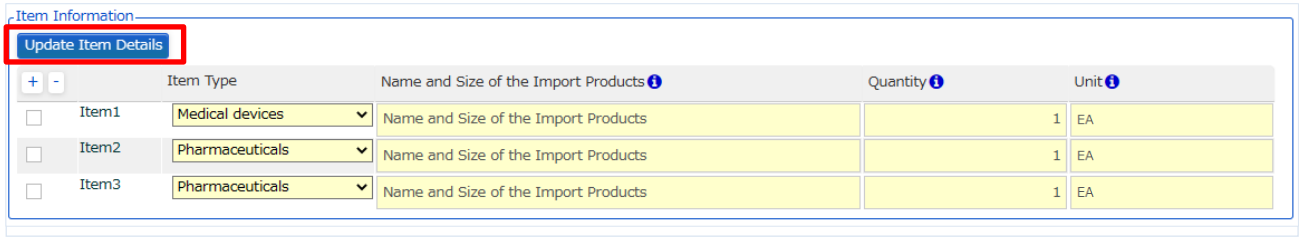
Enter the name and the quantity per unit described in the invoice in “Name and Size of the Import Products.”

Enter the quantity described in the invoice in “Quantity.”

Enter the unit of quantity such as 'tablets', 'pills', 'EA' in “Unit.”

When entry is completed, click “Update Item Details.” The entry in Item Information will be updated in the Item Details, so please continue to enter the Item Details.

If you edited Item Information after updating Item Details, click “Update Item Details” again. The edited data will be updated in the Item Details.



1. To add rows, click “+.”
2. To delete rows, check the rows to delete and click “-“ at 1.

[Item Details]

If the item type for “Chemical Name or Active Ingredients Name” is pharmaceuticals, select it from the pull-down list. If you selected Other from the pull-down list, enter the accepted name, etc. in “Other.” If the item type is other than pharmaceuticals, enter the accepted name, etc.

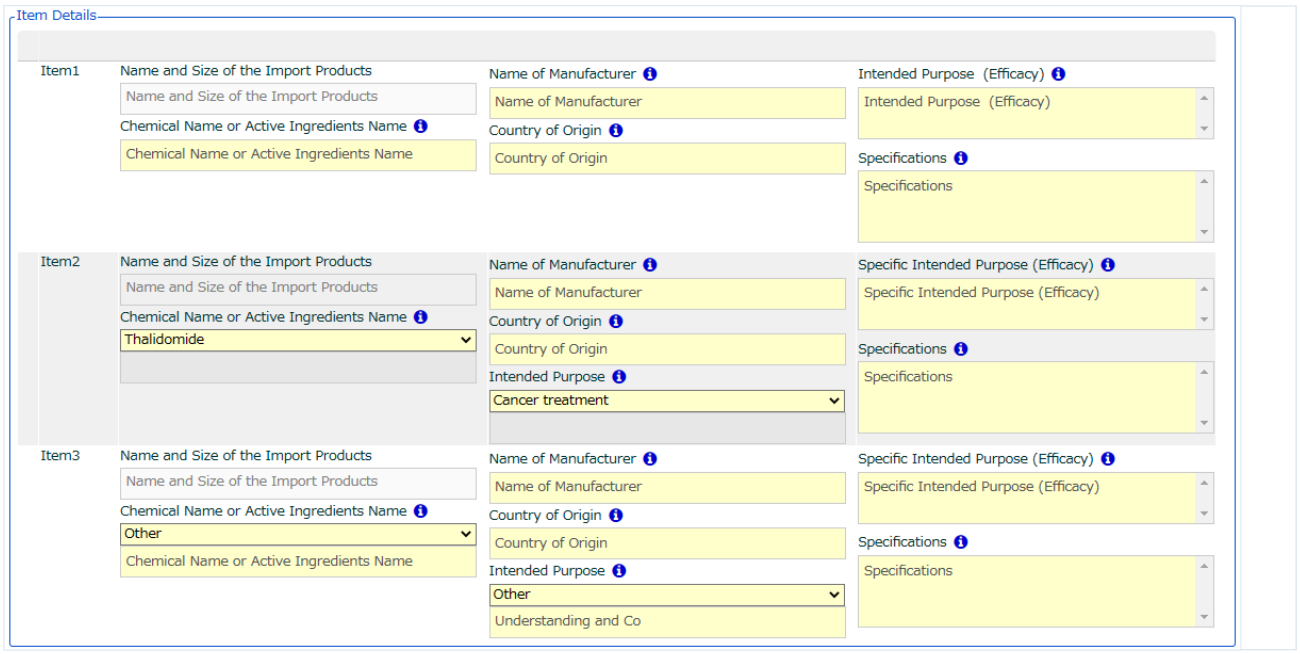
Enter the name of the manufacturer of the import products in “Name of Manufacturer.”

Enter a country of origin of the import products in “Country of Origin.” Enter part of the country name to see candidate country names and select one.

For pharmaceuticals, select the intended purpose of the import products from the “Intended Purpose” pull-down list. If you selected Other, briefly enter an intended purpose within 20 characters.

Enter a specific purpose of use, general efficacy, etc. of the import products in “Specific Intended Purpose (Efficacy)” for pharmaceuticals and enter it in “Intended Purpose (Efficacy)” for non-pharmaceuticals.

Enter the dosage form, etc. for pharmaceuticals, a summary of rationale and structure, etc. for medical devices, and characteristics of the product for regenerative medicine products in “Specifications.”



[Reason]

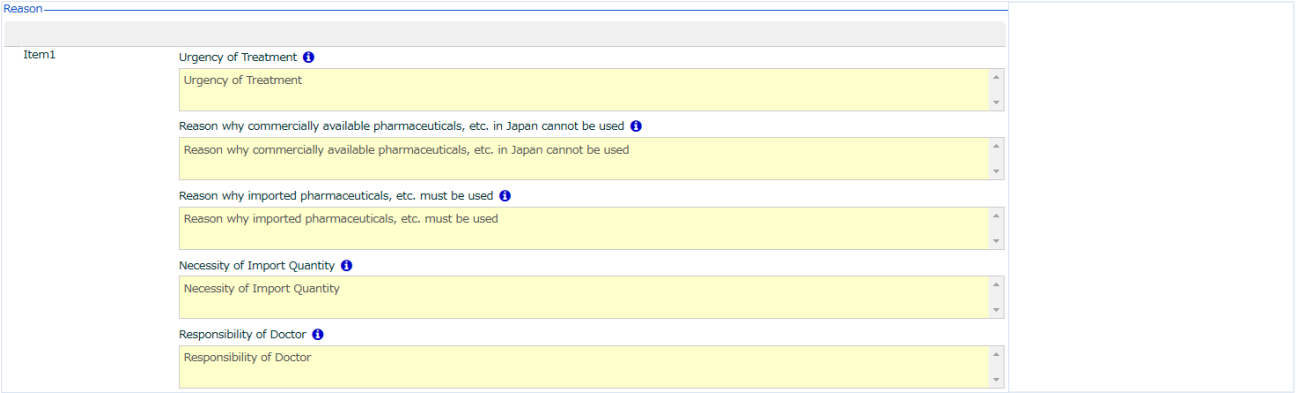
Enter a specific explanation in “Urgency of Treatment.” “Urgency of Treatment” means “a case of patient life and death,” “a case that if the imported pharmaceuticals, etc. are not used for treatment now, the opportunity will be missed,” etc.

Enter a specific explanation such as “no approved active ingredient in Japan” in “Reason why commercially available pharmaceuticals, etc. in Japan cannot be used.”

Enter a specific explanation in “Reason why imported pharmaceuticals, etc. must be used.” Even if the intended purpose is described in Explanation of Product, fill this in.

Enter a specific explanation in “Necessity of Import Quantity.”

Enter that the doctor will use the import pharmaceuticals, etc. for his/her patients and take full responsibility in “Responsibility of Doctor.”



[Reason/Thalidomide, etc.]

Select “Thalidomide, etc.” from the format selection pull-down of the left entry field when you apply for import confirmation for thalidomide, etc.

Enter a specific explanation such as “no approved active ingredient in Japan” in “Reason why commercially available pharmaceuticals, etc. in Japan cannot be used.”

Enter a specific explanation in “Reason why imported pharmaceuticals, etc. must be used.” Even if the intended purpose is described in Explanation of Product, fill this in.

Enter a specific explanation in “Necessity of Import Quantity.”

Enter that the doctor will use the import pharmaceuticals, etc. for his/her patients and take full responsibility in “Responsibility of Doctor.”

For an import thalidomide formulation, etc., enter the oath that you will strictly control the thalidomide formulation, etc. referring to the “Guideline for the appropriate use of Thalidomide in the treatment of multiple myeloma” (2003/2004 Project to Promote Appropriate Use of Pharmaceuticals by the Ministry of Health, Labour and Welfare and related society) and that you will have the patients who need the thalidomide formulation, etc. use it appropriately referring to the “Handbook for safe use of thalidomide,” which is distributed to doctors who personally import thalidomide formulation, etc. by the SMUD Bureau

and given to patients as appropriate in “Strict Control and Compliance of Proper Use of Thalidomide, Lenalidomide, or Pomalidomide (“Thalidomide Formulation, etc.”).”

Enter the oath that you will import the product to use for treatment, and not for sale or transfer in “Sale, Transfer.”



[Reason/Innovative Pharmaceuticals]

Select “Innovative Pharmaceuticals” from the format selection pull-down of the left entry field when you apply for import confirmation for innovative pharmaceuticals.

Enter a specific explanation such as “no approved active ingredient in Japan” in “Reason why commercially available pharmaceuticals, etc. in Japan cannot be used.”
Enter a specific explanation in “Reason why imported pharmaceuticals, etc. must be used.” Even if the intended purpose is described in Explanation of Product, fill this in.
Enter a specific explanation in “Necessity of Import Quantity.”
Enter that the doctor will use the import pharmaceuticals, etc. for his/her patients and take full responsibility in “Responsibility of Doctor.”

Enter the oath that you will thoroughly read and understand the applicable guidelines and administer treatment according to their intent in “Understanding and Compliance of the “Optimal Clinical Use Guidelines”.”
For reference: [The Optimal Clinical Use Guidelines (Pharmaceuticals) | Pharmaceuticals and Medical Devices Agency (pmda.go.jp)]

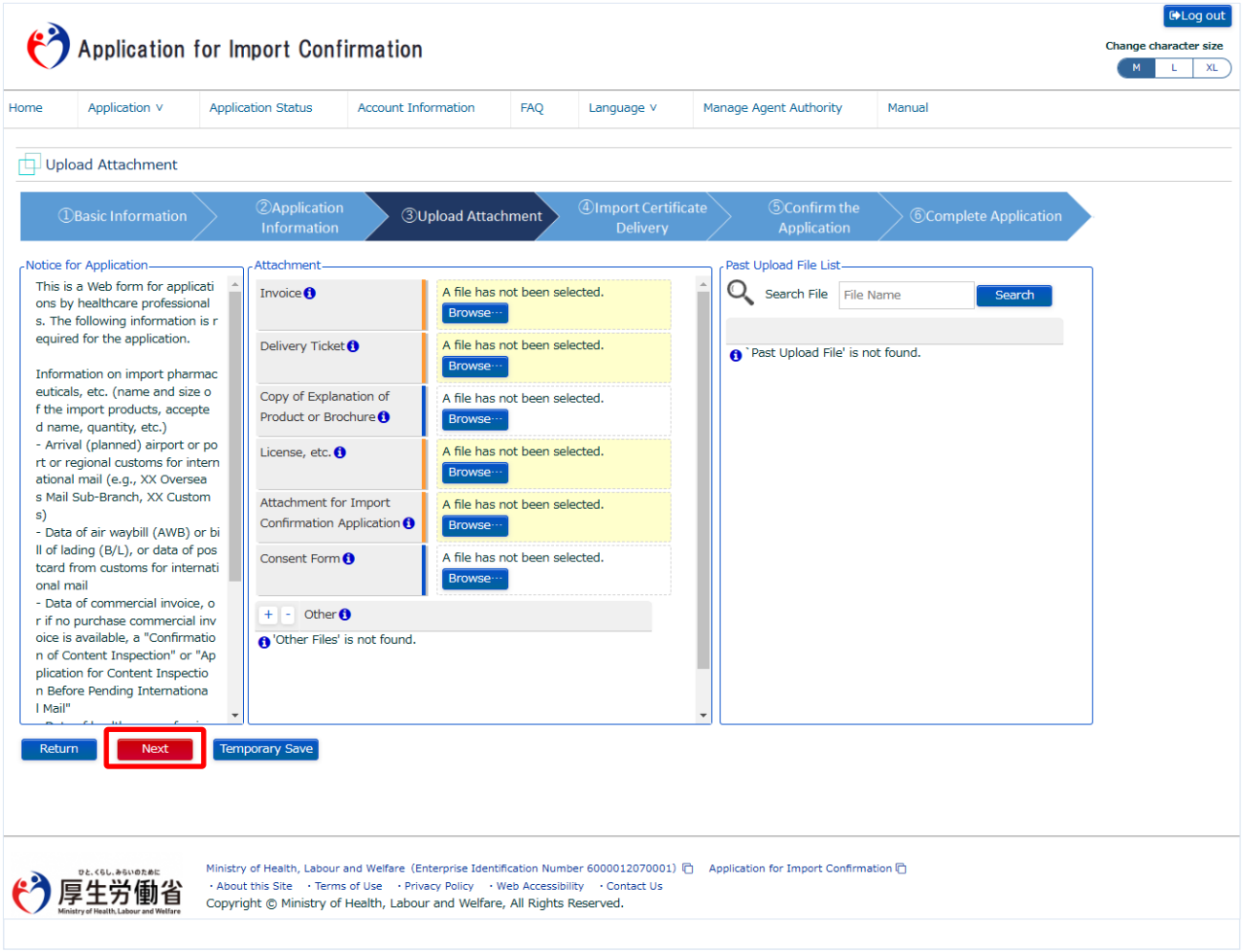


(4) Upload attachments

The screen to upload attachments is displayed.

In principle, the fields in orange are required and should be filled in according to the instructions provided by the information icons.

<Upload Attachment/Import for Treatment, etc. by Doctors, etc.>



[Attachments]

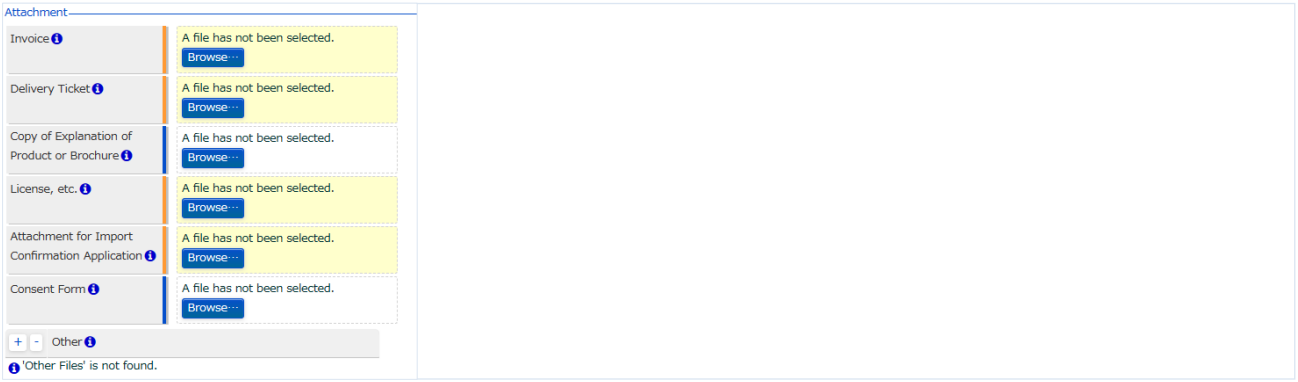
Attach the invoice in “Invoice.” If you do not have an invoice, please attach a “Content Inspection Confirmation” (for international cargo: customs broker) or a “Pending International Mail Item Inspection Form” (for international mail: customs) as an alternative document. If you are bringing medicines, etc. into Japan yourself, please attach a copy of your e-ticket or itinerary showing your name, flight number, and airport of arrival.

Attach the Air Waybill (AWB) or Bill of Lading (B/L) in “Delivery Ticket.” Attach the “Notice from Customs Clearance Procedure for Postal Matter from Abroad” for international mail.

Copies of product explanations or brochures of distributors, etc. can be attached in “Copy of Explanation of Product or Brochure” as additional material.

Make sure to attach the medical license, etc. in “License, etc.”
Attach the attachments for import confirmation application issued by the Safety Management system for Unapproved Drugs (SMUD) in “Attachment for Import Confirmation Application.” This is required to import thalidomide.
Attach the “Consent Form.” This is necessary to import pharmaceuticals, medical devices, etc. that use human-derived or animal-derived ingredients (including bovine, etc.) or innovative pharmaceuticals.

If you upload files other than the above, attach them in “Other.” To add rows, click “+.” To delete rows, check the rows to delete and click “-.”

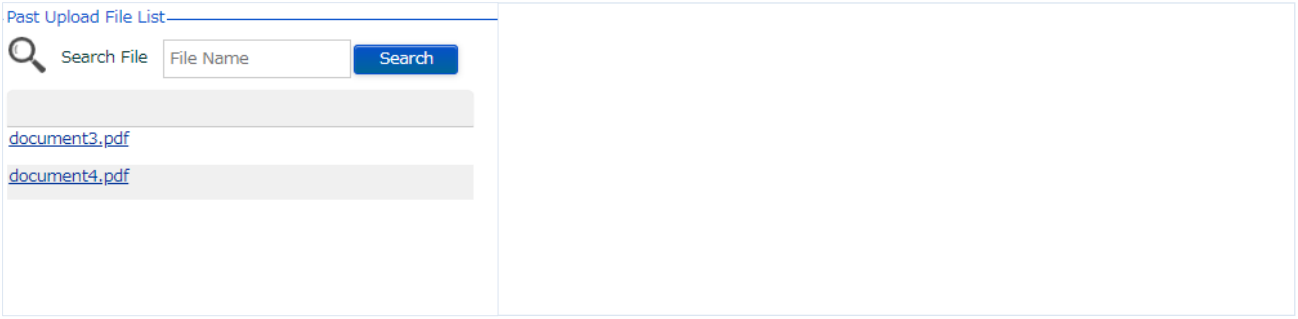


*The file formats that can be uploaded are as follows. The maximum upload size is 100 MB.

- Image files (jpeg, jpg, png)
- Office files (doc, docx, xls, xlsx)
- PDF files (pdf)
- Zipped files (zip) *Files cannot be uploaded if there are subfolders in the ZIP file

[Past Upload File List]

To reattach files from the Past Upload File List, select the files.
To search files from Past the Upload File List, enter a keyword in “Search File” and click “Search.”
However, “Invoice,” and “Delivery Ticket,” are not displayed in the list because they cannot be used interchangeably.



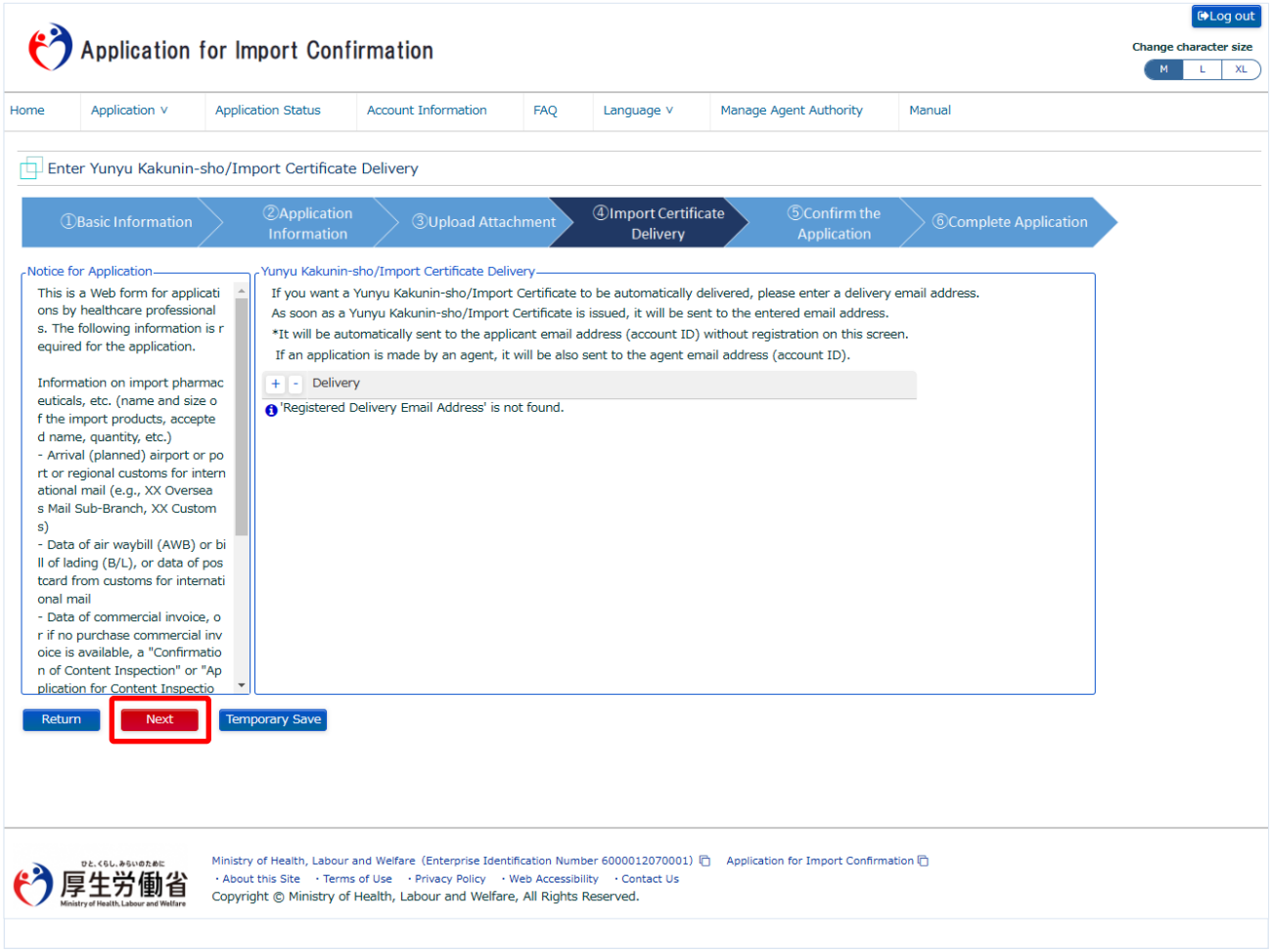
When entry is completed, click “Next.”

(5) Enter a delivery address for a Yunyu Kakunin-sho/Import Certificate

The screen to enter a delivery address for a Yunyu Kakunin-sho/Import Certificate is displayed.
If you want the import confirmation certificate to be sent to an address other than the one you registered when you created your account, please enter the email address to which it should be sent in “Delivery”.
As soon as a Yunyu Kakunin-sho/Import Certificate is issued, it will be sent to the entered email address.
*It will be automatically sent to the applicant email address (account ID) without registration on this screen.
If an application is made by an agent, it will also be sent to the agent email address (account ID).

To add rows, click “+.” To delete rows, check the rows to delete and click “-.“

<Enter Yunyu Kakunin-sho/Import Certificate Delivery Address>



When entry is completed, click “Next.”

(6) After confirming the application, register

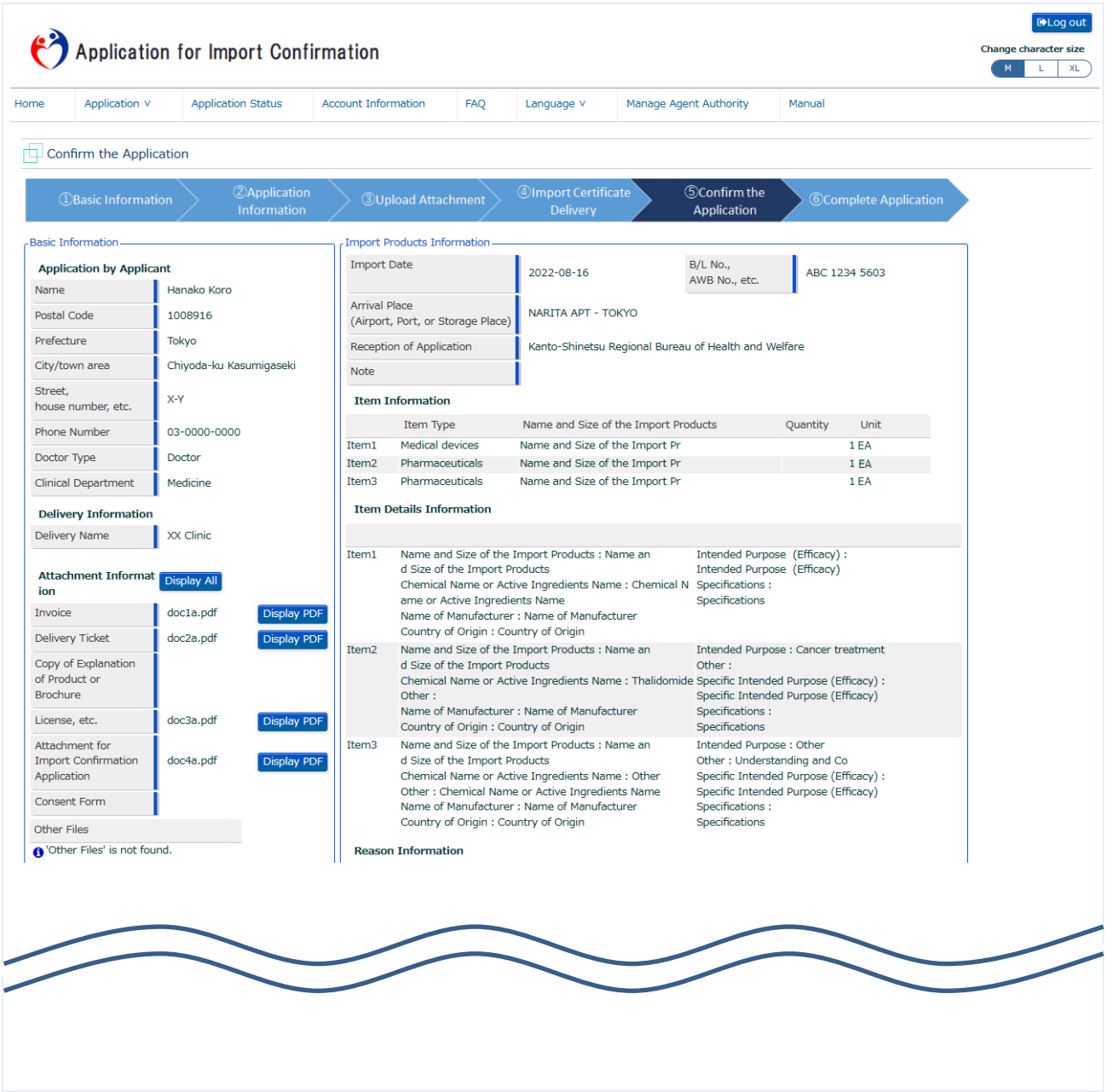
The screen to confirm the application is displayed.

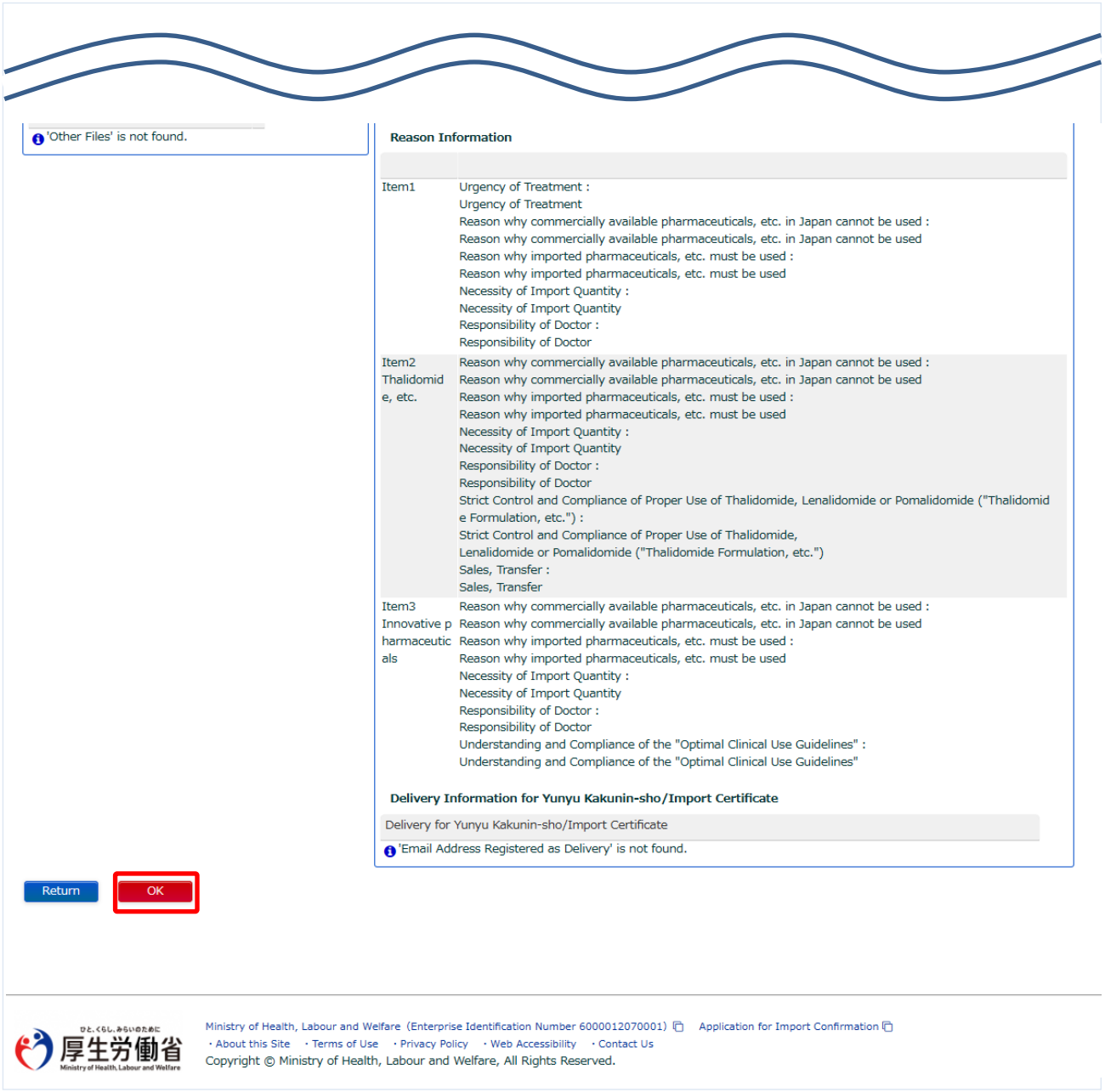
To refer to the information of attachments, click “Display All” or “Display PDF.”

*If all files are not displayed in a different tab after clicking “Display All,” change the pop-up block settings of the browser and set this site to be exempt from pop-up blocking. Please refer to page 8 of the Application for Import Confirmation Operation Manual (Common Functions) for details on how to set your browser's pop-up blocker to exempt sites from pop-up blocking.

Confirm the application and click “OK.”

<Confirm the Application/Import for Treatment, etc. by Doctors, etc.>



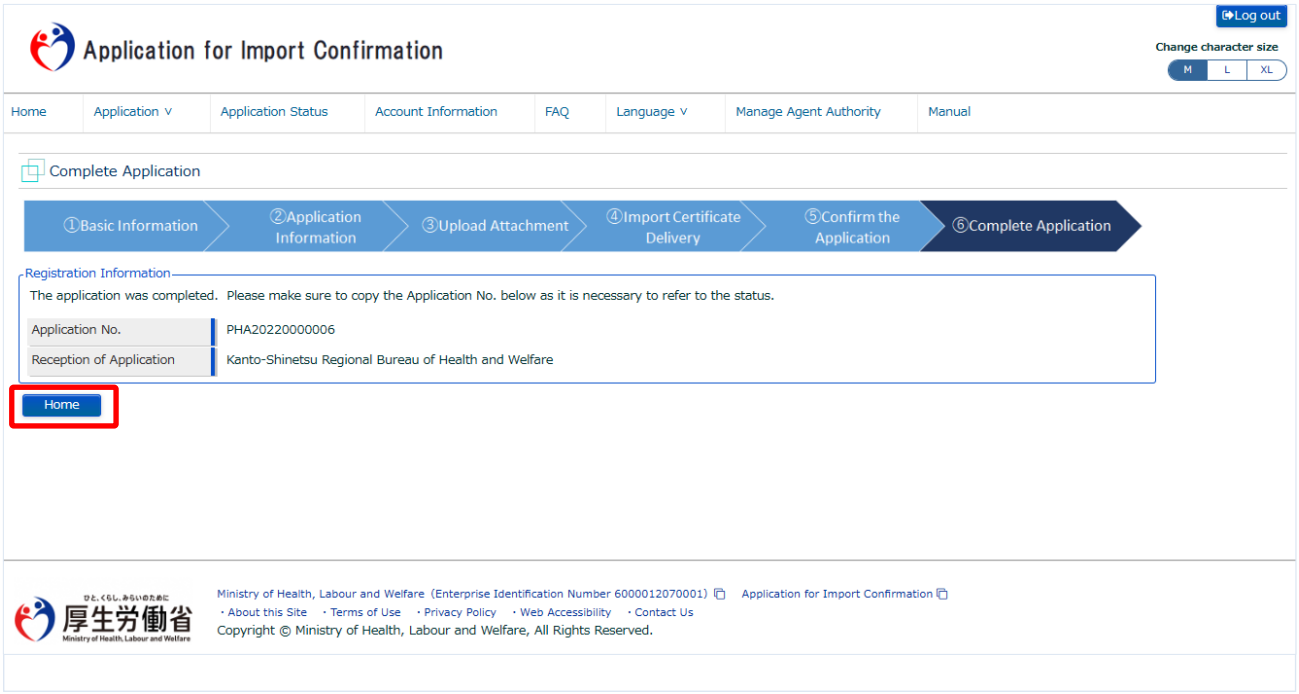

'Other Files' is not found.
Reason Information
Item1
Urgency of Treatment :
Urgency of Treatment
Reason why commercially available pharmaceuticals, etc. in Japan cannot be used :
Reason why commercially available pharmaceuticals, etc. in Japan cannot be used
Reason why imported pharmaceuticals, etc. must be used :
Reason why imported pharmaceuticals, etc. must be used
Necessity of Import Quantity :
Necessity of Import Quantity
Responsibility of Doctor :
Responsibility of Doctor
Item2
Thalidomide, etc.
Reason why commercially available pharmaceuticals, etc. in Japan cannot be used :
Reason why commercially available pharmaceuticals, etc. in Japan cannot be used
Reason why imported pharmaceuticals, etc. must be used :
Reason why imported pharmaceuticals, etc. must be used
Necessity of Import Quantity :
Necessity of Import Quantity
Responsibility of Doctor :
Responsibility of Doctor
Strict Control and Compliance of Proper Use of Thalidomide, Lenalidomide or Pomalidomide ("Thalidomide Formulation, etc.") :
Strict Control and Compliance of Proper Use of Thalidomide,
Lenalidomide or Pomalidomide ("Thalidomide Formulation, etc.")
Sales, Transfer :
Sales, Transfer
Item3
Innovative pharmaceuticals
Reason why commercially available pharmaceuticals, etc. in Japan cannot be used :
Reason why commercially available pharmaceuticals, etc. in Japan cannot be used
Reason why imported pharmaceuticals, etc. must be used :
Reason why imported pharmaceuticals, etc. must be used
Necessity of Import Quantity :
Necessity of Import Quantity
Responsibility of Doctor :
Responsibility of Doctor
Understanding and Compliance of the "Optimal Clinical Use Guidelines" :
Understanding and Compliance of the "Optimal Clinical Use Guidelines"
Delivery Information for Yunyu Kakunin-sho/Import Certificate
Delivery for Yunyu Kakunin-sho/Import Certificate
'Email Address Registered as Delivery' is not found.
Return
OK
Ministry of Health, Labour and Welfare (Enterprise Identification Number 6000012070001)
Application for Import Confirmation
・About this Site ・Terms of Use ・Privacy Policy ・Web Accessibility ・Contact Us
Copyright © Ministry of Health, Labour and Welfare, All Rights Reserved.

(7) Confirm completion of the application

When the application is complete, it transits to the Complete Application screen. Make sure to copy the displayed Application No.

Click “Home” to go back to the Home screen.

<Complete Application>



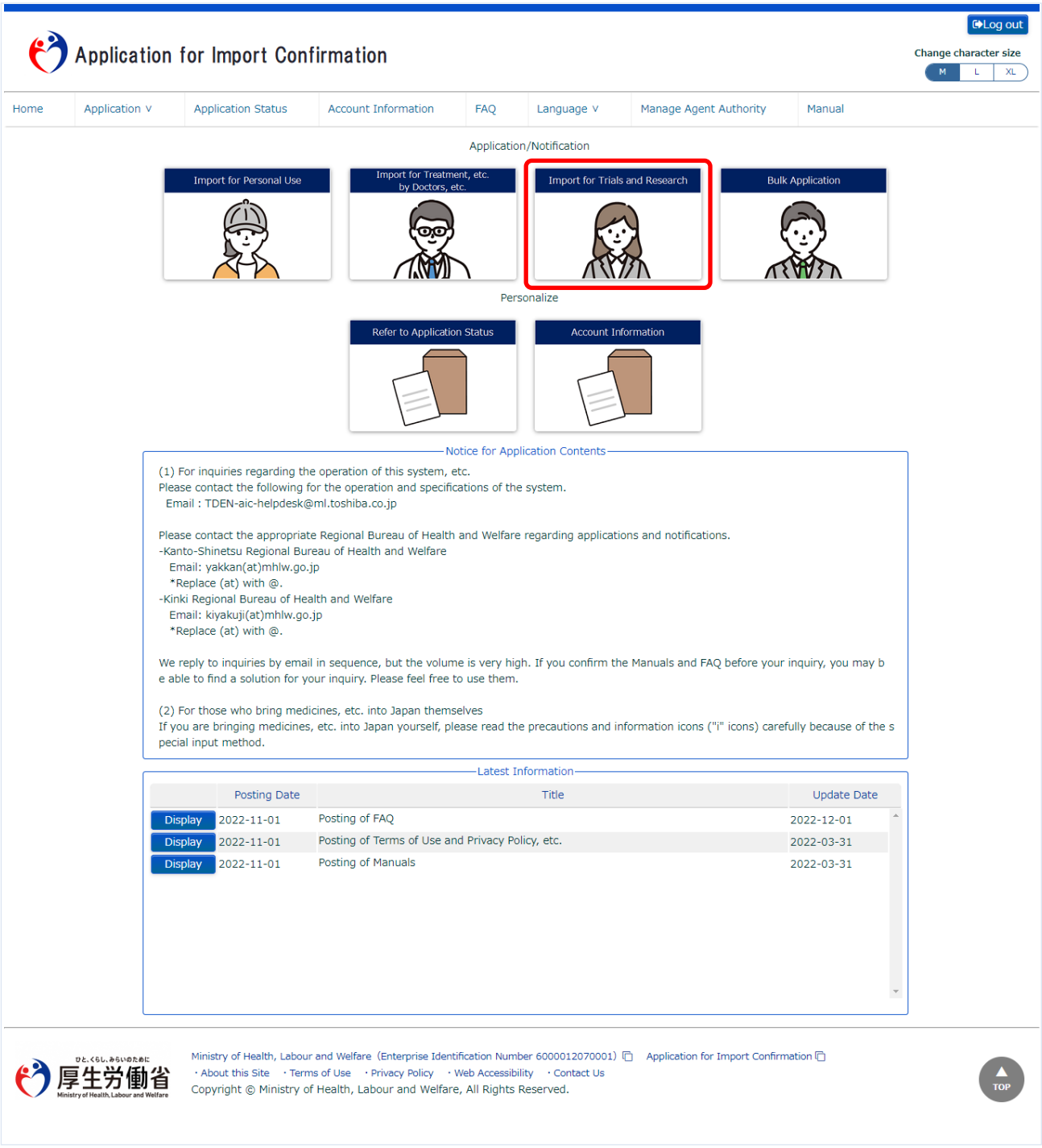
2.2.3 Import for Trials and Research

This is a function to submit an import confirmation application to import for trials and research.

(1) Open the screen to apply for import confirmation

Click “Import for Trials and Research” on the Home screen.

<Home Screen/Applicant>



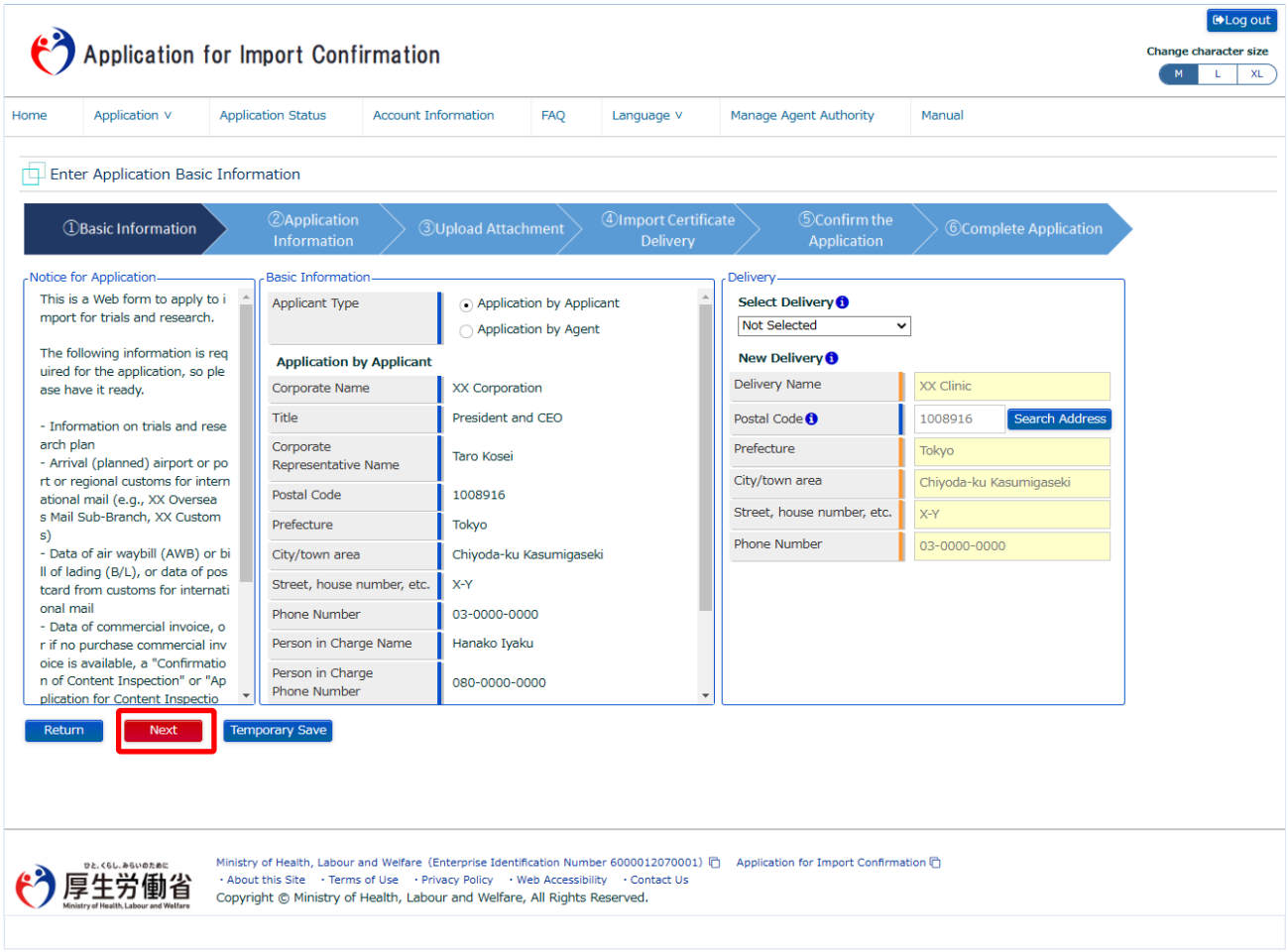
(2) Enter the application basic information

The screen to enter the application basic information is displayed.

The orange fields are required items, so make sure to enter them.

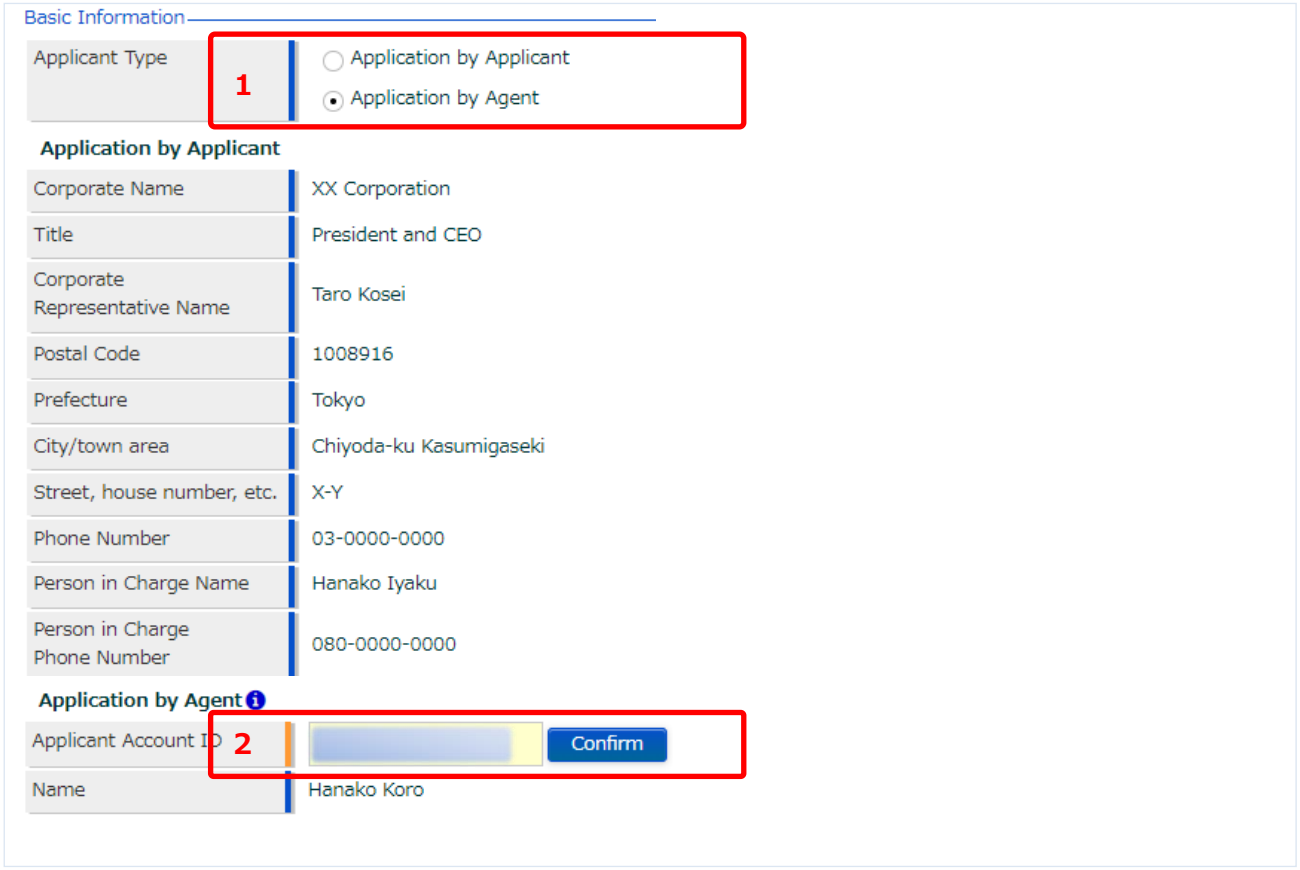
*Please consult with the Kanto Shinetsu or Kinki Health and Welfare Bureau that has jurisdiction over your application if you have any questions about the contents (what information should be included) or optional items (which items should be selected).

<Enter Application Basic Information>



[Basic Information]

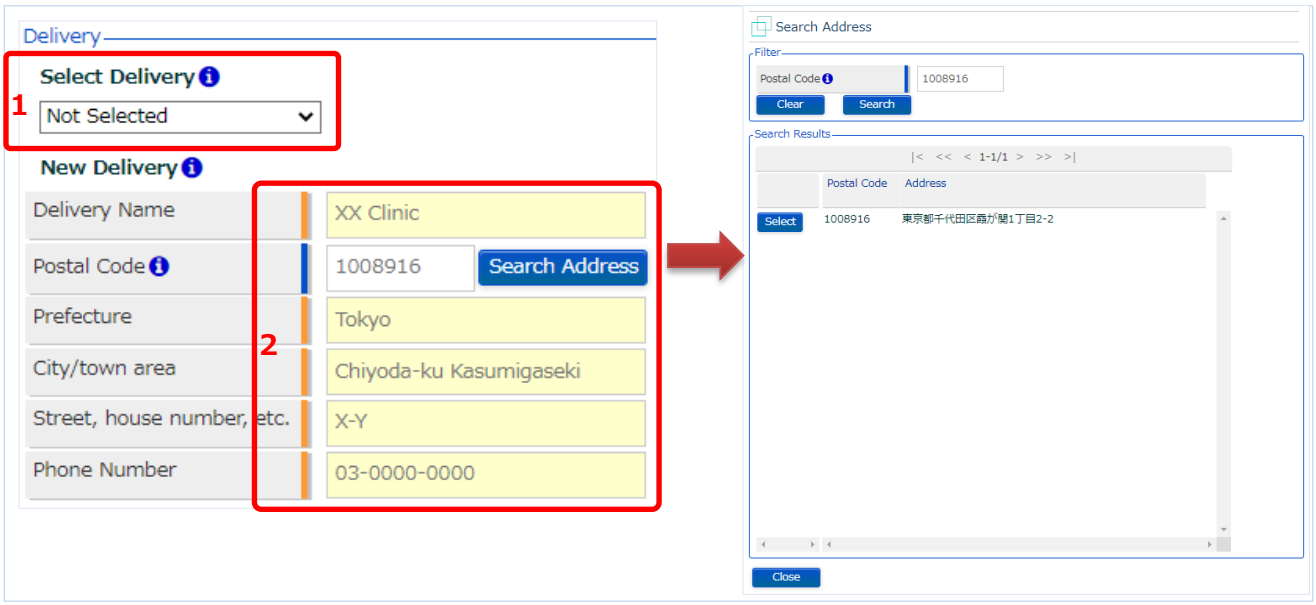
1. If the application is to be made by the applicant himself/herself, please confirm that “Application by Applicant” is selected.
2. Select “Application by Agent” if an agent will apply, enter “Applicant Account ID” in the Application by Agent section, and click “Confirm.”



[Delivery]

1. In the “Select Delivery” field, select a registered destination from the pull-down menu. (If you wish to increase the number of options, please add more addresses by changing your account information.)
2. If there is not a delivery destination in the pull-down, enter a delivery destination in “New Delivery.”

When you enter a postal code (without a hyphen) and click “Search Address,” the Search Address dialog is displayed. Click “Select” to select a postal code and an address.



Enter data and click “Next.”

To temporarily save, click “Temporary Save.” The contents in the process of entry will be saved with the correspondence status “Have not applied.” To resume the application, select the “Refer to Application Status” button on the Home screen, select the details button for the temporarily saved application, and enter the missing information using the “Revise and reapply” button.

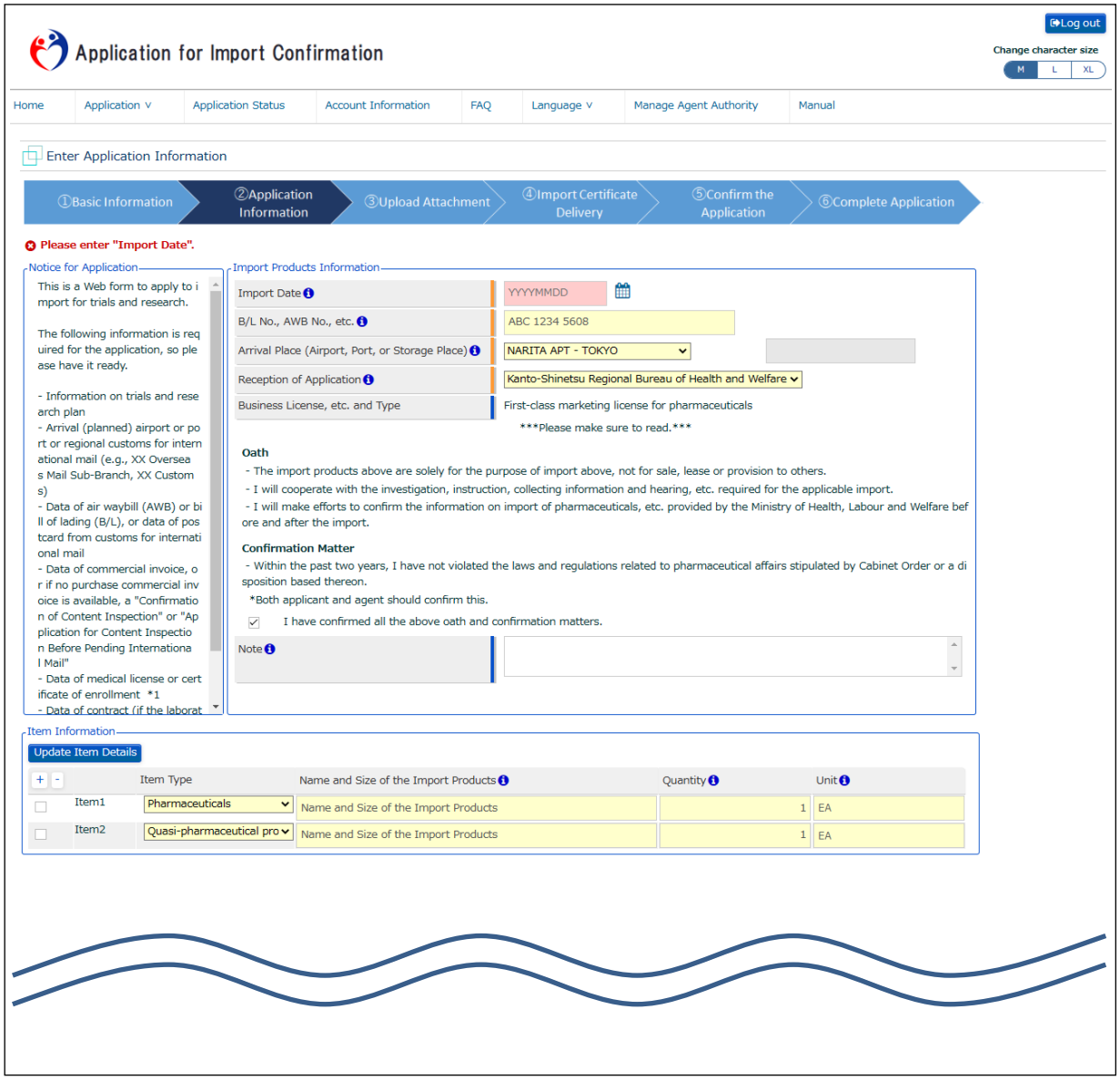
Click “Return” to go back to the Home screen.

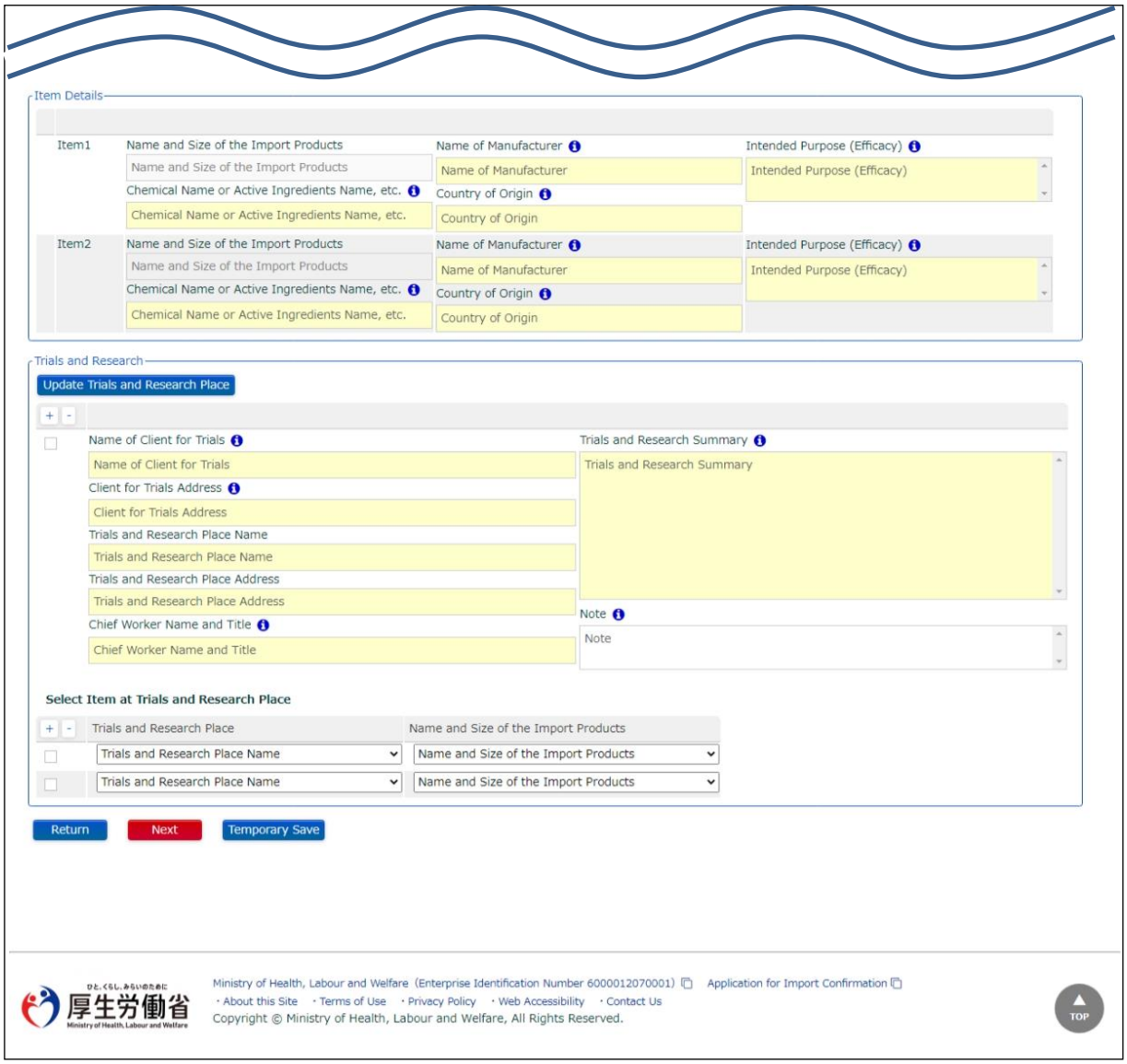
(3) Enter the application information

The screen to enter the application information is displayed.

Enter data according to the information icons and click “Next.”

<Enter Application Information/Import for Trials and Research>



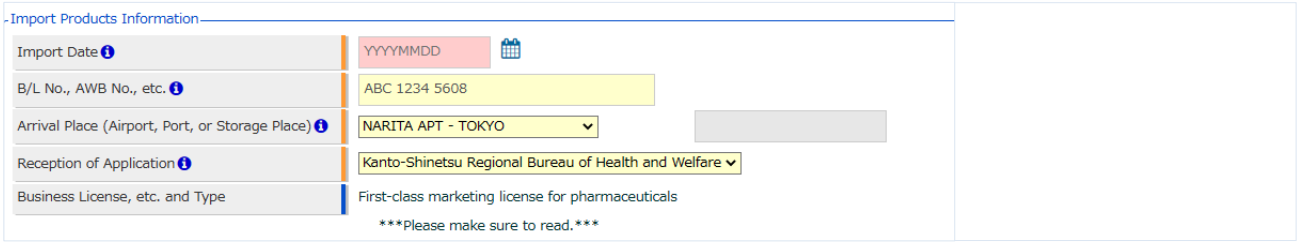

Item Details
Item1
Name and Size of the Import Products
Name and Size of the Import Products
Name of Manufacturer
Name of Manufacturer
Intended Purpose (Efficacy)
Intended Purpose (Efficacy)
Chemical Name or Active Ingredients Name, etc.
Chemical Name or Active Ingredients Name, etc.
Country of Origin
Country of Origin
Item2
Name and Size of the Import Products
Name and Size of the Import Products
Name of Manufacturer
Name of Manufacturer
Intended Purpose (Efficacy)
Intended Purpose (Efficacy)
Chemical Name or Active Ingredients Name, etc.
Chemical Name or Active Ingredients Name, etc.
Country of Origin
Country of Origin
Trials and Research
Update Trials and Research Place
Name of Client for Trials
Name of Client for Trials
Client for Trials Address
Client for Trials Address
Trials and Research Place Name
Trials and Research Place Name
Trials and Research Place Address
Trials and Research Place Address
Chief Worker Name and Title
Chief Worker Name and Title
Trials and Research Summary
Trials and Research Summary
Note
Note
Select Item at Trials and Research Place
Trials and Research Place
Name and Size of the Import Products
Trials and Research Place Name
Name and Size of the Import Products
Trials and Research Place Name
Name and Size of the Import Products
Return
Next
Temporary Save
厚生労働省
Ministry of Health, Labour and Welfare
Ministry of Health, Labour and Welfare (Enterprise Identification Number 6000012070001)
Application for Import Confirmation
About this Site
Terms of Use
Privacy Policy
Web Accessibility
Contact Us
Copyright © Ministry of Health, Labour and Welfare, All Rights Reserved.
TOP

[Import Products Information]

Enter the arrival date of the import products in Japan in “Import Date.” If you have not yet arrived in Japan, please enter the expected date of arrival.

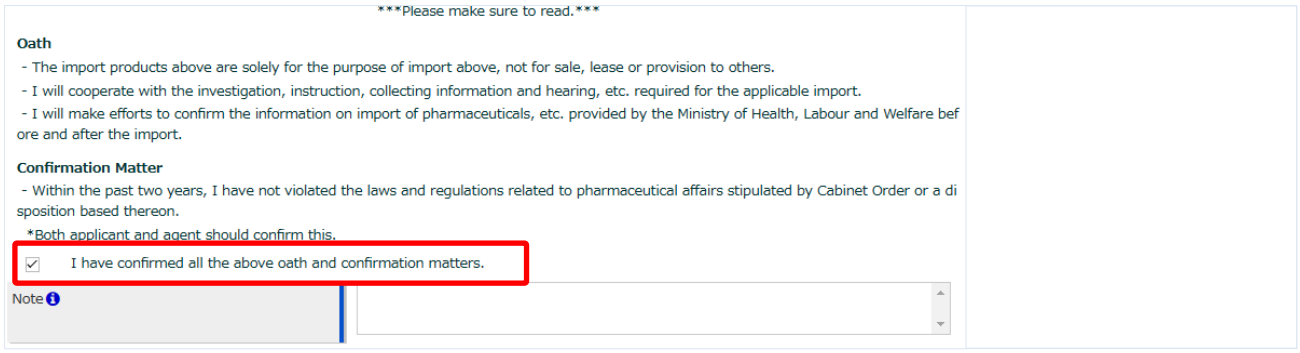
Enter the Air Waybill (AWB) No. or Bill of Lading (B/L) No. in “B/L No., AWB No., etc.” Enter the Notice No. (12 digits) of the postcard from customs if you received one.

Select the arrival place, etc. from the “Arrival Place (Airport, Port, or Storage Place)” pull-down. If you selected Other, enter it in “Other.” Enter a part of the name of the airport or other facility in the input field to see the candidates. Select “Reception of Application” from the pull-down.



Confirm the contents of the Oath and the Confirmation Matter and check the box, “I have confirmed all the above oath and confirmation matters.”

Enter a supplementary note, etc. for the application in “Note” if any.



[Item Information]

Select “Item Type” from the pull-down.

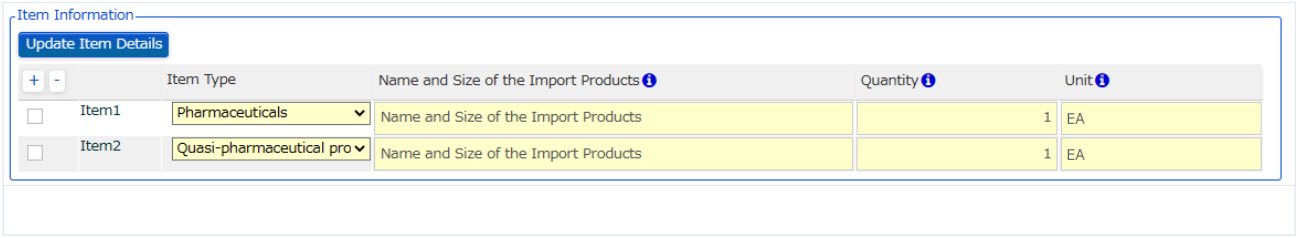
Enter the name and the quantity per unit described in the invoice in “Name and Size of the Import Products.”

Enter the quantity described in the invoice in “Quantity.”

Enter the unit of quantity such as 'tablets', 'pills', 'EA' in “Unit.”

When entry is completed, click “Update Item Details.” The entry in Item Information will be updated in the Item Details, so please continue to enter the Item Details.

If you edited Item Information after updating Item Details, click “Update Item Details” again. The edited data will be updated in the Item Details.



1. To add rows, click “+.”
2. To delete rows, check the rows to delete and click “-” at 1.

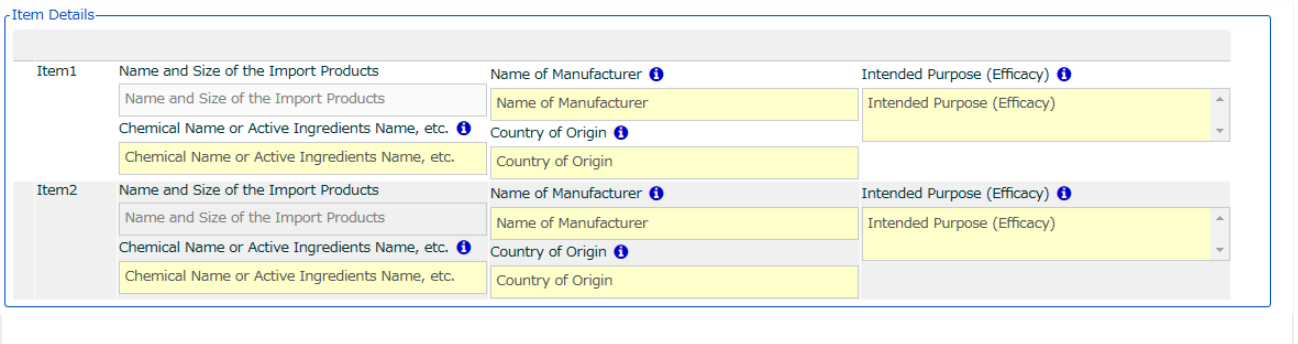
[Item Details]

Enter the accepted name, etc. in “Chemical Name or Active Ingredients Name, etc.”

Enter the name of the manufacturer of the import products in “Name of Manufacturer.”

Enter a country of origin of the import products in “Country of Origin.” Enter part of the country name to see candidate country names and select one.

Enter a specific purpose of use, general efficacy, etc. of the import products in ”Intended Purpose (Efficacy).”



[Trials and Research]

In "Name of Client for Trials," if the client for trials is a corporation, enter the corporate name and the representative name, and if it is a researcher, etc., enter the name of the institution to which the person belongs.

In "Client for Trials Address," if the client for trials is a corporation, enter the address of the head office, and if it is a researcher, etc., enter the address of the institution to which the person belongs.

Enter the name of the trials and research place in "Trials and Research Place Name."

Enter the address of the trials and research place in "Trials and Research Place Address."

Enter the name and title of the chief worker who is doing the research in "Chief Worker Name and Title."

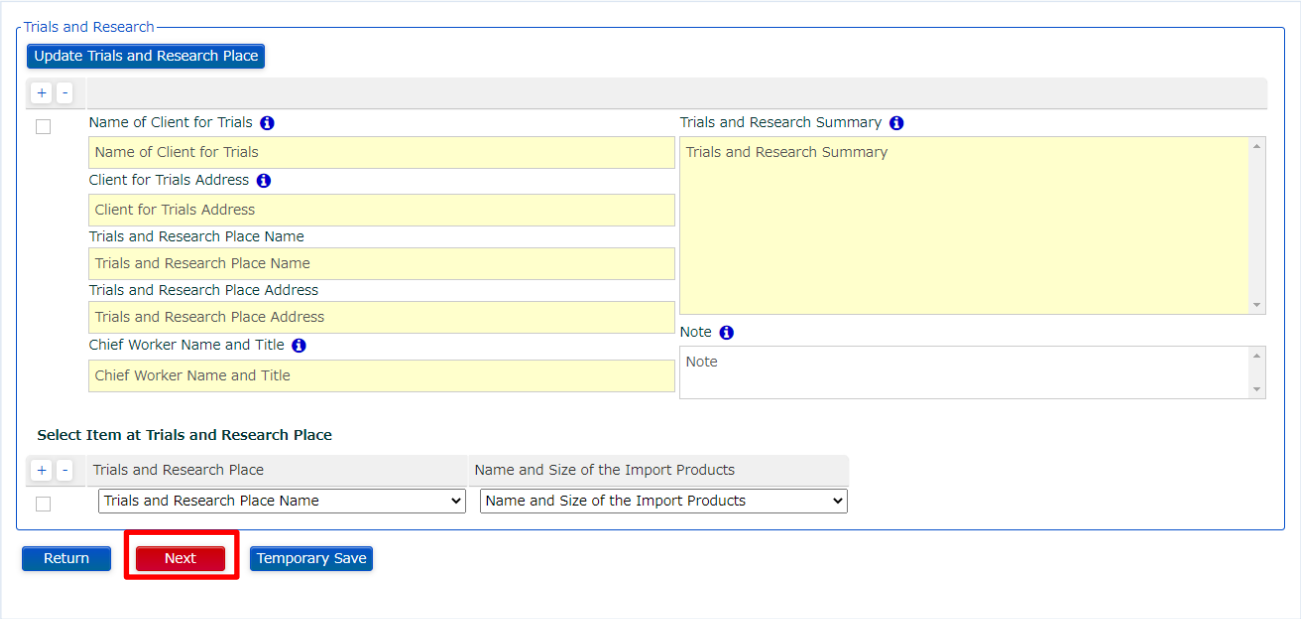
Enter the details of the trials and research to clarify the necessity of the quantity of import in "Trials and Research Summary." (Type of trial, trial items, breakdown of the quantity of specimens, etc.)

Enter the handling of remaining specimens after the trial (destroy, etc.) in "Note."

If you edited the Trials and Research Place Name, click "Update Trials and Research Place." The registered data will be updated in the "Item at Trials and Research Place" selection field. If you edited the Trials and Research Place Name after updating, click "Update Trials and Research Place" again after the edit.

Select a combination of a trials and research place and an item from "Trials and Research Place" and "Item" in the "Select Item at Trials and Research Place" section. Register combinations with laboratories for all the registered items. If there is only one trials and research place, the "Select Item at Trials and Research Place" field is automatically populated (all items are tied together) when the "Update Trials and Research Place" button is pressed.

To add rows, click "+." To delete rows, check the rows to delete and click "-."



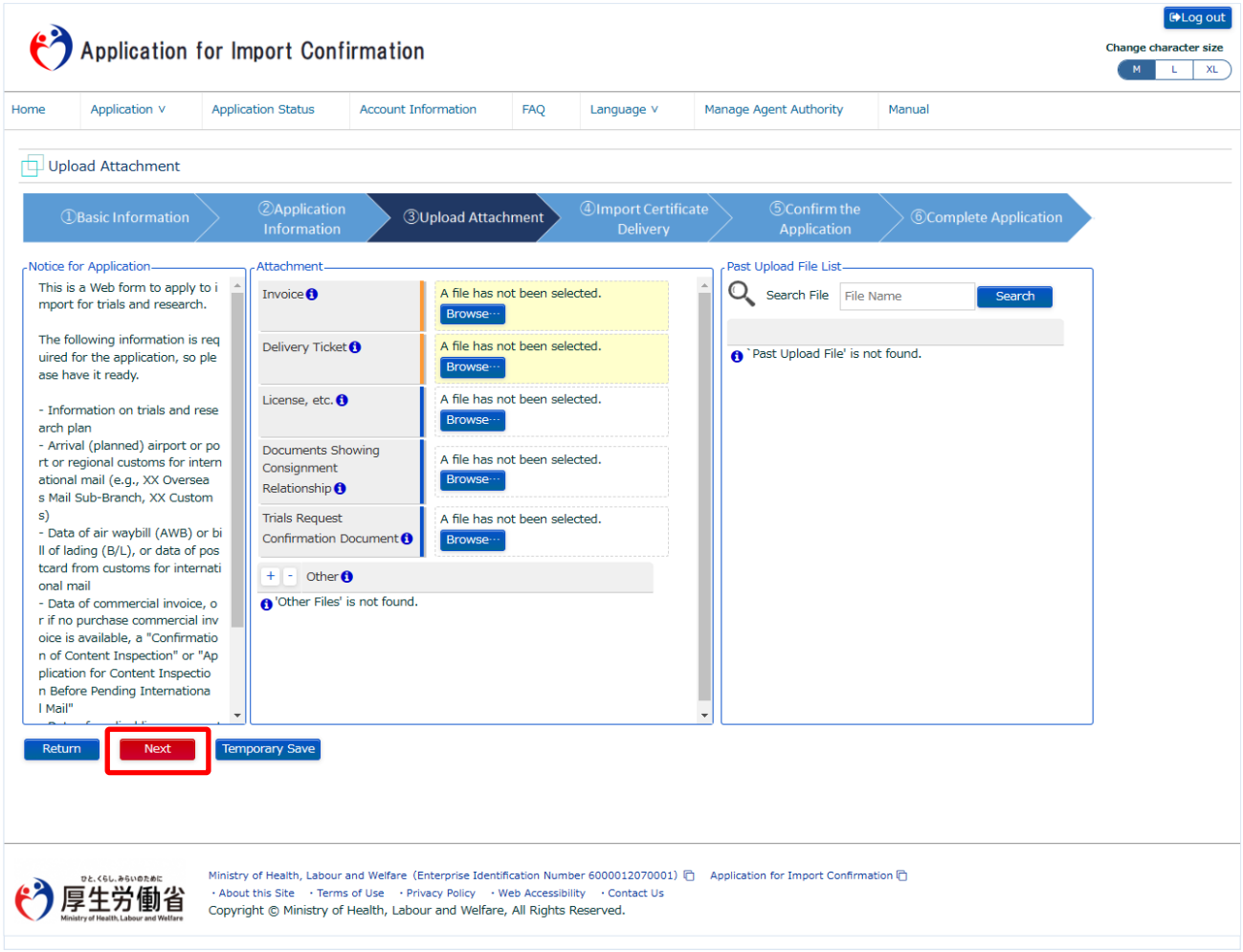
When entry is completed, click "Next."

(4) Upload attachments

The screen to upload attachments is displayed.

In principle, the fields in orange are required and should be filled in according to the instructions provided by the information icons.

<Upload Attachment/Import for Trials and Research>



[Attachments]

Attach the invoice in “Invoice.” If you do not have an invoice, please attach a “Content Inspection Confirmation” (for international cargo: customs broker) or a “Pending International Mail Item Inspection Form” (for international mail: customs) as an alternative document. If you are bringing medicines, etc. into Japan yourself, please attach a copy of your e-ticket or itinerary showing your name, flight number, and airport of arrival.

Attach the Air Waybill (AWB) or Bill of Lading (B/L) in “Delivery Ticket.” Attach the “Notice from Customs Clearance Procedure for Postal Matter from Abroad” for international mail.

Make sure to attach the medical license, etc. in “License, etc.”

If the trials and research place is another company, attach the contract, etc. (quotations are not accepted)

in “Documents Showing Consignment Relationship” to show the relationship with the outsourcing company. For a blanket agreement, attach documents (memorandums, etc.) that can confirm this trial request in addition to the blanket agreement in “Trials Request Confirmation Document.”

If you upload files other than the above, attach them in “Other.” To add rows, click “+.” To delete rows, check the rows to delete and click “-.”



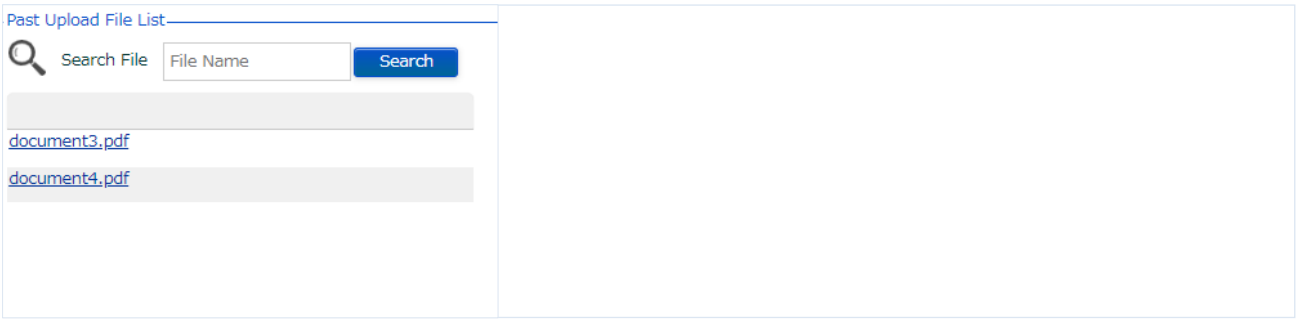
*The file formats that can be uploaded are as follows. The maximum upload size is 100 MB.

- Image files (jpeg, jpg, png)
- Office files (doc, docx, xls, xlsx)
- PDF files (pdf)
- Zipped files (zip) *Files cannot be uploaded if there are subfolders in the ZIP file

[Past Upload File List]

To reattach files from the Past Upload File List, select the files.

To search files from the Past Upload File List, enter a keyword in “Search File” and click “Search.”



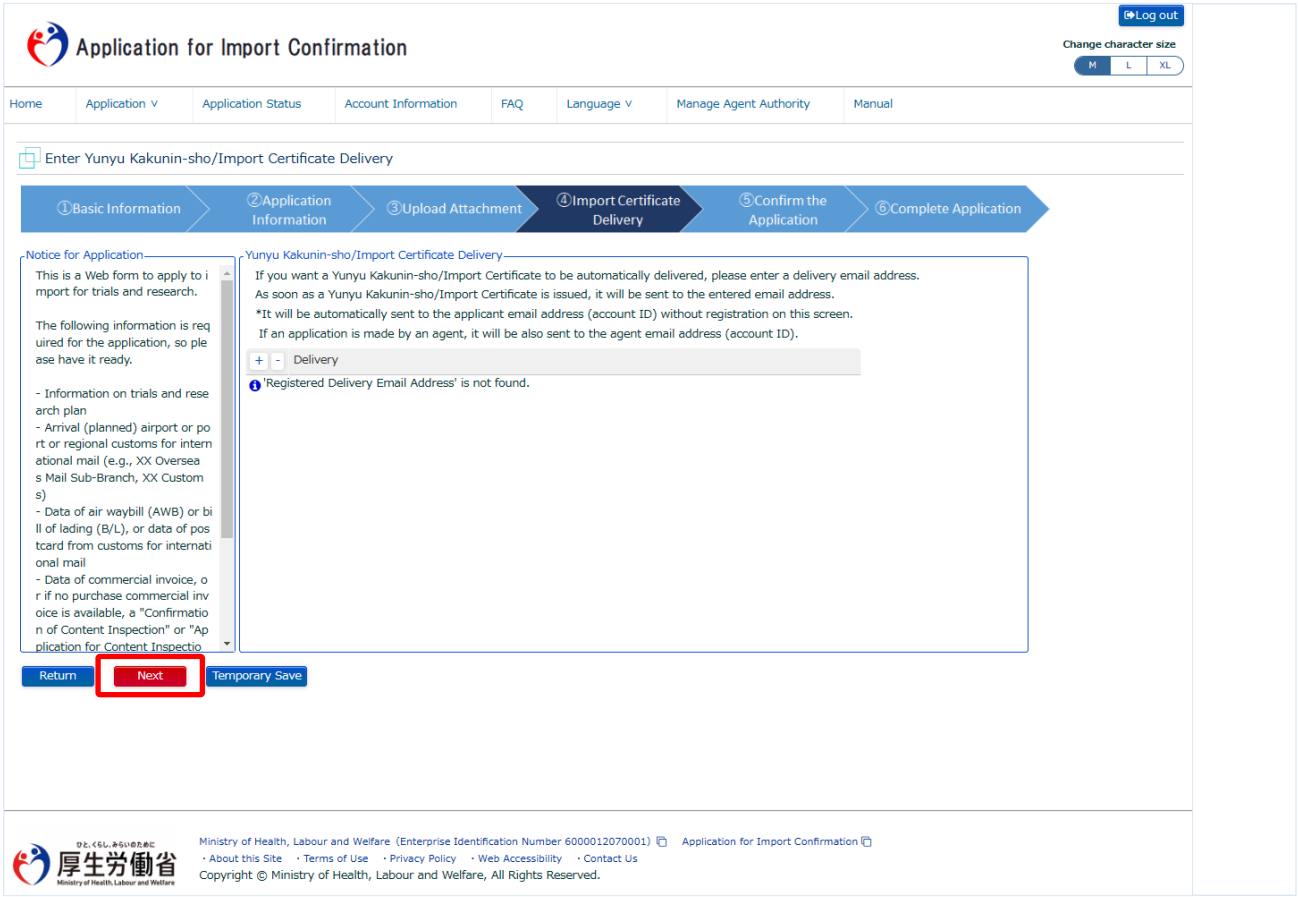
When entry is completed, click “Next.”

(5) Enter a delivery address for a Yunyu Kakunin-sho/Import Certificate

The screen to enter a delivery address for a Yunyu Kakunin-sho/Import Certificate is displayed.
If you want the import confirmation certificate to be sent to an address other than the one you registered when you created your account, please enter the email address to which it should be sent in “Delivery”.
As soon as a Yunyu Kakunin-sho/Import Certificate is issued, it will be sent to the entered email address.
*It will be automatically sent to the applicant email address (account ID) without registration on this screen.
If an application is made by an agent, it will also be sent to the agent email address (account ID).

To add rows, click “+.” To delete rows, check the rows to delete and click “-.“

<Enter Yunyu Kakunin-sho/Import Certificate Delivery Address>



When entry is completed, click “Next.”

(6) After confirming the application, register

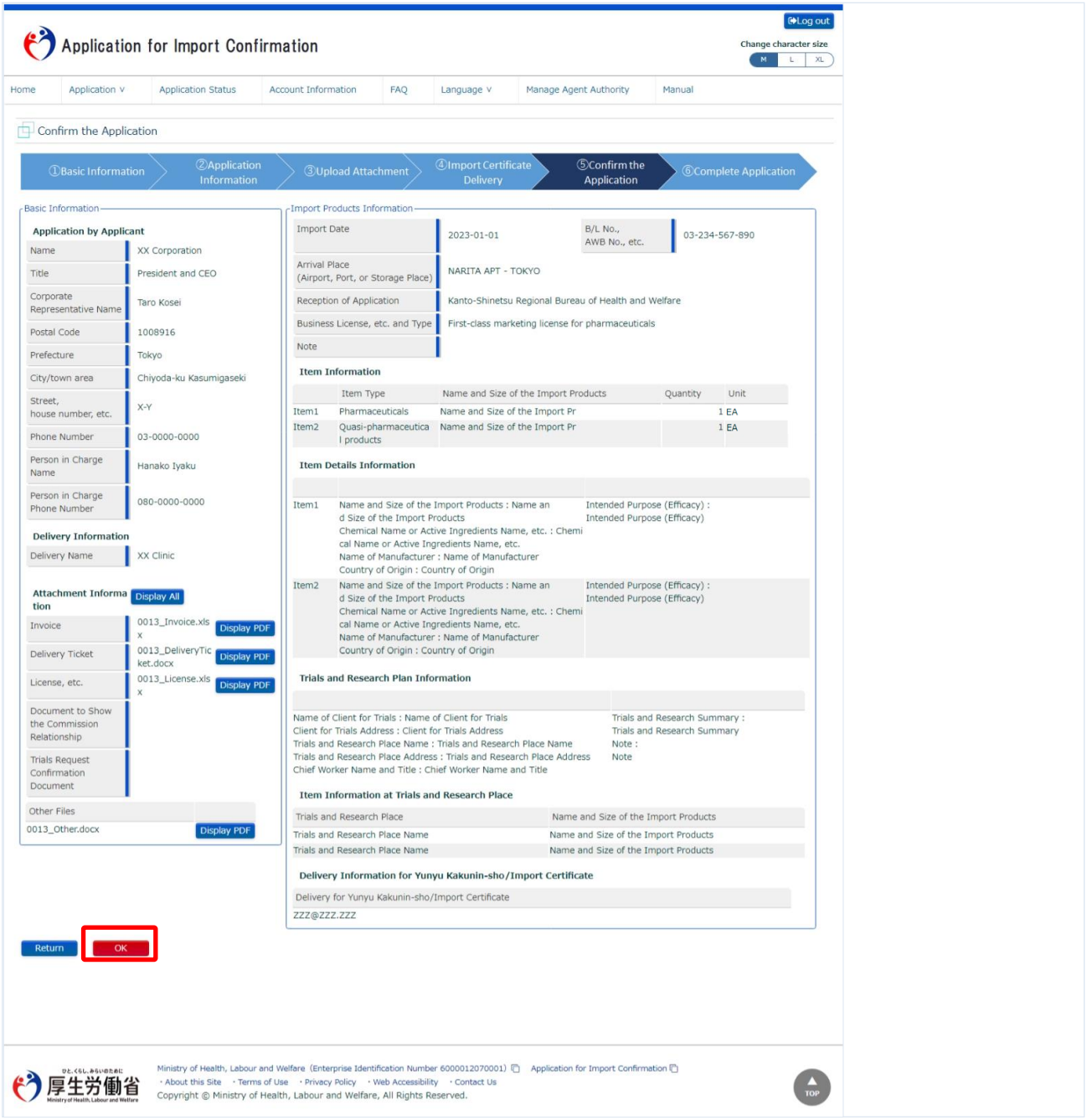
The screen to confirm the application is displayed.

To refer to the information of attachments, click “Display All” or “Display PDF.”

*If all files are not displayed in a different tab after clicking “Display All,” change the pop-up block settings of the browser and set this site to be exempt from pop-up blocking. Please refer to page 8 of the Application for Import Confirmation Operation Manual (Common Functions) for details on how to set your browser's pop-up blocker to exempt sites from pop-up blocking.

Confirm the application and click “OK.”

<Confirm the Application/Import for Trials and Research>

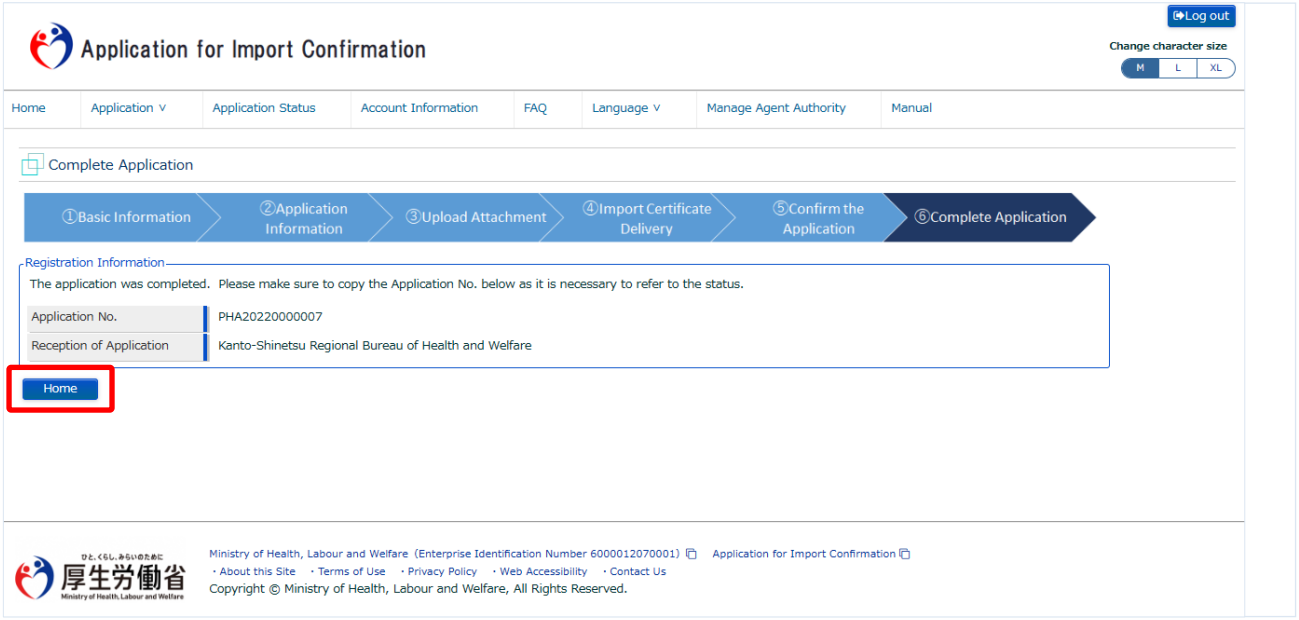


(7) Confirm completion of the application

When the application is complete, it transits to the Complete Application screen. Make sure to copy the displayed Application No.

Click “Home” to go back to the Home screen.

<Complete Application>



2.3 Bulk Application

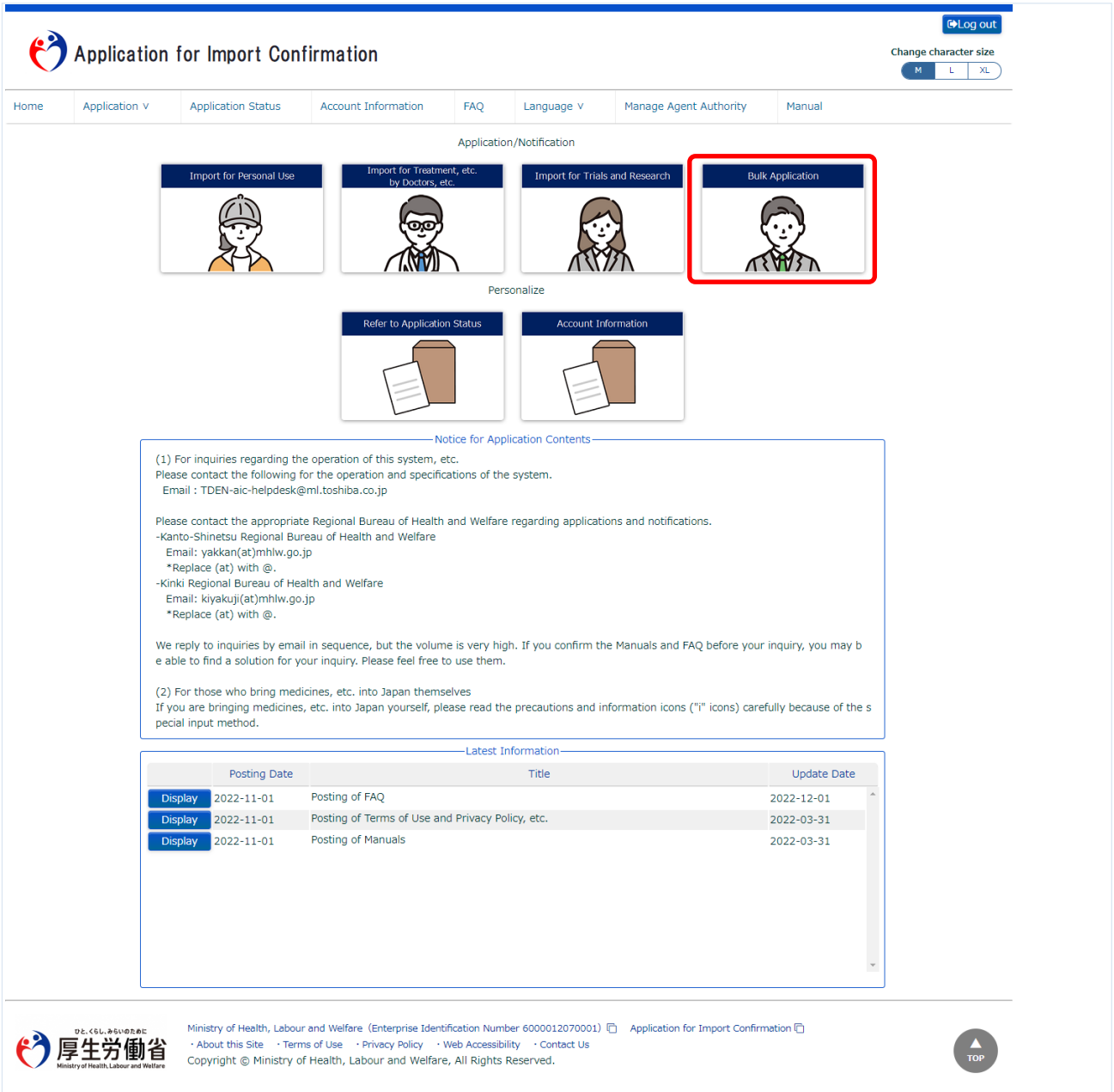
2.3.1 Register the Bulk Application Information

This is a function for an applicant to submit multiple import confirmation applications in one application. You can upload a ZIP file gathering CSV files, PDF files, etc. for each application (the basic information, application information, and attachments) and file multiple applications in one application.

(1) Open the Bulk Application screen

Click “Bulk Application” on the Home screen.

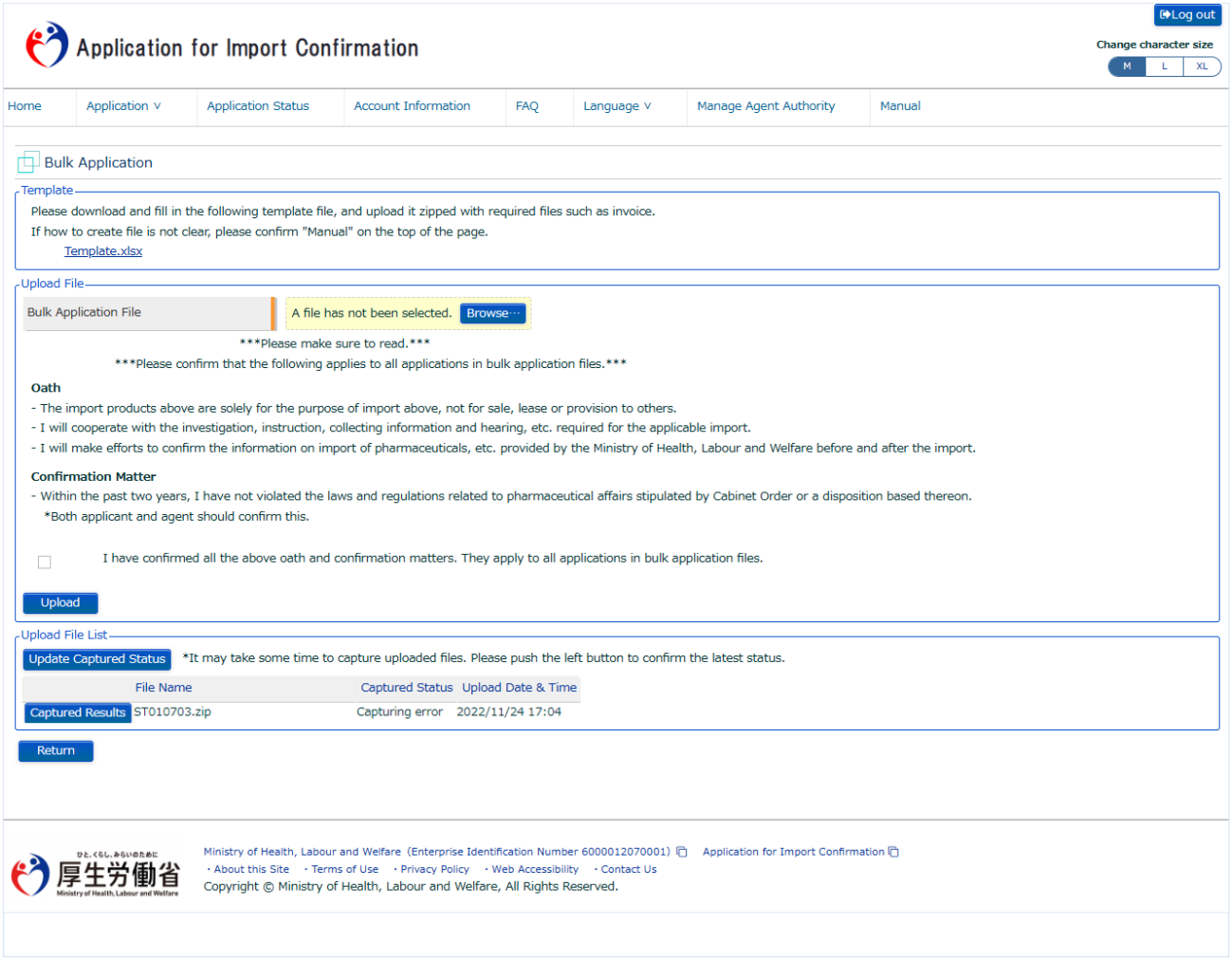
<Home Screen/Applicant>



(2) Upload files for a bulk application

The Bulk Application screen is displayed.

<Bulk Application>



[Create Files]

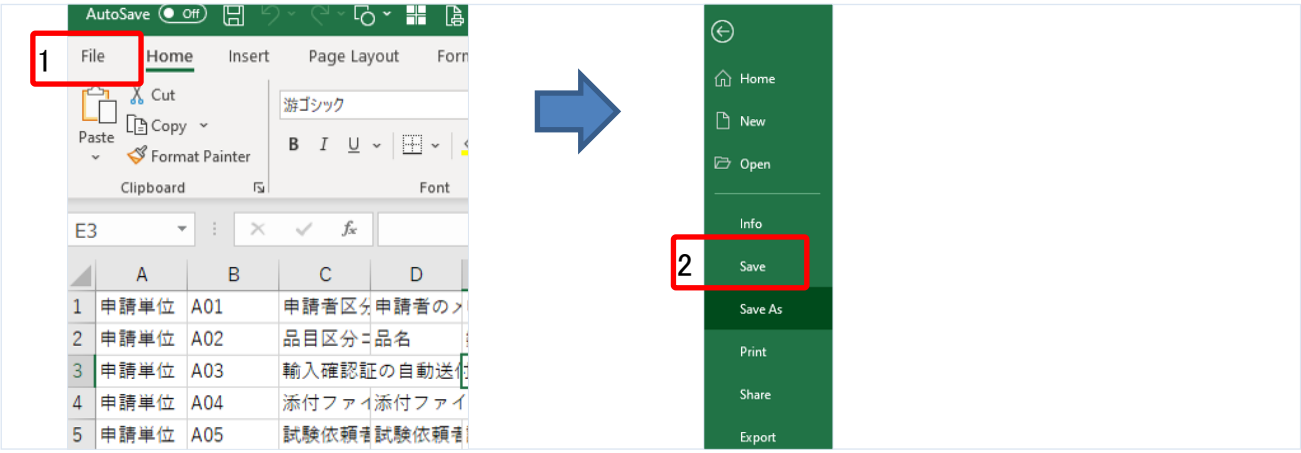
Download the template file (Template.csv) from “Template,” fill it in, and create a ZIP file with the required files (such as invoice data). To create files, note the following:

- To compress multiple files in ZIP format, do not create subfolders or ZIP files within a ZIP file. If you upload such a format, it will result in an error and cannot be registered.
- If attachment files have Excel files, check the Excel print preview in advance to ensure that the layout has not been corrupted.
- Uploadable file types are *.doc, *.docx, *.xls, *.xlsx, *.pdf, *.jpeg, *.jpg, *.png.
- Uploadable file size is less than 500MB.

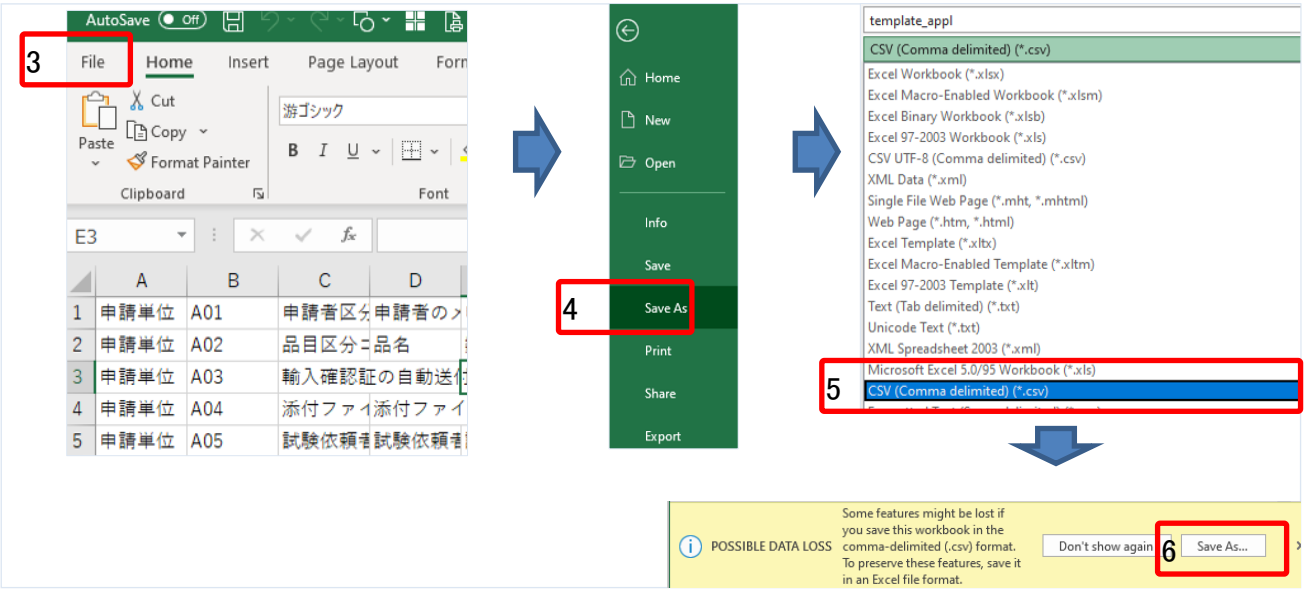
[Procedure for Editing and Saving CSV Files in Excel

When creating a CSV file, be careful when editing in Excel and saving in CSV file format. (The attribute of a cell where data has been entered must be a string, and the "previous zero" of the code value must not be missing and must be attached.) The procedure for editing and saving CSV files in Excel is as follows.

1. Download the template file, edit it in Excel, and after editing, select "File" from the menu.
2. Click "Save" from the "File" menu. (This Excel file will become the original data.)



3. Then select "File" from the Excel menu.
4. Click "Save As" from the "File" menu.
5. Save the file type (extension) as CSV (comma delimited) (*.csv).
6. If the confirmation dialog to save in CSV format is displayed, click "Yes."

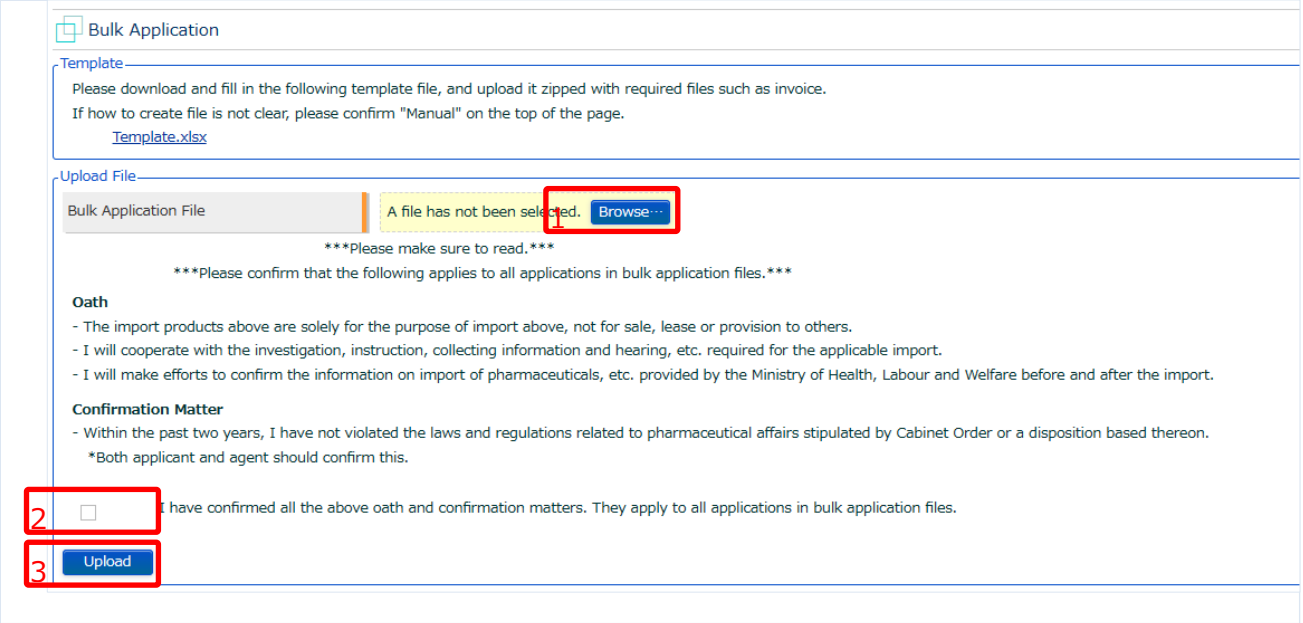


7. Close the opened Excel file without saving it.
8. Use the newly created CSV file as the file for bulk application.
9. If an import error or other problem occurs when uploading a bulk application file and you need to re-edit the CSV file, modify the original Excel (.xlsx) data saved in step 2 and recreate the CSV file.

[Upload Files]

After creating files, upload the files as follows:

1. Click the "Browse" button of "Bulk Application File" and specify the bulk application files. The maximum upload size is 500 MB.
2. Confirm the contents of the Oath and the Confirmation Matter and check the box.
3. Click "Upload" to upload the bulk application files.

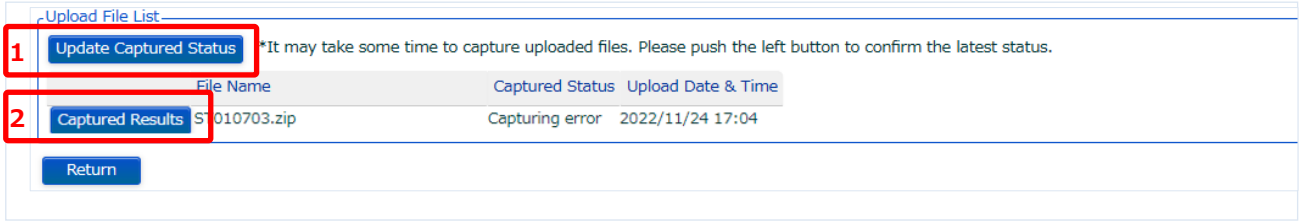


After uploading, the registration process will be sequentially performed.

[Upload File List]

Confirm the captured status of the uploaded files in "Upload File List."

1. Since it may take some time to import uploaded files, if the results of importing are not displayed, click the "Update Captured Status" button to check the latest status.
2. To confirm the captured results, click "Captured Results" in Upload File List and transit to the Refer to the Status of Bulk Application screen.



(3) Confirm the captured results

The Refer to the Status of Bulk Application screen is displayed.

Confirm the captured results and click “Close.”

If there was a capture error, confirm the contents displayed in “Captured Status Details,” deal with the requirements, and upload the bulk application files again.

*Refer to “6. Error messages and error descriptions in the process of registering bulk application information” in “2.3.2 Data Specifications of Bulk Application Files.”

<Refer to the Status of Bulk Application>



2.3.2 Data Specifications of Bulk Application Files

This section describes the file data specifications to submit multiple import confirmation applications to this system in one application.

To create and edit files for a bulk application, create CSV files with Microsoft Excel or a text editor. For how to use the software, refer to the user guides of the software.

(1) File definition

The file format is as follows:

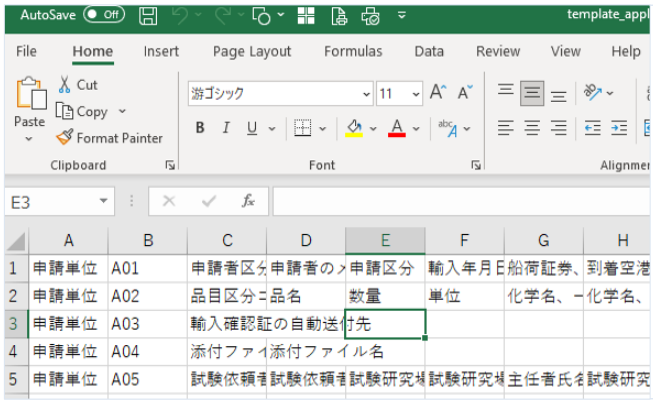
Format	**CSV format**
Header (Title)	**None**
Character Code	**SJIS**

1. CSV layout

   The CSV layout for this entry file is different depending on the data type. The relationship between the data type and the contents of the entry items is as follows. Refer to "(2) File Definition Specifications" for details.

Data Type	Contents of Entry Item
A01	Application Information
A02	Item Information
A03	Delivery Information
A04	Attachment File Information
A05	Trials and Research Plan Information

<CSV File Image>

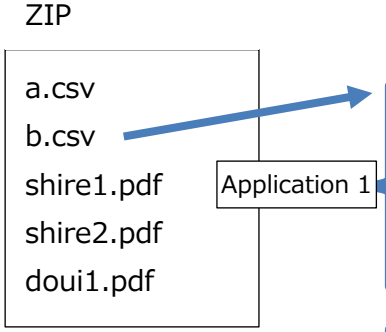


*The above image shows a CSV file image with Microsoft Excel. If you use a text editor, the file image will be the one with a comma-delimited format.

2. Overview of ZIP file contents and CSV entry items

A ZIP file can store multiple CSV files. Multiple applications can be filed in a CSV file.
Multiple CSV files can be placed in a ZIP file, but a single application with multiple CSV files cannot be registered.
Applications must be stored in a CSV file in sequential order, and the order is as follows:

Example of Storing Files in a ZIP File:



CSV (*The first row shows an explanation for descriptive purposes. In actuality, the application information is described from the first row.)

Application Unit	Data Type	Details
1	A01	Application Information ----
1	A02	Item Information 1 ----
1	A05	Trials and Research Plan Information 1 ----
1	A05	Trials and Research Plan Information 2 ----
1	A04	Attachment File Information ----
2	A01	Application Information ----
2	A02	Item Information 1 ----
2	A02	Item Information 2 ----
2	A03	Delivery Information ----
2	A04	Attachment File Information ----

*CSV is originally comma-delimited, but commas are omitted because this is an image.

*Explanations of the titles in the first row of the CSV in the above image:

- Application Unit: Item to identify data within the same application in the CSV file
- Data Type: Item to determine the information type included in the applicable row
- Details: Detailed information of the application information

3. The relationship between A02 Item Information and A05 Trials and Research Plan Information

A05 Trials and Research Plan Information is linked with A02 Item Information and the relationship is shown by describing the Trials and Research Plan Information following the Item Information.

The Relationship between Item Information and Trials and Research Plan Information:

Example: The conditions of the example are as follows:

- The trial and research plan information linked with "Item Information 1" is "Trials and Research Plan Information 1" and "Trials and Research Plan Information 2"
- The trial and research plan information linked with "Item Information 2" is "Trials and Research Plan Information 3"

Data Type	Details
A01	Application Information ----
A02	Item Information 1 ----
A05	Trials and Research Plan Information 1 ----
A05	Trials and Research Plan Information 2 ----
A02	Item Information 2 ----
A05	Trials and Research Plan Information 3 ----
A03	Delivery Information ----
A03	Delivery Information ----
A04	Attachment File Information ----
A04	Attachment File Information ----
A04	Attachment File Information ----

4. Required items

Required items are marked with an asterisk (*) in the column "Required" of "(2) File Definition Specifications."

5. CSV specifications

<To use Microsoft Excel>

- Save files in CSV format.
- Change the cell formatting to "Text" when entering characters that begin with 0 (e.g., "01") to avoid missing 0s.

<To use a text editor>

- Separate columns (items) with commas (,).
- To include commas (,) in the data, enclose all the data specified for the column (item) in double quotation marks (").
- To include double quotation marks (") in the data, use double quotation marks (") twice in succession.

* Two consecutive double quotation marks (") are used to represent a single double quotation mark (").

- To include a new line in the data, use ¥r¥n.

Example 1: When a comma (,) is specified (to express "Comment,D" in the last column)

```
1,A02,1,,"Comment,D"
```

Example 2: Double quotation marks (") are used (to express "Comment "D"" in the last column)

```
1,A02,1,," Comment ""D"""
```

To write an abbreviated value, specify an empty string in either of the following forms.

Example 1: Nothing is written between the delimiter commas (,). (If you specify an abbreviated value for the last two columns)

```
1,A02,1,,
```

Example 2: Nothing is written between the enclosing double quotation marks ("). (If you specify an abbreviated value for the last two columns)

```
1,A02,1,,"","",""
```

6. Error messages and error descriptions in the process of registering bulk application information

Error Description	Error Message	Measures
File attachment check error	Please attach "a file for importing application information. "	Please attach a file for importing application information.
File format check error	Please upload the file for importing application information as a *.zip file.	Upload the ZIP file.
File size check error	The file size of the file for importing application information exceeds 500 MB. Please reduce the file size and attach the file again.	Please modify the size of the ZIP file to less than 500MB and upload it.
Harmless file format error	There are files which are not *.doc,*.docx,*.xls,*.xlsx,*.pdf,*.jpeg,*.jpg, or *.png in the attached Zip file. Please change files to the foregoing formats only in the Zip file and attach them again.	Please make sure that the files in the ZIP file are in the format shown on the left only, and reattach them.
Harmless failure error	Sanitize files failed. Please confirm the attachment files and attach them again. If failure continues, please make contact after confirming "Contact Us."	Please check that the attached file is complete and reattach it. If the failure persists, please contact the help desk below.

Error Description	Error Message	Measures
		Email: TDEN-aic-helpdesk@ml.toshiba.co.jp
CSV existence check error	CSV files do not exist.	Upload the CSV file by storing it in the ZIP.
Character code error	Character code of CSV is different. Please use and edit downloaded template.	Please set the character code of the CSV file to "SJIS."
Same name file check error	The same name file exists in zip file.	Correct the file names of files with the same name that have different extensions in the ZIP to different names.
PDF conversion error	There are files which cannot be changed to PDF. Please confirm the contents of the files. "Name of file to be processed"	Please correct the contents of files that cannot be converted to PDF and reattach them.
Required item error	Data type is a required item. CSV name: "CSV name" Row: "Number of rows to check "	Please enter the data type.
Item check error	Please enter either A01, A02, A03, A04 or A05 for data type. CSV name: "CSV name" Target rows: "Number of rows to check"	Correct the data type value to the value shown on the left.
Item error in the application	Error if illegal code is entered or characters are entered in numerical items, etc.	Correct illegal code or character types.

(2) File definition specifications

Explanatory note for "Required":
*: Required; x: Required with conditions;
No mark: Optional

File Item Specifications_Application Information[A01](Bulk Application)

No.	Required	Item Name	Format	Digits	Settings
1	*	Application Unit	String	8	Optionally set by users to determine an application unit.
2	*	Data Type	String	3	A01: Application Information
3	*	Applicant Type	String	1	0: Applicant 1: Agent
4	x	Applicant Email Address	String	255	Required when the applicant category is "1: Agent"
5	*	Application Type	String	2	01: Import for Personal Use 02: Import for Treatment, etc. by Doctors, etc. 03: Import for Trials and Research
6	*	Import Date	YYYYMMDD	-	
7	*	B/L No., AWB No., etc.	String	35	
8	*	Arrival Place (Airport, Port, or Storage Place) Code	String	5	02010: NARITA APT - TOKYO 02011: HANEDA APT - TOKYO 02016: CHUBU APT - AICHI 02017: KANSAI INT APT - OSAKA 02023: FUKUOKA APT - FUKUOKA 01030: TOKYO - TOKYO 03001: TOKYO CUSTOMS 03002: YOKOHAMA CUSTOMS 03003: NAGOYA CUSTOMS 03004: OSAKA CUSTOMS 03005: MOJI CUSTOMS 04001: OTHER
9	x	Arrival Place (Airport, Port, or Storage Place)_Other	String	150	*Required if No. 8 "Arrival Place (Airport, Port, or Storage Place) Code" is Other
10	*	Reception of Application Code	String	4	1101: Kanto-Shinetsu Regional Bureau of Health and Welfare 2701: Kinki Regional Bureau of Health and Welfare

No.	Required	Item Name	Format	Digits	Settings
11	x	Business License, etc. and Type	String	99	*Required if a corporate applicant has marketing licenses of pharmaceuticals, etc. for import for trials and research
12		Note	String	400	
13	*	Delivery Name	String	50	
14		Delivery_Postal Code	String	7	Enter a postal code from 3 to 7 digits in half-width numbers without a hyphen.
15	*	Delivery_Prefecture	String	15	
16	*	Delivery_City/town area	String	64	
17	*	Delivery_Street, house number, etc.	String	300	
18	*	Delivery_Phone Number	String	13	Enter a phone number in half-width numbers with "- (hyphens)", or "+" only.

File Item Specifications_Item Information[A02]

No.	Required	Item Name	Format	Digits	Settings
1	*	Application Unit	String	8	
2	*	Data Type	String	3	A02: Item Information
3	*	Item Type Code	String	2	01: Pharmaceuticals 02: Extracorporeal diagnostic agents 03: Quasi-pharmaceutical products 04: Cosmetics 05: Medical devices 06: Regenerative medicine products
4	*	Name and Size of the Import Products	String	100	Item to set the name of the import products.
5	*	Quantity	Numerical value	8	Item to set the quantity of the import products.
6	*	Unit	String	10	Item to set the unit of the import products. *Numbers cannot be entered.
7	x	Chemical Name or Active Ingredients Name	String	2	01: (1) Hyaluronic acid 02: (2) Botulinum toxin 03: (3) Ascorbic acid 04: (4) Tooth bleaching agents 05: (5) Minoxidil 06: (6) Bevacizumab

No.	Required	Item Name	Format	Digits	Settings
					07: (7) Thalidomide 08: (8) Inactivated polio vaccine 09: (9) Lidocaine 10: (10) Melatonin 11: (11) Oseltamivir phosphate 12: (12) Sildenafil 13: (13) Kampo 14: (14) Other *Required if the application type is not "03: Import for Trials and Research" and the item type is "1: Pharmaceuticals"
8	x	Chemical Name or Active Ingredients Name_Other	String	150	*Required if any of the following applies: No. 7 "Chemical Name or Active Ingredients Name" is "(14) Other," the item type is non-pharmaceuticals, or the applicant type is "03: Import for Trials and Research"
9	*	Name of Manufacturer	String	150	
10	*	Country of Origin	String	2	Refer to the appendix "Country of Origin" for code values of the country of origin.
11	x	Intended Purpose	String	2	01: (1) Cancer treatment 02: (2) Tonic/erectile dysfunction drug 03: (3) Antidepressant/mood disorder/insomnia treatment 04: (4) Nutritional supplement 05: (5) Beauty care 06: (6) Slimming 07: (7) Birth control 08: (8) Allergy therapy 09: (9) Hair growth 10: (10) Vaccine 11: (11) Cutaneous anesthesia 12: (12) Ophthalmic treatment 13: (13) Dental therapy 14: (14) Specified disease 15: (15) Treatment of animals 16: (16) Other *Required if the application type is "01: Import for Personal Use" or "02: Import for

No.	Required	Item Name	Format	Digits	Settings
					Treatment, etc. by Doctors, etc." and the item type is "1: Pharmaceuticals"
12	x	Intended Purpose_Other	String	20	*Required if the intended purpose is "16: (16) Other"
13	*	Specific Intended Purpose (Efficacy)	String	998	
14	x	Specifications	String	200	* Required if the application type is "01: Import for Personal Use" or "02: Import for Treatment, etc. by Doctors, etc."
15		Statement of Reasons Format Type	String	1	1: Thalidomide, etc. 2: Innovative Pharmaceuticals
16	x	Urgency of Treatment	String	500	*Required except for the case that the application type is "02: Import for Treatment, etc. by Doctors, etc." and No. 7 "Statement of Reasons Format Type" is "1: Thalidomide, etc." or "2: Innovative Pharmaceuticals"
17	x	Reason why commercially available pharmaceuticals, etc. in Japan cannot be used	String	500	*Required if the application type is "02: Import for Treatment, etc. by Doctors, etc."
18	x	Reason why imported pharmaceuticals, etc. must be used	String	500	*Required if the application type is "02: Import for Treatment, etc. by Doctors, etc."
19	x	Necessity of Import Quantity	String	500	*Required if the application type is "02: Import for Treatment, etc. by Doctors, etc."
20	x	Responsibility of Doctor	String	150	*Required if the application type is "02: Import for Treatment, etc. by Doctors, etc."
21	x	Oath_Thalidomide Formulation, etc.	String	500	*Required if No. 15 "Statement of Reasons Format Type" is "1: Thalidomide, etc."
22	x	Oath_Sales, Transfer	String	150	*Required if No. 15 "Statement of Reasons Format Type" is "1: Thalidomide, etc."
23	x	Oath_Innovative Pharmaceuticals	String	500	*Required if No. 15 "Statement of Reasons Format Type" is "2: Innovative Pharmaceuticals"

File Item Specifications_Delivery Information[A03]

No.	Required	Item Name	Format	Digits	Settings
1		Application Unit	String	8	
2		Data Type	String	3	A03: Delivery Information

No.	Required	Item Name	Format	Digits	Settings
3		Delivery of Yunyu Kakunin-sho/Import Certificate	String	255	

File Item Specifications_Attachment File Information[A04]

No.	Required	Item Name	Format	Digits	Settings
1	*	Application Unit	String	8	
2	*	Data Type	String	3	A04: Attachment File Information
3	*	Attachment File Type	String	3	B01: Invoice B02: Delivery Ticket B03: Copies of Product Explanations or Brochures B04: Prescription, etc. by Doctor B05: License, etc. B06: Attachment for Import Confirmation Application B07: Documents Showing Consignment Relationship B08: Trials Request Confirmation Document B10: Consent Form B11: Other You are required to attach at least the following documents to file an application. Import for personal use: Invoice（B01） and Delivery Ticket（B02） Prescription or Direction, etc. by Doctor（B04） Statement of Reasons（B11） (when the import product is delivered to any place other than your home) Import for treatment, etc. by doctors, etc.: Invoice（B01） and Delivery Ticket（B02） Healthcare Professional's License（B05）

					Attachment for Import Confirmation Application（B06） (only in the case of thalidomide formulation, etc.) Consent Form（B10） (only in the case of import of products which use human-derived or animal-derived ingredients or innovative pharmaceuticals) Import for trials and research: Invoice（B01） and Delivery Ticket（B02） Medical License or Certificate of Enrollment（B05） (excluding corporate applicants)
4	*	Attachment File Name	String	100	

File Item Specifications_Trials and Research Plan Information[A05]

No.	Required	Item Name	Format	Digits	Settings
1	x	Application Unit	String	8	
2	x	Data Type	String	3	A05: Trials and Research Plan Information
3	x	Client for Trials Name	String	80	* Required if the application type is "03: Import for Trials and Research"
4	x	Client for Trials_Address	String	60	* Required if the application type is "03: Import for Trials and Research"
5	x	Trials and Research Place_ Address	String	60	* Required if the application type is "03: Import for Trials and Research"
6	x	Trials and Research Place_Name	String	60	* Required if the application type is "03: Import for Trials and Research"
7	x	Chief Worker Name	String	50	* Required if the application type is "03: Import for Trials and Research"
8	x	Trials and Research_Summary	String	998	* Required if the application type is "03: Import for Trials and Research"
9		Note	String	400	

Country of Origin

Code	Country Name	Code	Country Name	Code	Country Name	Code	Country Name
AD	ANDORRA	DZ	ALGERIA	LB	LEBANON	RS	SERBIA
AE	UNITED ARAB EMIRATES	EC	ECUADOR	LC	SAINT LUCIA	RU	RUSSIAN FEDERATION
AF	AFGHANISTAN	EE	ESTONIA	LI	LIECHTENSTEIN	RW	RWANDA

Code	Country Name	Code	Country Name	Code	Country Name	Code	Country Name
AG	ANTIGUA AND BARBUDA	EG	EGYPT	LK	SRI LANKA	SA	SAUDI ARABIA
AI	ANGUILLA	EH	WEST SAHARA	LR	LIBERIA	SB	SOLOMON ISLANDS
AL	ALBANIA	ER	ERITREA	LS	LESOTHO	SC	SEYCHELLES
AM	REPUBLIC OF ARMENIA	ES	SPAIN	LT	LITHUANIA	SD	SUDAN
AN	NETHERLANDS ANTILLES	ET	ETHIOPIA	LU	LUXEMBOURG	SE	SWEDEN
AO	ANGOLA	FI	FINLAND	LV	LATVIA	SG	SINGAPORE
AP	AZORES	FJ	FIJI	LY	LYBIAN ARAB JAMAHIRIYA	SH	ST.HELENA
AR	ARGENTINA	FK	FALKLAND ISLANDS	MA	MOROCCO	SI	SLOVENIA
AS	AMERICAN SAMOA	FM	MICRONESIA	MC	MONACO	SJ	SVALBARD AND JAN MAYEN
AT	AUSTRIA	FO	FAROE ISLANDS	MD	REPUBLIC OF MOLDOVA	SK	SLOVAK
AU	AUSTRALIA	FR	FRANCE	ME	MONTENEGRO	SL	SIERRA LEONE
AW	ARUBA	GA	GABON	MG	MADAGASCAR	SM	SAN MARINO
AZ	AZERBAIDJAN REPUBLIC	GB	UNITED KINGDOM	MH	MARSHALL ISLANDS	SN	SENEGAL
BA	BOSNIA HERCEGOVINA	GD	GRENADA	MK	NORTH MACEDONIA	SO	SOMALIA
BB	BARBADOS	GE	GEORGIA	ML	MALI	SR	SURINAME
BD	BANGLADESH	GF	FRENCH GUIANA	MM	UNION OF MYANMAR	SS	SOUTH SUDAN
BE	BELGIUM	GH	GHANA	MN	MONGOLIA	ST	SAO TOME AND PRINCIPE
BF	BURKINA FASO	GI	GIBRALTAR	MO	MACAU	SV	EL SALVADOR
BG	BULGARIA	GL	GREENLAND	MP	NORTH MARIANA IS.	SY	SYRIAN ARAB REPUBLIC
BH	BAHRAIN	GM	GAMBIA	MQ	MARTINIQUE	SZ	ESWATINI
BI	BURUNDI	GN	GUINEA	MR	MAURITANIA	TC	TURKS AND CAICOS ISLANDS
BJ	BENIN	GP	GUADELOUPE	MS	MONTSERRAT	TD	CHAD
BL	SAINT BARTHELEMY	GQ	EQUATORIAL GUINEA	MT	MALTA	TG	TOGO
BM	BERMUDA	GR	GREECE	MU	MAURITIUS	TH	THAILAND

Code	Country Name	Code	Country Name	Code	Country Name	Code	Country Name
BN	BRUNEI DARUSSALAM	GS	S.GEORGIA & S.SANDWICH ISLANDS	MV	MALDIVES	TJ	REPUBLIC OF TADZHIKISTAN
BO	BOLIVIA	GT	GUATEMALA	MW	MALAWI	TK	TOKELAU ISLANDS
BQ	BRITISH ANTARCTIC TERRITORY	GU	GUAM	MX	MEXICO	TL	TIMOR-LESTE
BR	BRAZIL	GW	GUINEA-BISSAU	MY	MALAYSIA	TM	TURKMENISTAN
BS	BAHAMAS	GY	GUYANA	MZ	MOZAMBIQUE	TN	TUNISIA
BT	BHUTAN	HK	HONG KONG	NA	NAMIBIA	TO	TONGA
BW	BOTSWANA	HN	HONDURAS	NC	NEW CALEDONIA	TP	EAST TIMOR
BY	REPUBLIC OF BELARUS	HR	CROATIA	NE	NIGER	TR	TURKEY
BZ	BELIZE	HT	HAITI	NF	NORFOLK ISLAND	TT	TRINIDAD AND TOBAGO
CA	CANADA	HU	HUNGARY	NG	NIGERIA	TV	TUVALU
CC	COCOS ISLANDS	ID	INDONESIA	NI	NICARAGUA	TW	TAIWAN PROVINCE OF CHINA
CD	ROCONGO	IE	IRELAND	NL	NETHERLANDS	TZ	TANZANIA,UNITED REPUBLIC OF
CE	CEUTA AND MELILLA	IL	ISRAEL	NO	NORWAY	UA	UKRAINE
CF	CENTRAL AFRICAN REPUBLIC	IN	INDIA	NP	NEPAL	UG	UGANDA
CG	CONGO	IO	BRITISH INDIAN OCEAN TERRITORI	NR	NAURU	UM	AMERICAN OCEANIA
CH	SWITZERLAND	IQ	IRAQ	NU	NIUE	US	UNITED STATES
CI	COTE D'IVOIRE	IR	IRAN,ISLAMIC REPUBLIC OF	NZ	NEW ZEALAND	UY	URUGUAY
CK	COOK	IS	ICELAND	OM	OMAN	UZ	REPUBLIC OF UZBEKISTAN
CL	CHILE	IT	ITALY	PA	PANAMA	VA	VATICAN CITY
CM	CAMEROON	JM	JAMAICA	PE	PERU	VC	SAINT VINCENT & THE GRENADINES
CN	CHINA	JO	JORDAN	PF	FRENCH POLYNESIA	VE	VENEZUELA

Code	Country Name	Code	Country Name	Code	Country Name	Code	Country Name
CO	COLOMBIA	JP	JAPAN	PG	PAPUA NEW GUINEA	VG	BRITISH VIRGIN ISLANDS
CR	COSTA RICA	KE	KENYA	PH	PHILIPPINES	VI	UNITED STATES VIRGIN ISLANDS
CS	CANARY ISLANDS	KG	KYRGYZ	PK	PAKISTAN	VN	VIET NAM
CU	CUBA	KH	CAMBODIA	PL	POLAND	VU	VANUATU
CV	CAPE VERDE	KI	KIRIBATI	PM	ST.PIERRE AND MIQUELON	WF	WALLIS AND FUTUNA ISLANDS
CX	CHRISTMAS ISLANDS	KM	COMOROS	PN	PITCAIRN	WG	THE WEST BANK AND GAZA
CY	CYPRUS	KN	ST.KITTS-NEVIS	PR	PUERTO RICO	WS	SAMOA
CZ	THE CZECH REPUBLIC	KP	KOREA DEMOCRATIC PEOPLE'S REPUBLIC OF	PT	PORTUGAL	YE	YEMEN
DE	GERMANY	KR	KOREA REPUBLIC OF	PW	PALAU	YT	MAYOTTE
DJ	DJIBOUTI	KW	KUWAIT	PY	PARAGUAY	ZA	SOUTH AFRICA
DK	DENMARK	KY	CAYMAN ISLANDS	QA	QATAR	ZM	ZAMBIA
DM	DOMINICA	KZ	KAZAKHSTAN	RE	REUNION	ZW	ZIMBABWE
DO	DOMINICAN REPUBLIC	LA	LAO PEOPLE'S DEMOCRATIC REPUBLIC	RO	ROMANIA	ZZ	UNKNOWN

2.4 Refer to the Status

2.4.1 Search Import Confirmation Applications

This is a function for an applicant to search import confirmation applications.

(1) Open the Refer to the Status screen

Click “Refer to Application Status” on the Home screen.

<Home Screen/Applicant>

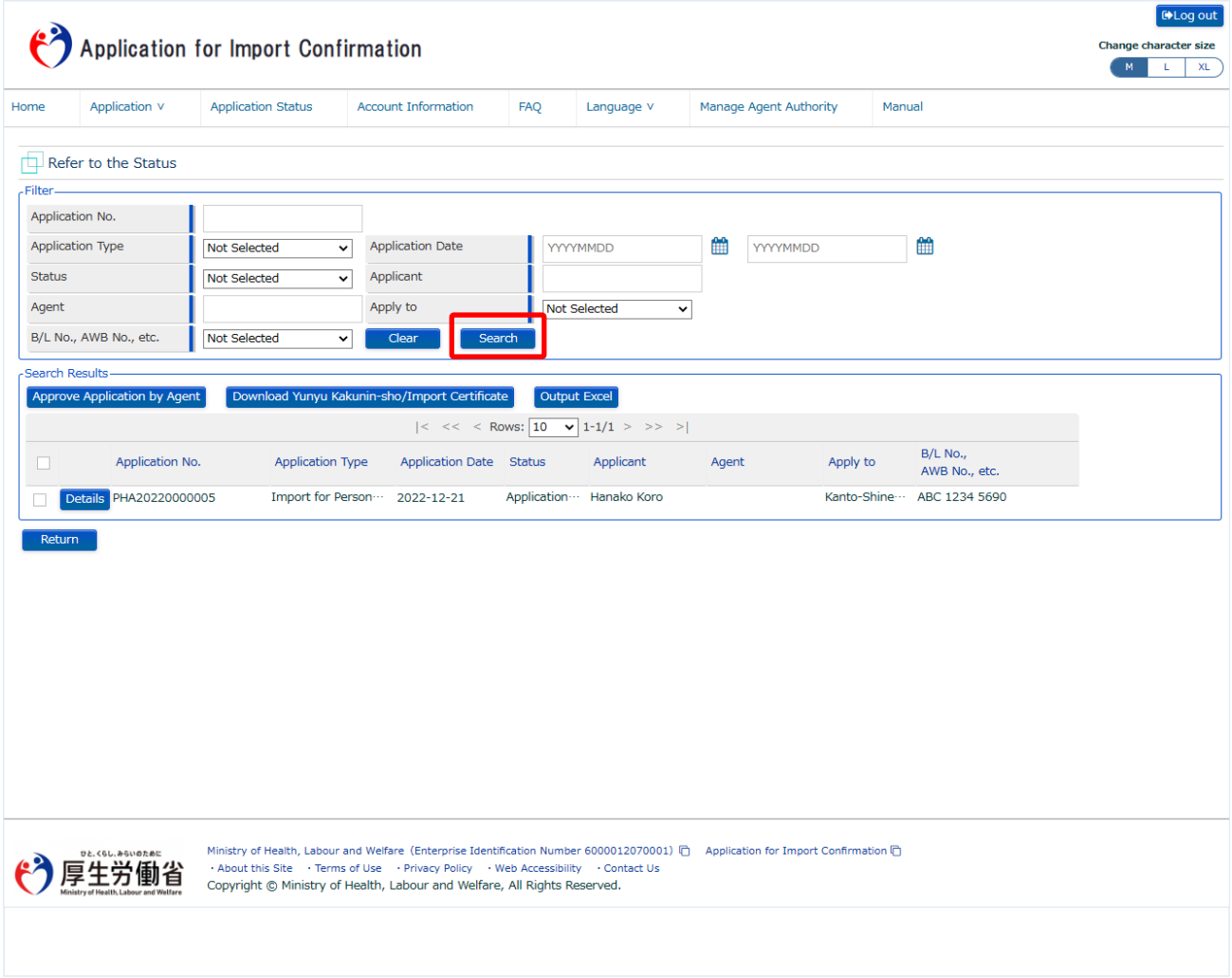


(2) Search import confirmation applications

The screen to search import confirmation applications is displayed.

When you filter and click “Search,” a list of import confirmation applications that match the search conditions is displayed in Search Results.

<Refer to the Status>



[Filter]

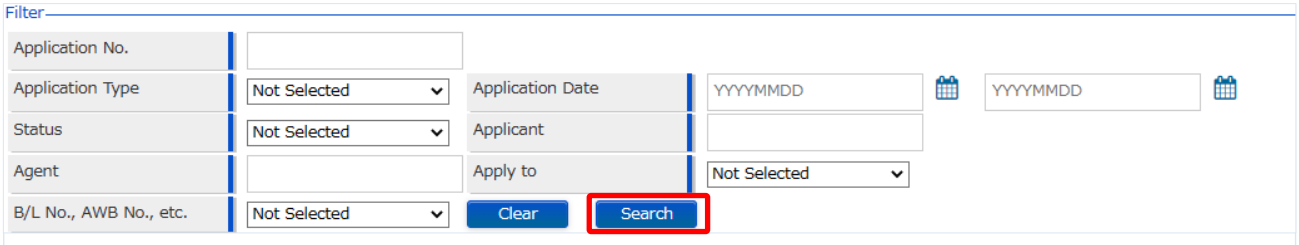
When you enter search conditions in Filter and click “Search,” you can narrow the target.

Enter an application No. of the search target application in “Application No.”
Select an application type of the search target application from the “Application Type” pull-down.
Enter a period of the application date for the search target application with a start date of the application in the left field and an end date in the right field of “Application Date.”
Select a status of the search target application from the “Status” pull-down.

- Have not applied: Status before the application
- Application in process: Status after the application
- Confirming: Status of the application being reviewed and confirmed
- Waiting for issuance: Status of waiting for issuance of the Yunyu Kakunin-sho/Import Certificate
- Processing for issuance: Status of issuing the Yunyu Kakunin-sho/Import Certificate
- Issued: Status that the Yunyu Kakunin-sho/Import Certificate has been issued
- Withdrawn: Status that the application has been withdrawn
- Returned: Status that the application has been returned
- Rejected: Status that the application has been rejected
- Waiting for agent approval: Status of waiting for agent approval

Enter the applicant name of the search target application in “Applicant.”
Enter the agent name of the search target application in “Agent.”
Select the application destination of the search target application from the “Apply to” pull-down.
Select the B/L No., AWB No., etc. of the search target application from the “B/L No., AWB No., etc.” pull-down.

When the entry of search conditions is complete, click “Search.”
To clear search conditions, click “Clear.”



The search results that match the search conditions are displayed in the “Search Results” list.

2.4.2 View Import Confirmation Applications

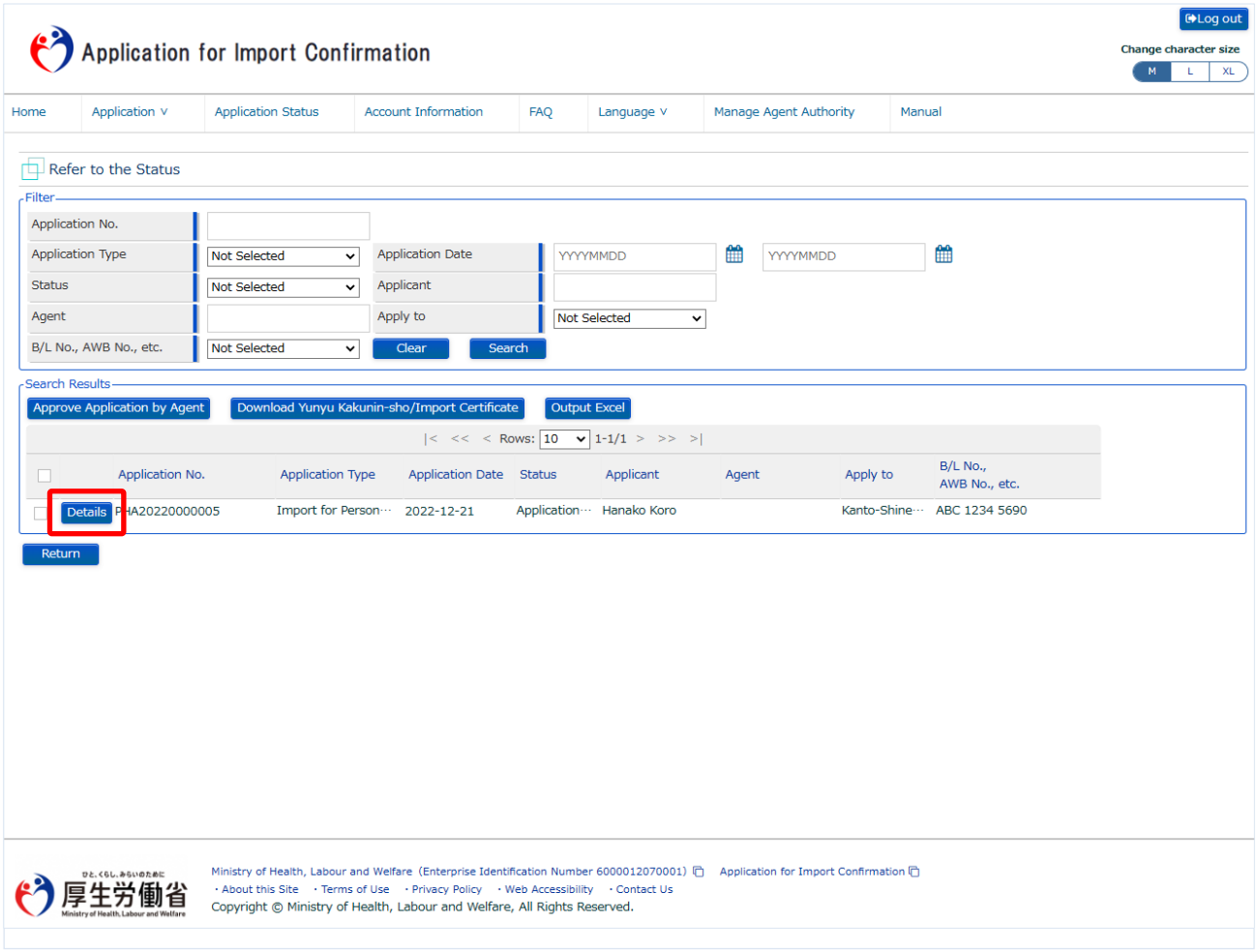
This is a function for an applicant to view the contents of an import confirmation application.

(1) Select an import confirmation application to view

Open the Refer to the Status screen.

Click “Details” of the application to view from the Search Results list.

<Refer to the Status>

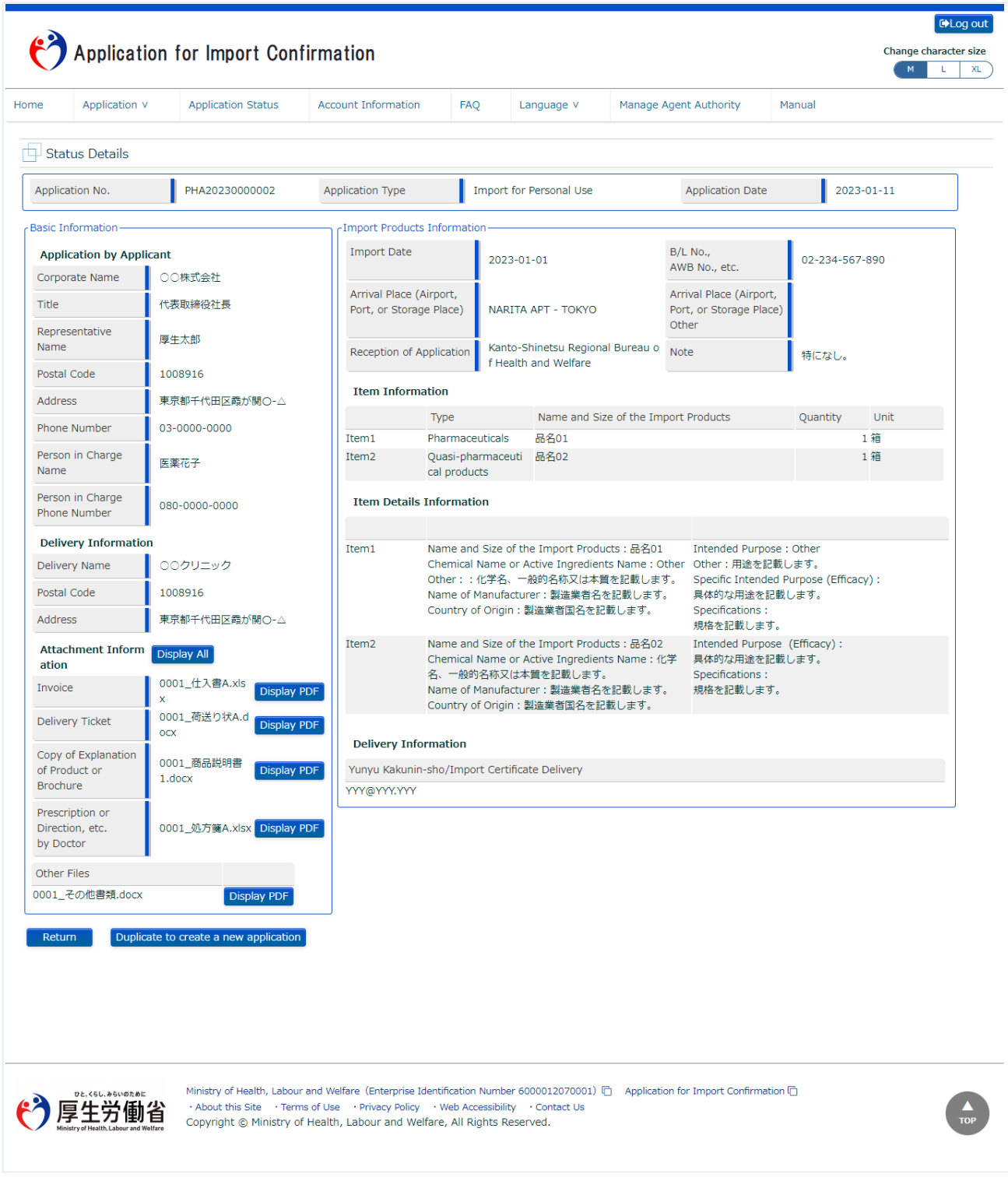


(2) View the import confirmation application

The Status Details screen of the selected import confirmation application is displayed.

View the displayed Status Details screen.

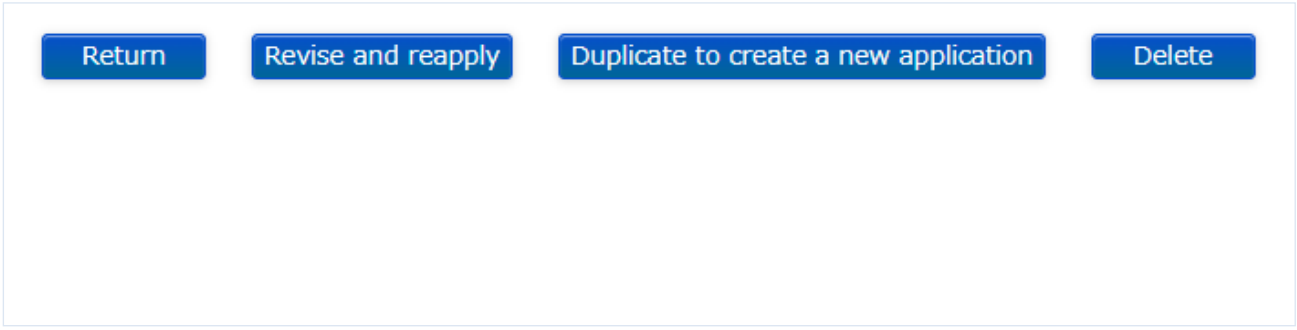
<Status Details/Import for Personal Use>



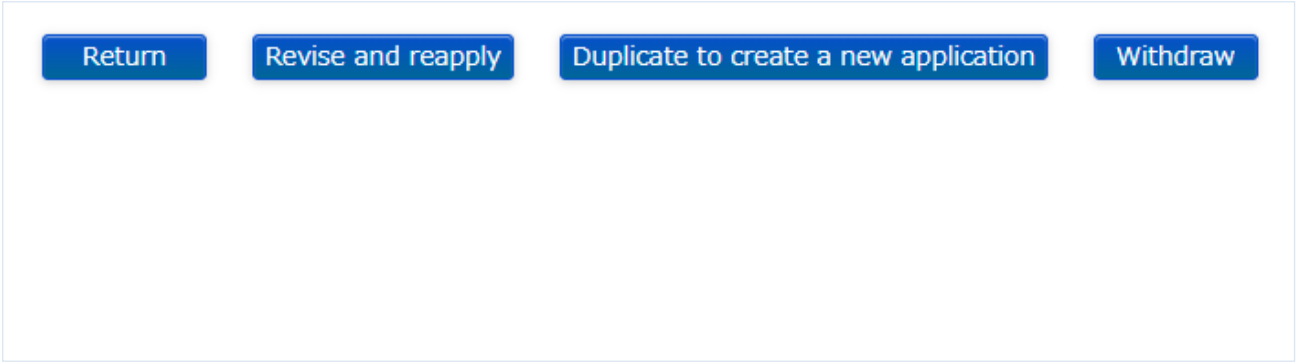
The following buttons will be displayed depending on the status of the import confirmation application.

To delete an import confirmation application, click “Delete” and delete the application. To edit or withdraw an import confirmation application, refer to “2.4.3 Edit or Withdraw Import Confirmation Applications.”
*Delete: Delete the data before the application is finalized.
Withdraw: Button to withdraw an application after the application has been finalized or an correction request has been received from the Health and Welfare Bureau.
To duplicate for import confirmation, refer to “2.4.7 Duplicate Import Confirmation Application.”

<Import Confirmation Application Status “Have not applied”>



<Import Confirmation Application Status “Application in process” or “Returned“>



2.4.3 Edit or Withdraw an Import Confirmation Application

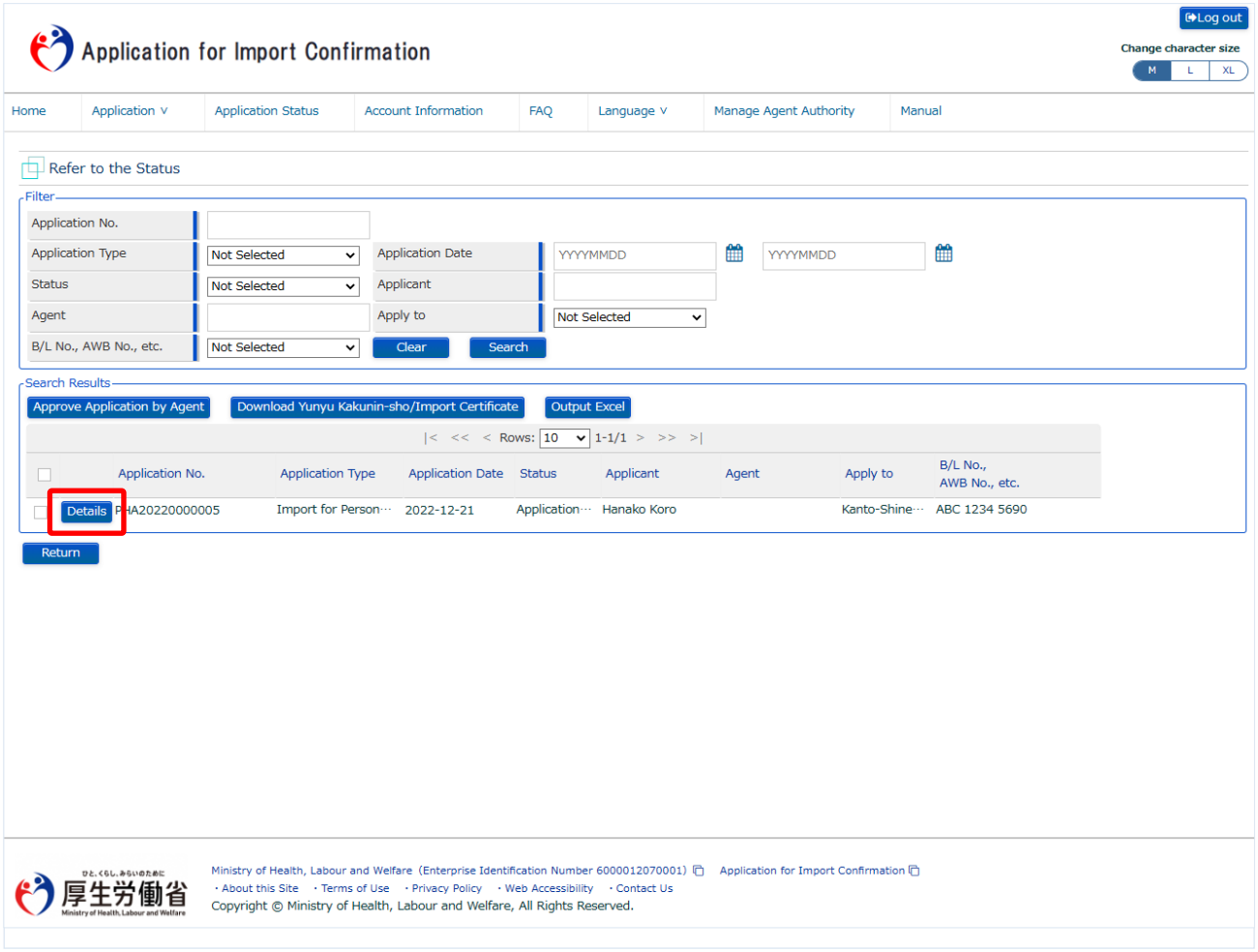
This is a function for an applicant to edit or withdraw an import confirmation application.

(1) Select an import confirmation application to edit or withdraw

Open the Refer to the Status screen.

Click “Details” of the application to edit or withdraw from the Search Results list.

<Refer to the Status>



(2) Edit an import confirmation application

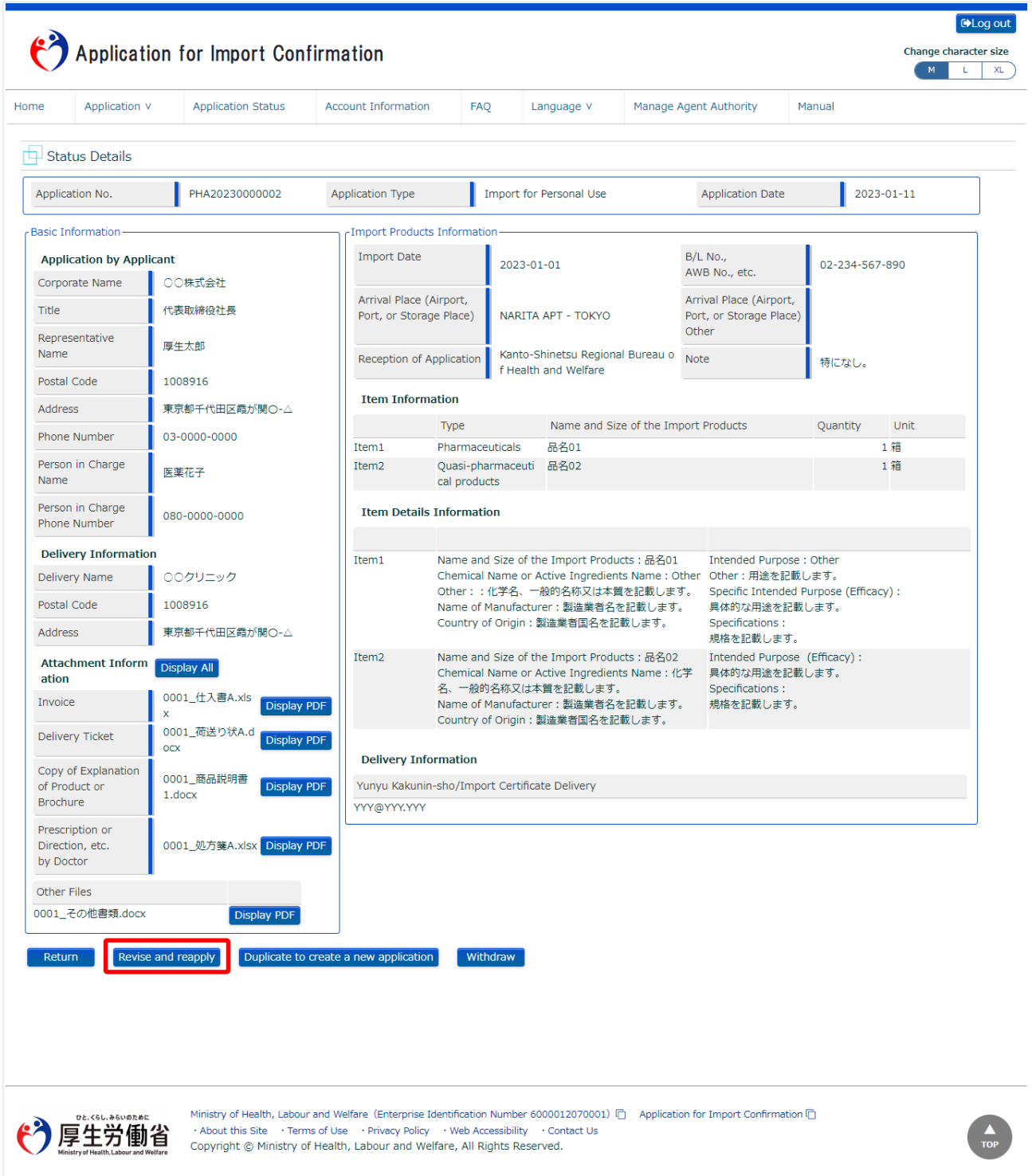
Edit an import confirmation application on the Status Details screen.

When the application status is “Application in process” or “Returned,” “Revise and reapply” is displayed.

To edit the application, click “Revise and reapply.” The screen to edit the application is displayed.

Refer to the explanation of “2.2 Import Confirmation Application” for how to enter further information.

<Status Details/Import for Personal Use>



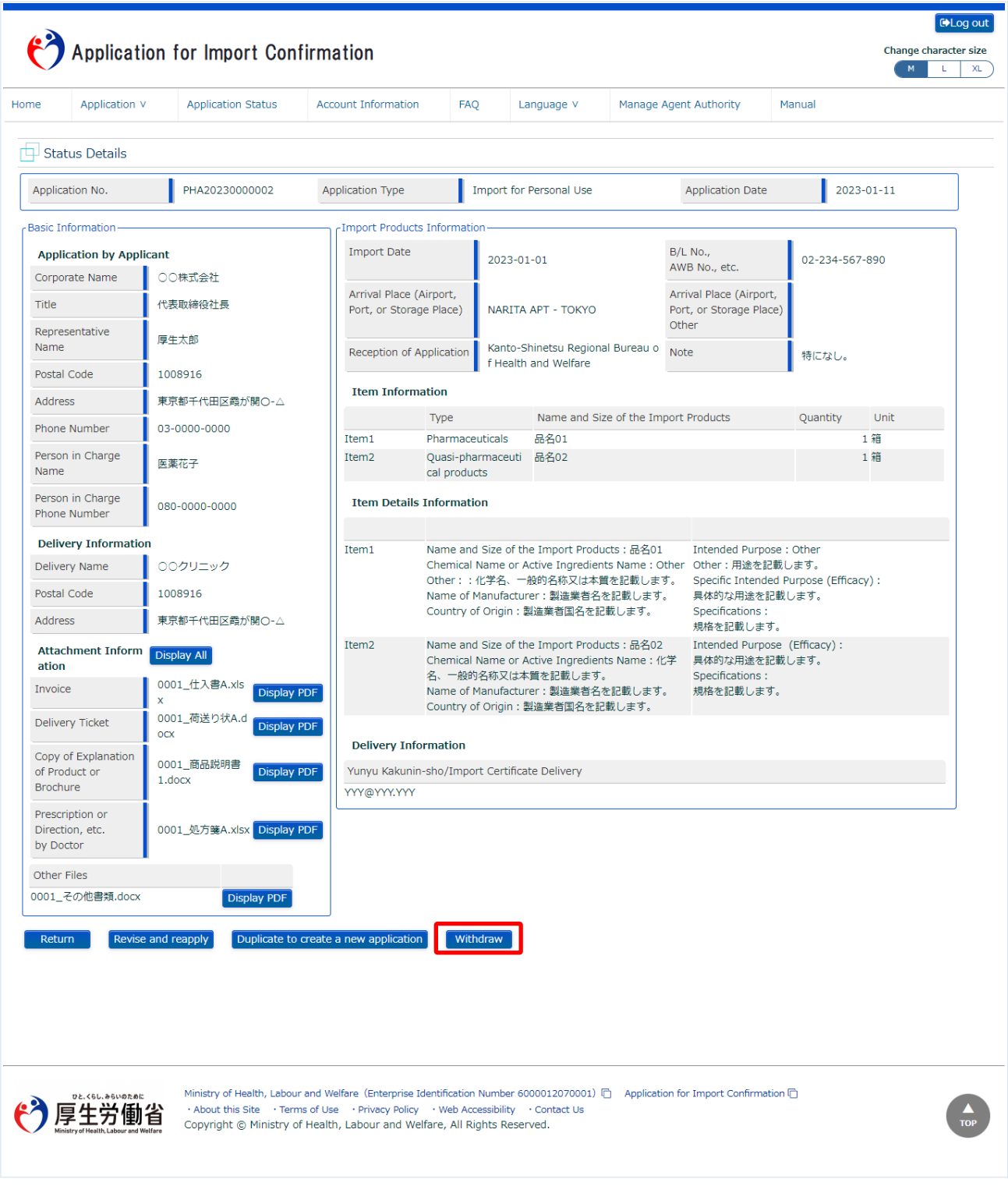
(3) Withdraw an import confirmation application

Withdraw an import confirmation application on the Status Details screen.

When the application status is “Application in process” or “Returned,” “Withdraw” is displayed.

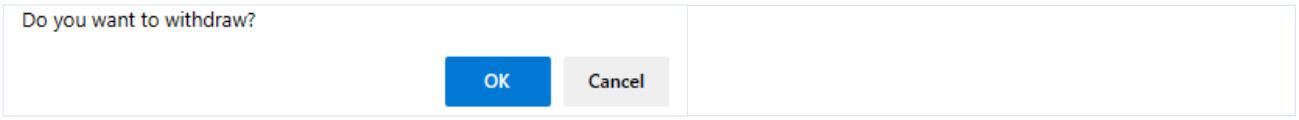
To withdraw the import confirmation application, click “Withdraw.”

<Enter Application Basic Information/Import for Personal Use >



When the confirmation dialog is displayed, confirm it, and click OK.

<Confirmation Dialog>



*If another user updates the same data and the following message is displayed, return to the Home screen and try again.

<Error Message>



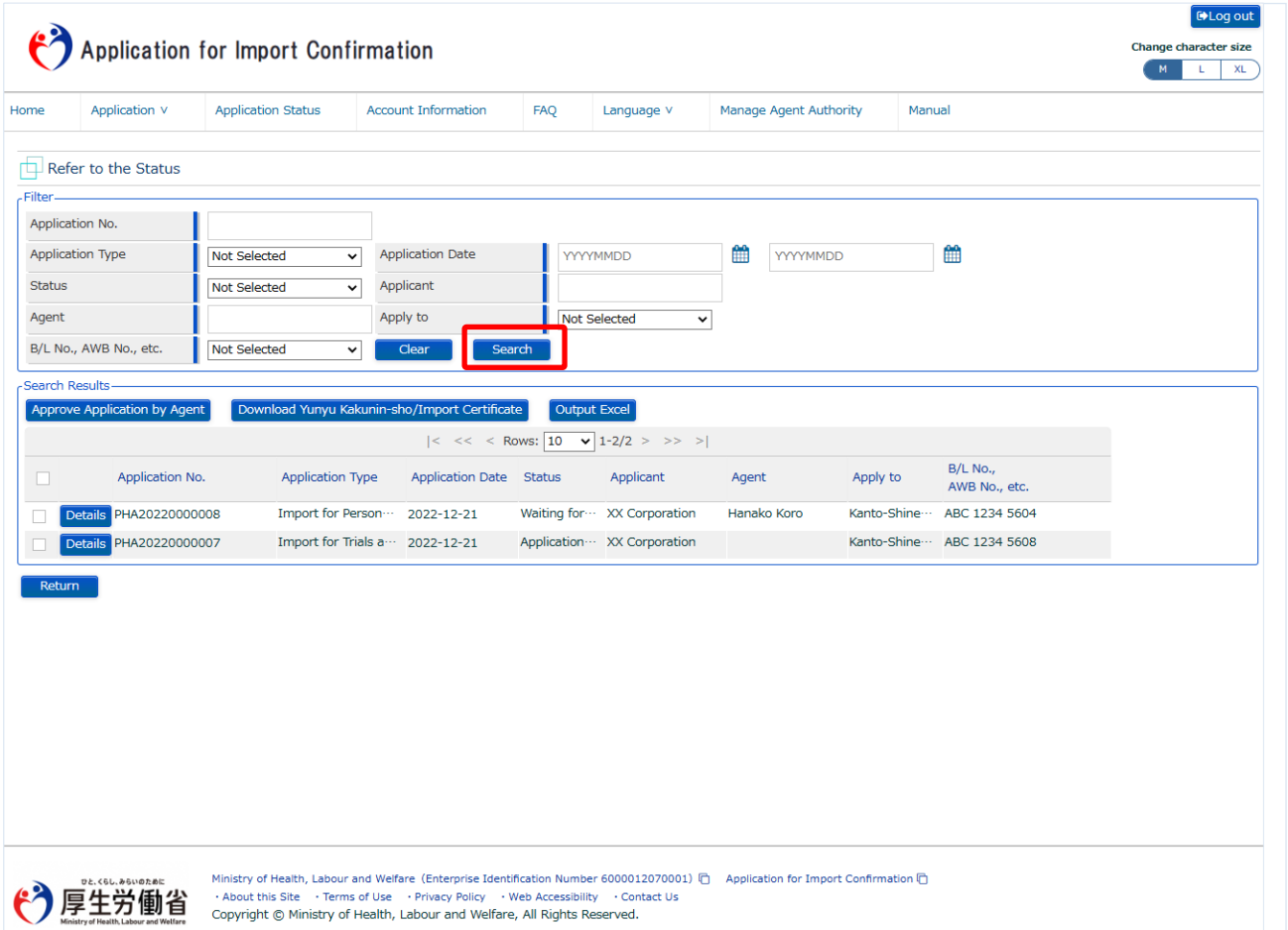
2.4.4 Approve Application by Agent

This is a function for an applicant to approve an import confirmation application by an agent.
If an agent has not been set or the validity period has expired for applications by the agent, approval by the applicant himself/herself is required.

(1) Search import confirmation applications by an agent to approve

Open the Refer to the Status screen.
Applications in “Waiting for agent approval” status are targets for application by an agent.
To search applications with “Waiting for agent approval” status, select “Waiting for agent approval“ from the “Status” pull-down in Filter and click “Search.”

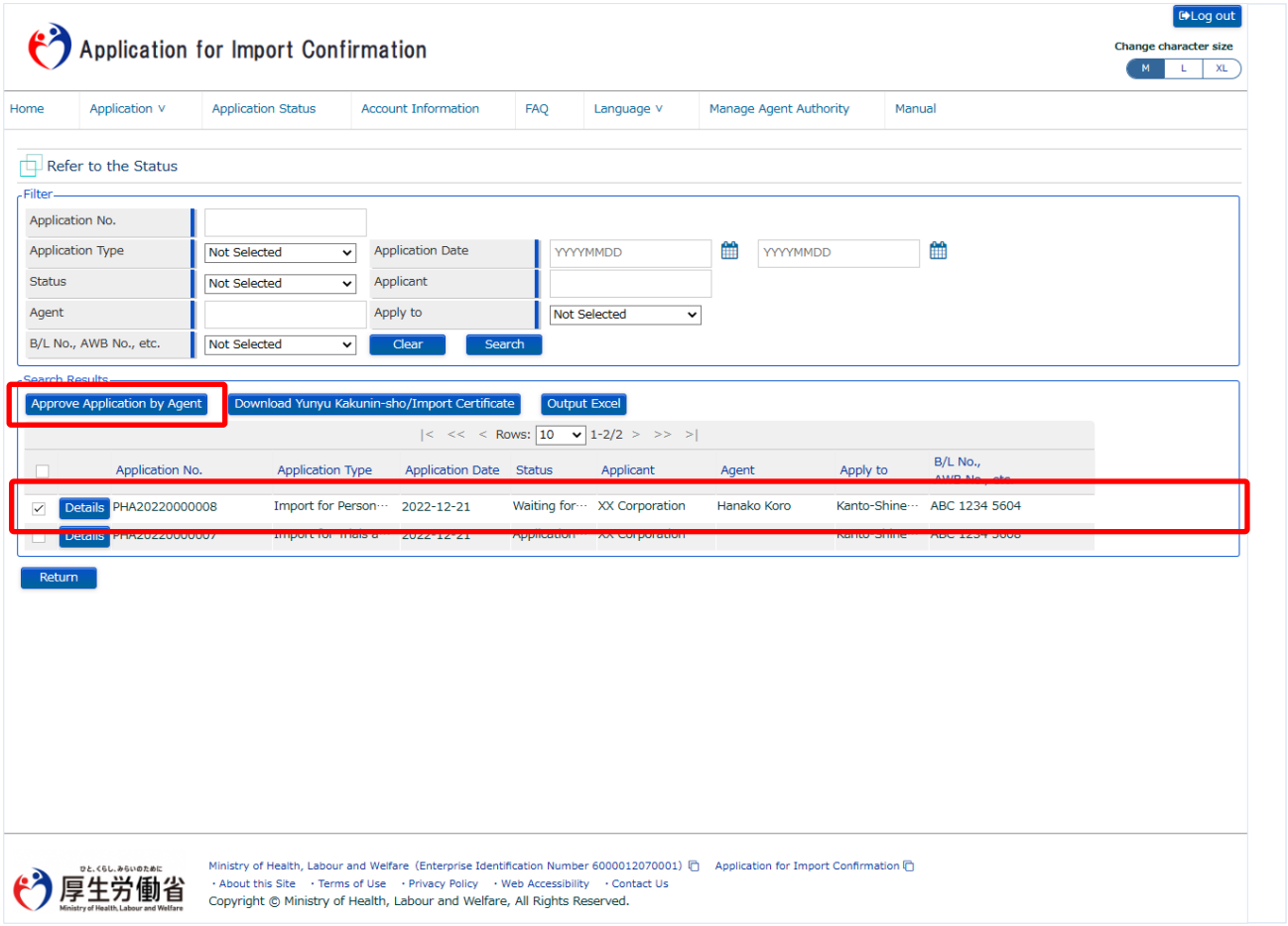
<Refer to the Status>



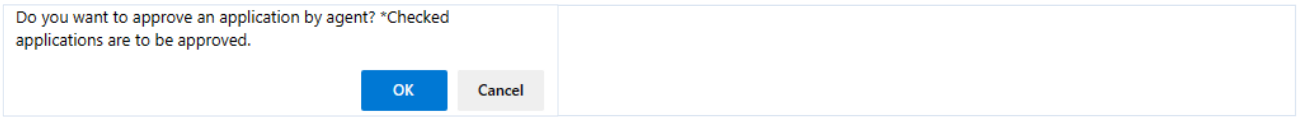
(2) Approve import confirmation applications by an agent

Check the applications in “Waiting for agent approval” status and click “Approve Application by Agent.” When the confirmation dialog is displayed, confirm it, and click OK.

<Refer to the Status>



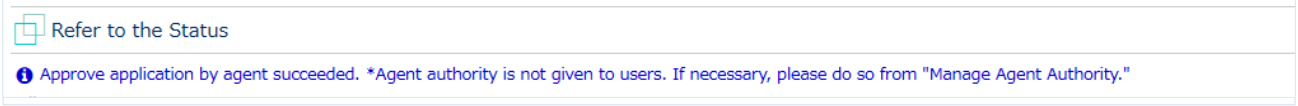
<Confirmation Dialog>



When application by an agent is approved, a completion message is displayed and the application status becomes “Application in process.”

If it is not approved, an application will not be made and the status will remain “Waiting for agent approval.”

<Completion Message>



2.4.5 Download a Yunyu Kakunin-sho/Import Certificate

This is a function for an applicant to download a Yunyu Kakunin-sho/Import Certificate.

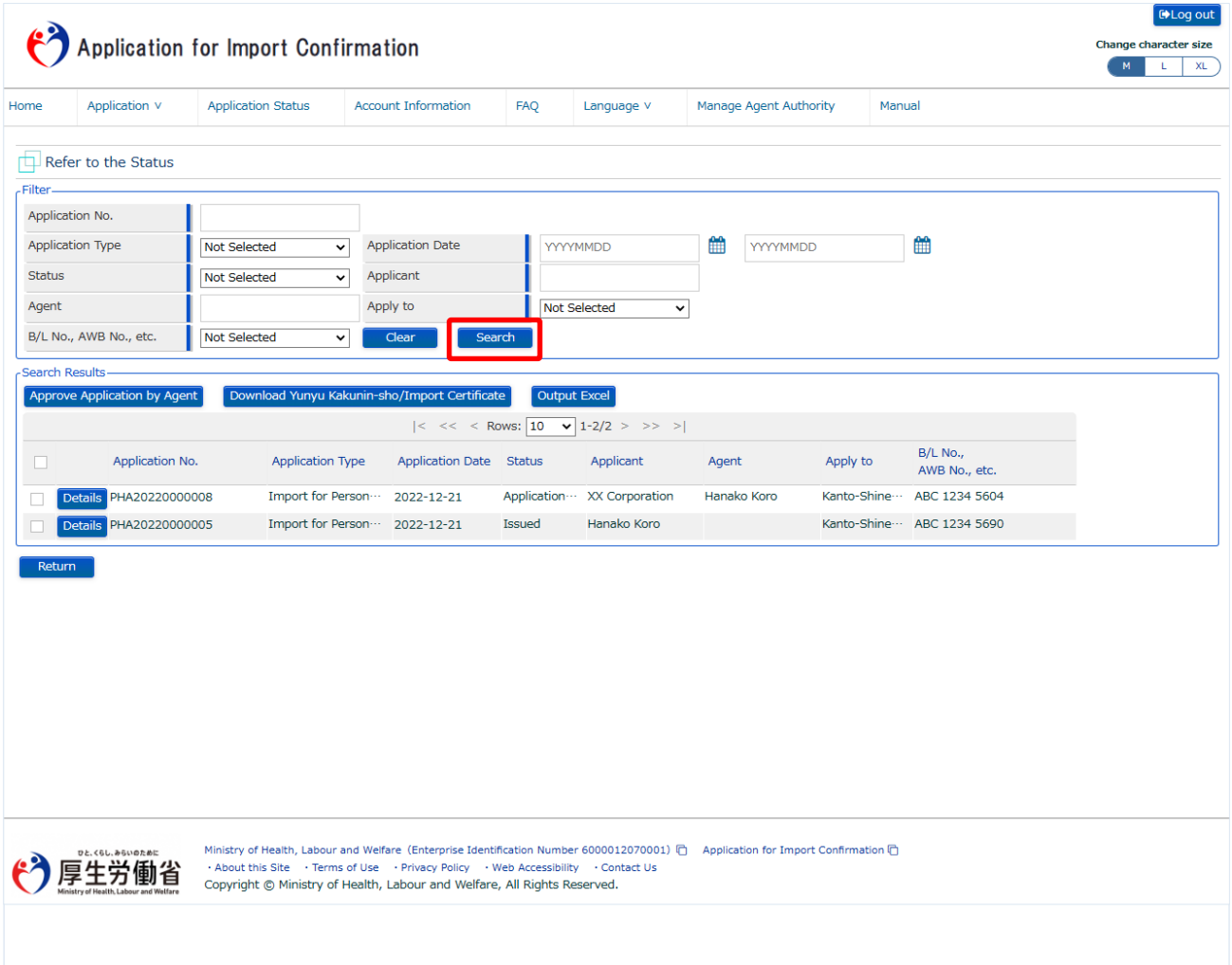
(1) Search import confirmation applications to download a Yunyu Kakunin-sho/Import Certificate

Open the Refer to the Status screen.

The status of an import confirmation application for which a Yunyu Kakunin-sho/Import Certificate is to be downloaded is “Issued.”

To search applications with “Issued” status, select “Issued” from the “Status” pull-down of Filter and click “Search.”

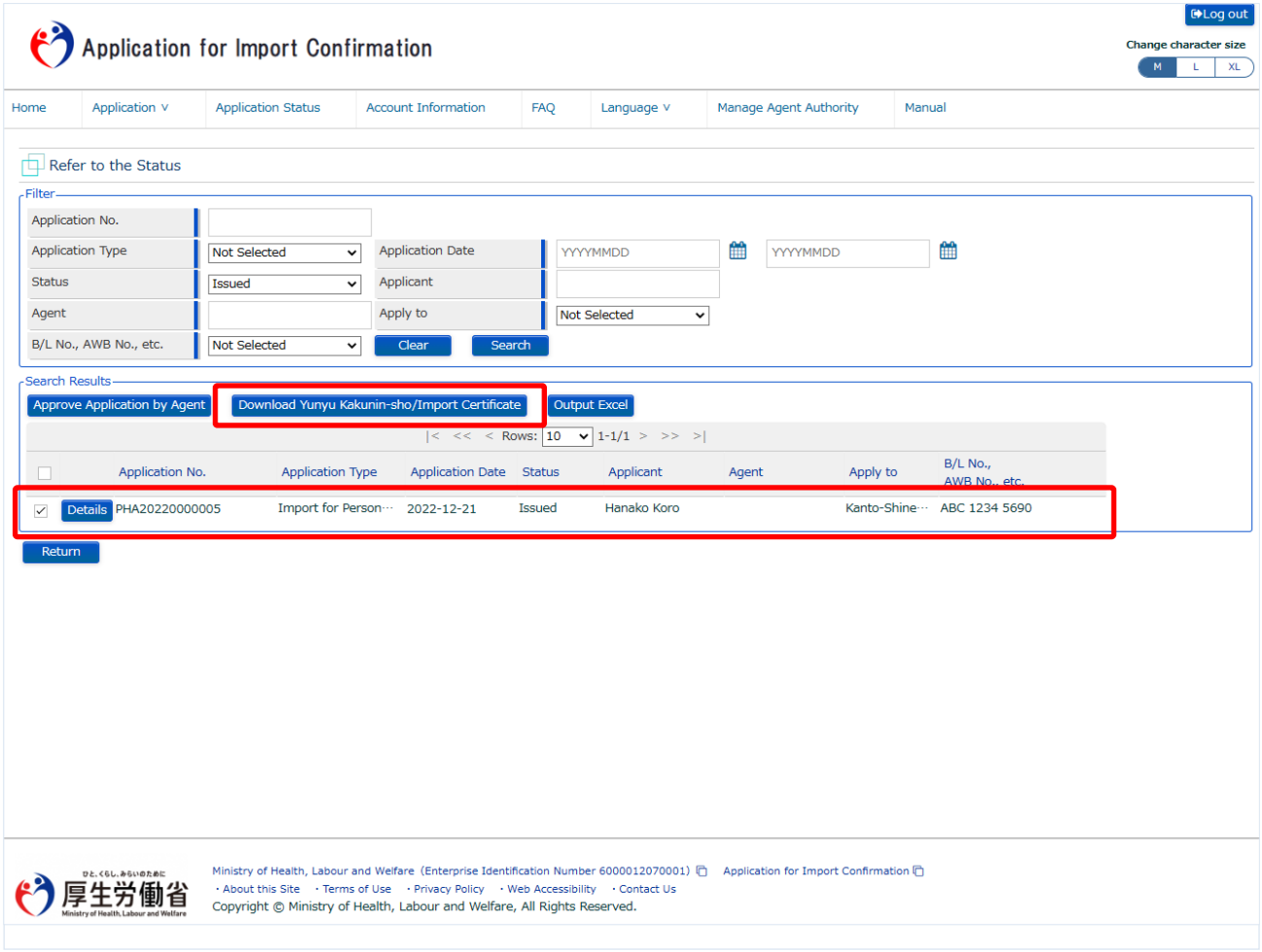
<Refer to the Status>



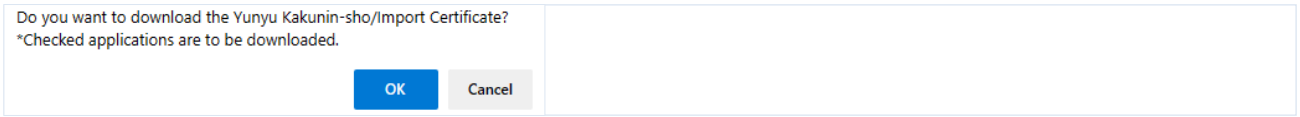
(2) Download the Yunyu Kakunin-sho/Import Certificate

Check the applications with “Issued” status and click “Download Yunyu Kakunin-sho/Import Certificate.” When the confirmation dialog is displayed, confirm it, and click OK.

<Refer to the Status>



<Confirmation Dialog>



Confirm that Yunyu Kakunin-sho/Import Certificate downloading has completed and the ZIP file has been downloaded.

Confirm that the ZIP file includes the PDF file of the Yunyu Kakunin-sho/Import Certificate.

＜PDF of Yunyu Kakunin-sho/Import Certificate＞

様式第九十七の三（第二百十八条の二の二関係）

医　　薬　　品　　輸入　　確認申請書

品　　名	数　　量	業許可等の有無及びその種類
Name and Size of the Import Products	1.00Box	

輸入の目的	①治験(企業)用、　②臨床試験(医師)用、　③試験研究・社内見本用、　④展示用、　⑤個人用、 ⑥医療従事者個人用、　⑦再輸入品・返送品用、　⑧その他（　　）
誓約事項	☑ 上記輸入の目的のために使用するもので、他に販売、貸与又は授与するものではありません。 ☑ 当該輸入に係る必要な調査、指導、情報の収集、意見の聴取その他必要な協力を行います。 ☑ 医薬品等の輸入に関して厚生労働省等から提供される情報を輸入する前及び輸入した後に確認するよう努めます。
確認事項	☑ 過去二年以内に薬事に関する法令で政令で定めるもの又はこれに基づく処分に違反したことはありません。

輸入しようとする品目の製造業者名及び国名

（製造業者名）　Name of Manufacturer　　（国名）　Country of Origin

輸入年月日	船荷証券、航空運送状等の番号	到着空港、到着港又は蔵置場所
2022年08月16日	ABC 1234 5673	成田国際空港

当該申請に関する手続きを申請者に代わつて行うものがいる場合	氏名	
	住所	
	連絡先	
	確認事項	□ 過去二年以内に薬事に関する法令で政令で定めるもの又はこれに基づく処分に違反したことはありません。

備考	
確認欄	特記事項 2022年12月08日　Y0001179900 厚生労働大臣（関東信越厚生局長）　㊞

上記により、医　　薬　　品の輸入に係る確認を申請します。

住所　TokyoChiyoda-ku KasumigasekiX-Y

連絡先　03-0000-0000

氏名　Hanako Koro

2022年12月08日

（送付先の名称）　XX Clinic

（送付先の住所）　TokyoChiyoda-ku KasumigasekiX-Y

（送付先の連絡先）　03-0000-0000

厚生労働大臣 (関東信越厚生局長)　殿

2.4.6 Download Application Status List

An applicant can download the data of an application status list from a search as an Excel file.

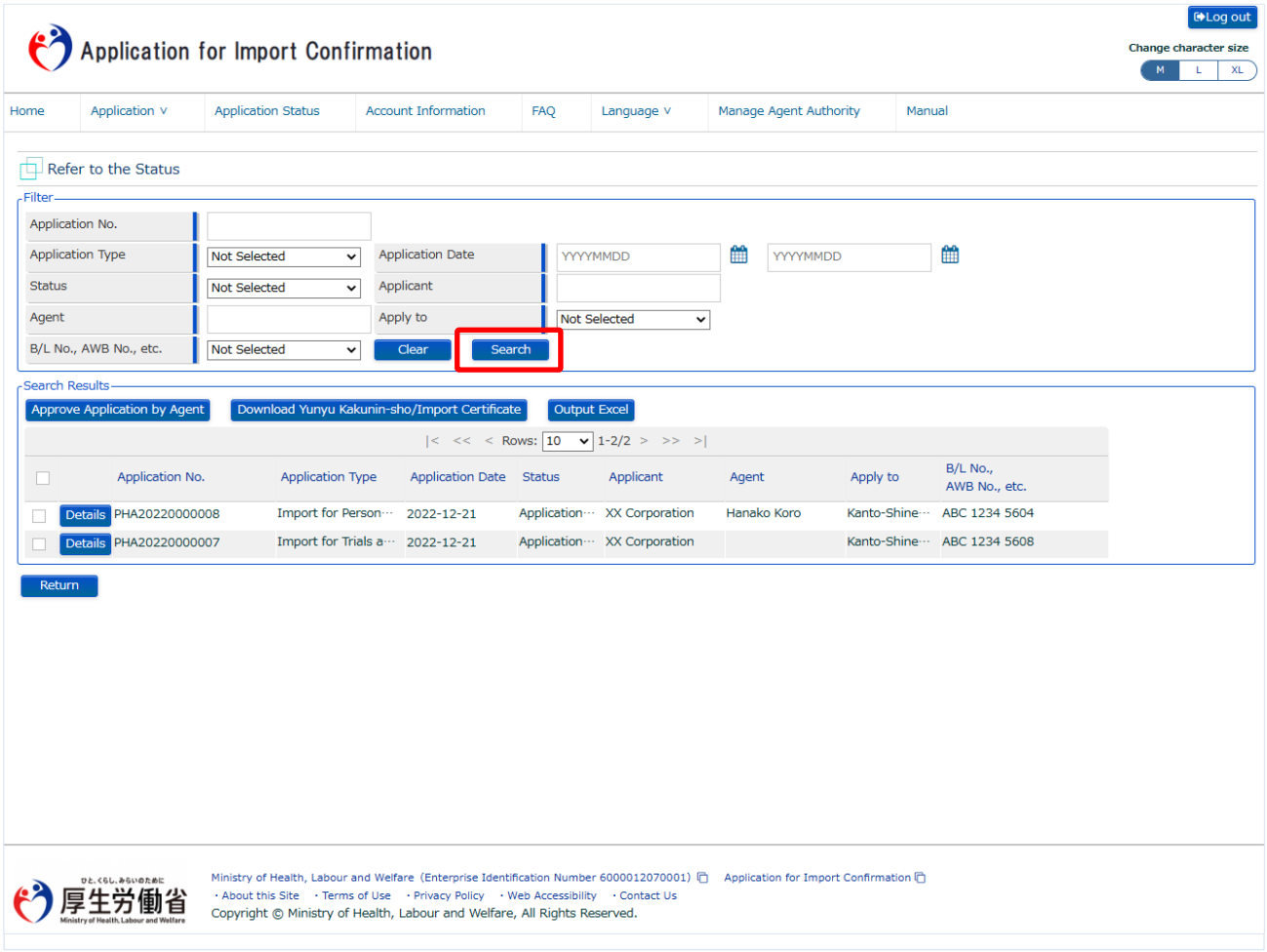
(1) Search for import confirmation applications to download

Open the Refer to the Status screen.

The applications displayed as Search Results are to be downloaded.

To filter, enter search conditions and click “Search.”

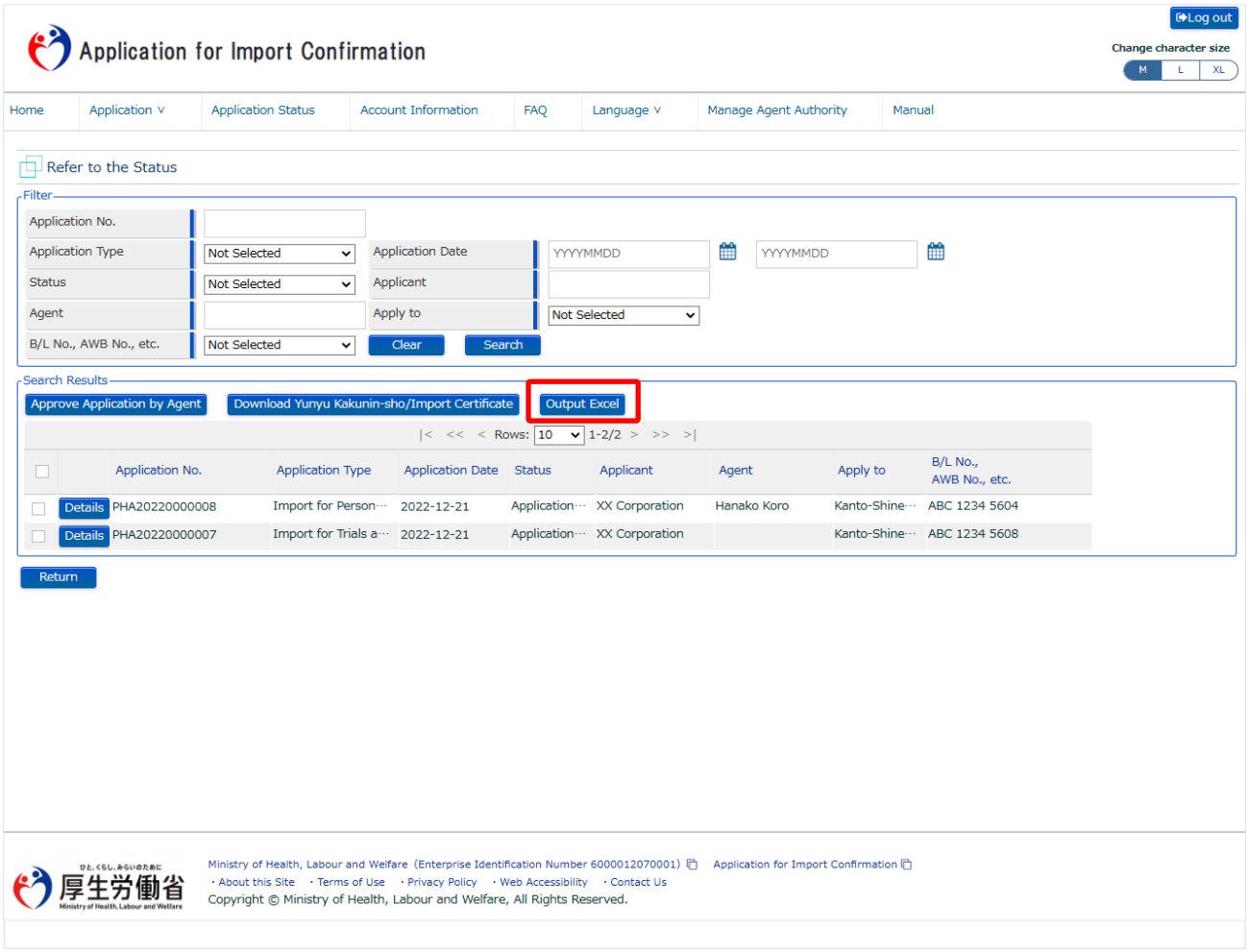
<Refer to the Status>



(2) Download the application status list

After displaying the search target applications in Search Results, click “Output Excel.”
When the confirmation dialog is displayed, confirm it, and click OK.

<Refer to the Status>



<Confirmation Dialog>



Confirm that output of the application status list as an Excel file has completed and has been downloaded.
*If an application has multiple items, the information of the application is downloaded as multiple rows of information.

<Multiple Items>

Application No.	Application Type	Application Status	Application Date	Import Date	B/L No., AWB No., etc.	Arrival Place (Airport, Port, or Storage Place)	Item ID	Item Type	Name and Size of the Import Products	Quantity	Unit
PHA20220000007	Import for Trials and Research	Application in process	2022/12/21	2022/8/16	ABC 1234 5608	NARITA APT - TOKYO	1	Pharmaceuticals	Name and Size of the Import Products	1.0	EA
PHA20220000007	Import for Trials and Research	Application in process	2022/12/21	2022/8/16	ABC 1234 5608	NARITA APT - TOKYO	2	Quasi-pharmaceutical products	Name and Size of the Import Products	1.0	EA
PHA20220000008	Import for Personal Use	Application in process	2022/12/21	2022/8/16	ABC 1234 5604	NARITA APT - TOKYO	1	Pharmaceuticals	Name and Size of the Import Products	1.0	EA

2.4.7 Duplicate Import Confirmation Application

This is a function for an applicant to reuse existing application information to apply.

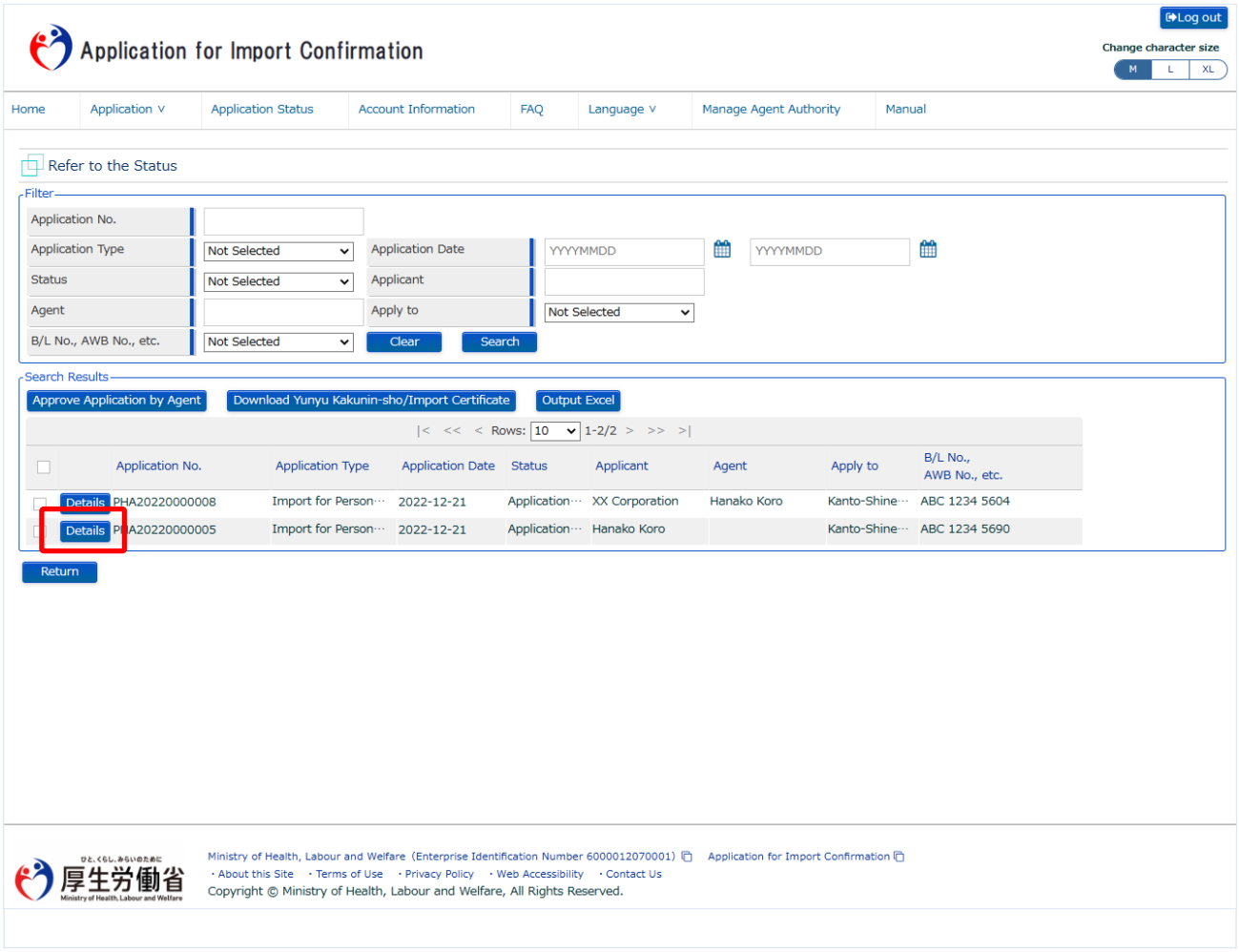
If you want to use past application information for a new application, use the duplication function.

(1) Select an import confirmation application to duplicate

Open the Refer to the Status screen.

Click “Details” of the application to duplicate from the Search Results list.

<Refer to the Status>

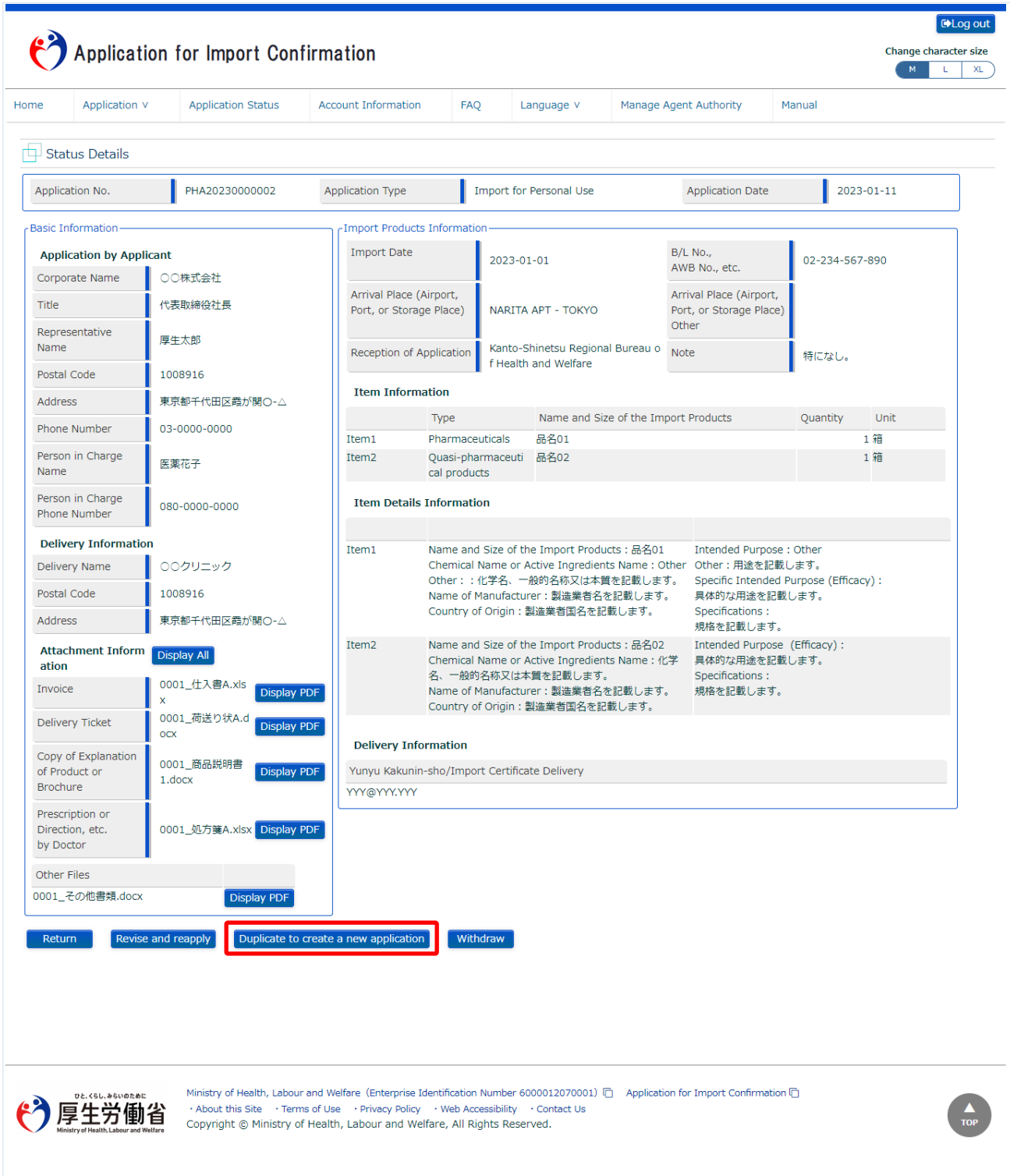


(2) Duplicate the import confirmation application

The selected import confirmation application is displayed on the Status Details screen and reapplication is made using the selected application.

Confirm the application and click “Duplicate to create a new application.”

<Status Details/Import for Personal Use>



(3) Enter new application information

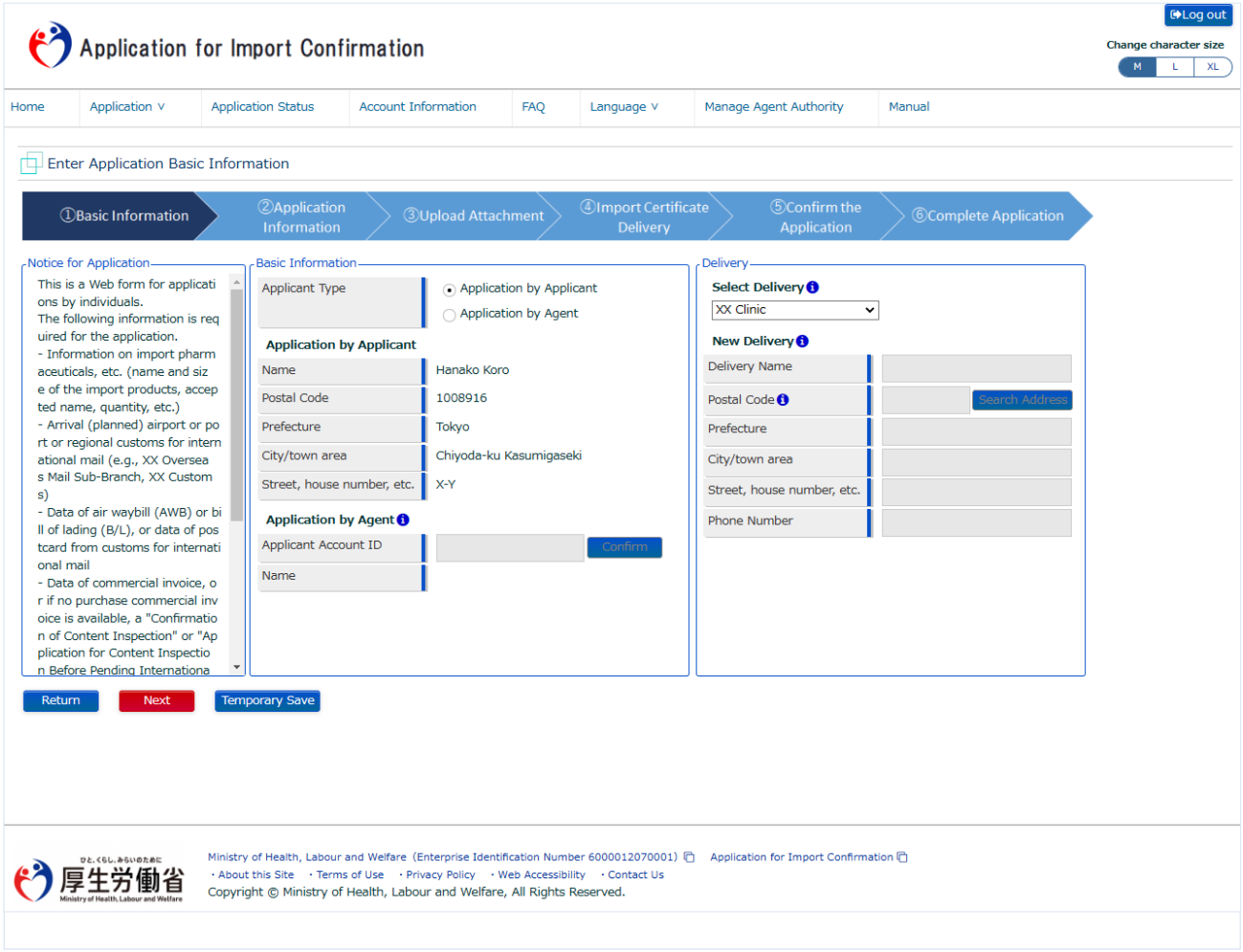
The screen to enter application information is displayed.

Since the reusable items are already entered, edit as required.

*"B/L No., AWB No., etc.," "Invoice," "Delivery Ticket," and "Prescription or Direction, etc. by Doctor" are not reused.

Refer to the explanation of "2.2 Import Confirmation Application" for how to enter further information.

<Enter Application Basic Information>



変更記録

変 更 記 録　REVISIONS		
変更回数 REV.	変更発行日 REV.ISSUED	変 更 箇 所・変 更 内 容 CHANGED PLACE AND CONTENT
1.00	2023/02/01	First edition
1.01	2023/02/20	Corrected contact information
1.02	2023/03/08	The wording of the "Reapply" button has been changed.
1.03	2023/03/10	Corrected contact information
1.04	2023/04/27	2.3.2 Data Specifications of Bulk Application Files (1) File definition Example of ZIP file storage, example of relationship between item information and research plan information ⇒ Corrected the consistency of data types and details (2) File definition specifications A01_14.Delivery_Postal Code ⇒Deleted the fact that it is unconditionally required A01_15.Delivery_Prefecture,A02_12.Intended Purpose_Other ⇒ Corrected number of digits A02_13.Specific Intended Purpose (Efficacy) ⇒ Required depending on conditions → Required unconditionally A02_14.Specifications, A02_20.Responsibility of Doctor ⇒ unconditionally required → conditionally required A02_16.Urgency of Treatment ⇒ Modified essential conditions File Item Specifications_Delivery Information[A03] ⇒ Deleted the fact that it is unconditionally required File Item Specifications_Trials and Research Plan Information[A05] ⇒ Required unconditionally → Required depending on conditions A03_3.Delivery of Yunyu Kakunin sho/Import Certific ⇒ Corrected the item name A04_3.Attachment File Type ⇒ Fixed the required condition

変 更 記 録　REVISIONS		
1.10	2023/09/19	2.2 Modified the following regarding Application for Import Confirmation (revised only in English version) Changed the explanation regarding input of units in [item information] of "(3) Enter application information" 2.3.2 Data Specifications of Bulk Application Files The following corrections were made to the data specifications. (2) File definition specifications A02_5.Quantity ⇒ The number of digits has been corrected. A02_6.Unit ⇒ The settings have been corrected.