



Programme on International
Nonproprietary Names (INN)

INN Data Management Integrated System

INN On-line Application User Manual

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Abstract: This document describes only the user interface for the INN on-line application. For more details about the INN process refer to INN web site.

Keyword list: On-line application, User Manual



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1. Requirements

In order to use the INN on-line application the user needs:

- the INN request PDF file;
- the INN Programme certificate for PDF document;
- Acrobat Reader
- an internet browser (tested on FireFox 3.0 and earlier versions, MS Internet Explorer 6.0);

1.1 How to obtain the INN request PDF file

To obtain the INN request PDF file follow the link below.

https://extranet.who.int/tools/inn_online_application/INN_online_application_files/INNFORM_072010.pdf

Please open the INN request PDF file using Acrobat Reader as a stand-alone application.

1.2 How to obtain the INN Programme SSL Certificate

To obtain a INN Programme SSL Certificate follow the link below.

https://extranet.who.int/tools/inn_online_application/INN_online_application_files/INN_Pdf.crt

The steps to install the certificate have been described in chapter 2.1.

1.3 How to obtain the Acrobat Reader

To obtain Acrobat Reader follow the link below.

<http://get.adobe.com/reader/>

2. Assuring security

The INN online application assures security using digital certificates (integrity and authentication) and strong encryption algorithms (confidentiality).

The following steps are mandatory for your security and to give access to your submitted application to the INN secretariat.

2.1 Install the INN certificate on Acrobat Reader

Due to the sensible contents managed by the INN Programme some security policies have been adopted. To guarantee the source of the document exchanged during the submit process the use of trusted digital certificates is needed.

To install the INN certificate for PDF (See Figure 1) download the certificate from the INN on line application site (See the link in 1.2 or click [here](#)).

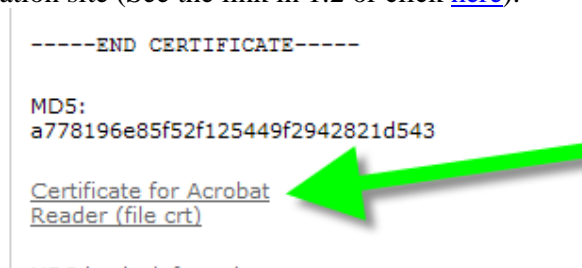


Figure 1 link on the INN site to the certificate

Open Acrobat Reader looking to the menu bar (see Figure 2) select "Document" (the red arrow in Figure 2) and the item "Manage Trusted Identities.." (the green arrow in Figure 2)

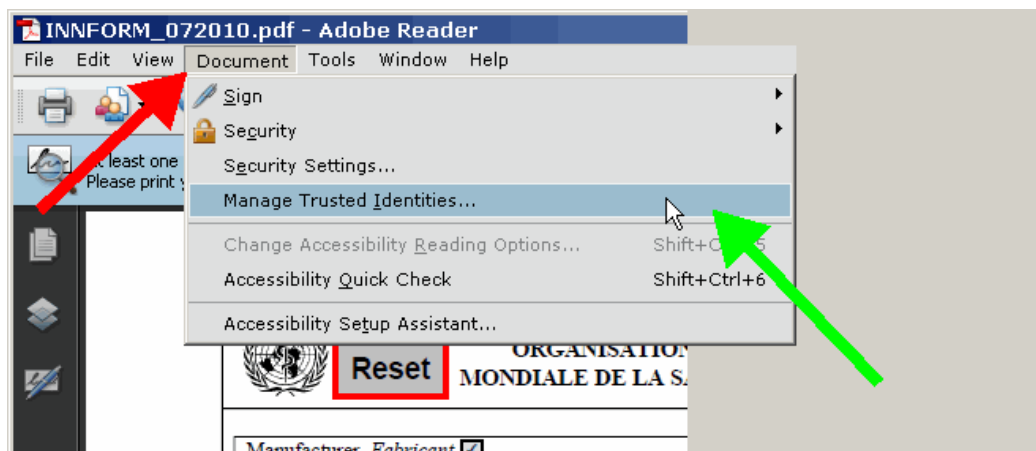


Figure 2 "Manage Trusted Identities..." menu on Acrobat Reader

Clicking on the "Manage Trusted...." item, the window in Figure 3 appears.

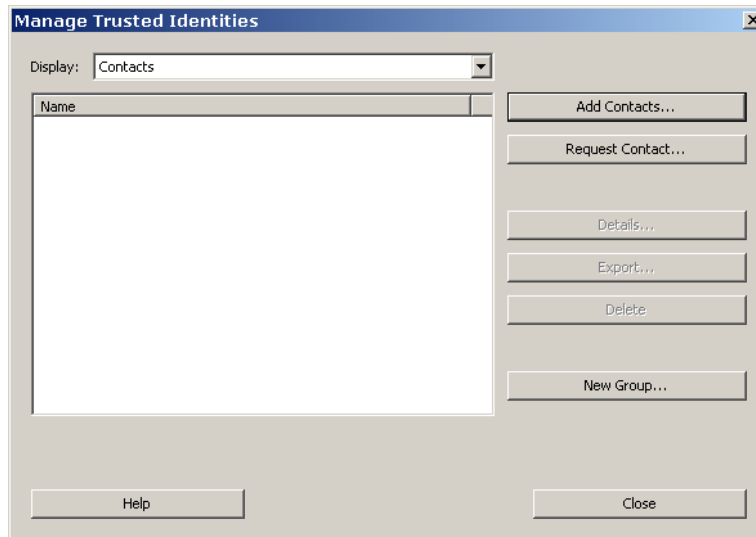


Figure 3 "Manage Trusted Identities..." list of contacts and certificates

Clicking on the "Add Contacts..." button the dialog window in Figure 4 will show the list of the contacts and/or certificate. Click on the "Browse" button and the classic window dialog box to select files will appear (see Figure 5). Select the INN PDF certificate (see 1.2 and green arrow in Figure 5)

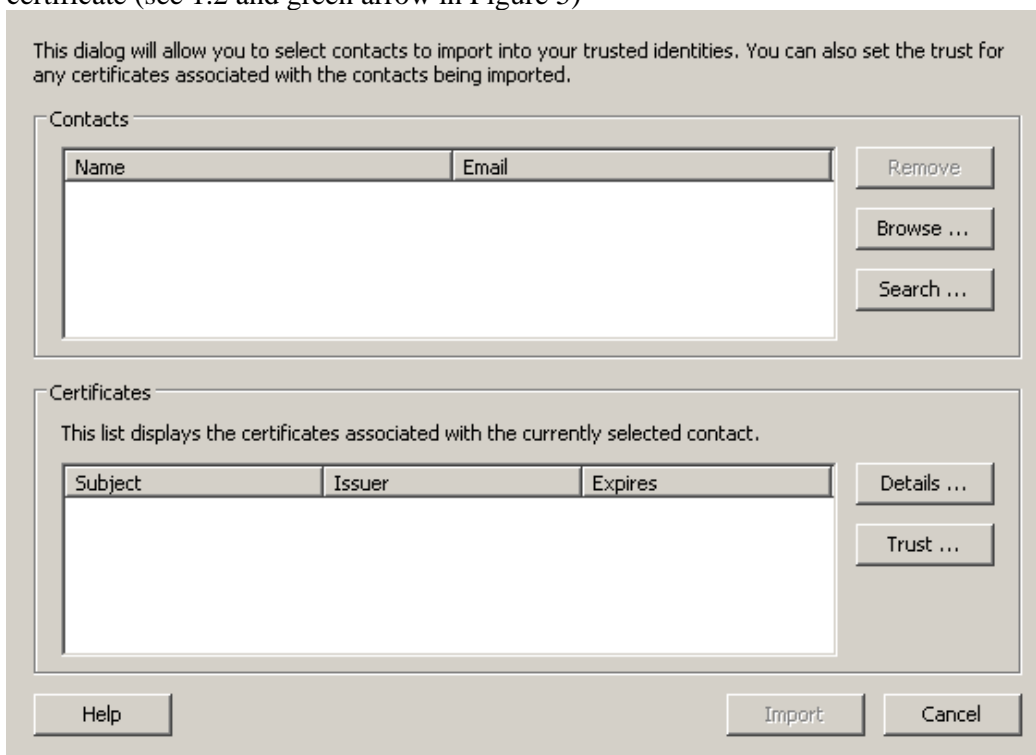


Figure 4 "Add Contacts..." dialog box

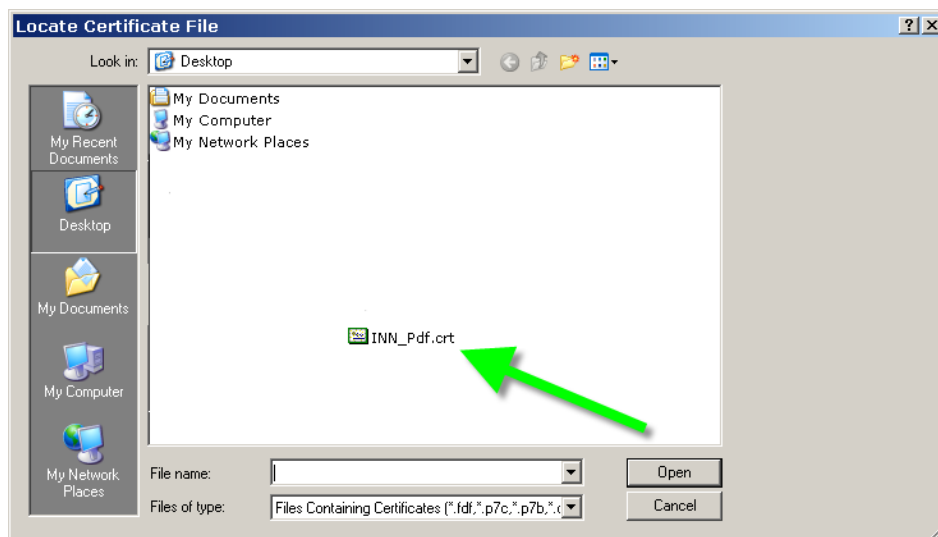


Figure 5 Browse windows

The certificate selected has to be trusted in order to assign the rights (see green arrow in Figure 6).

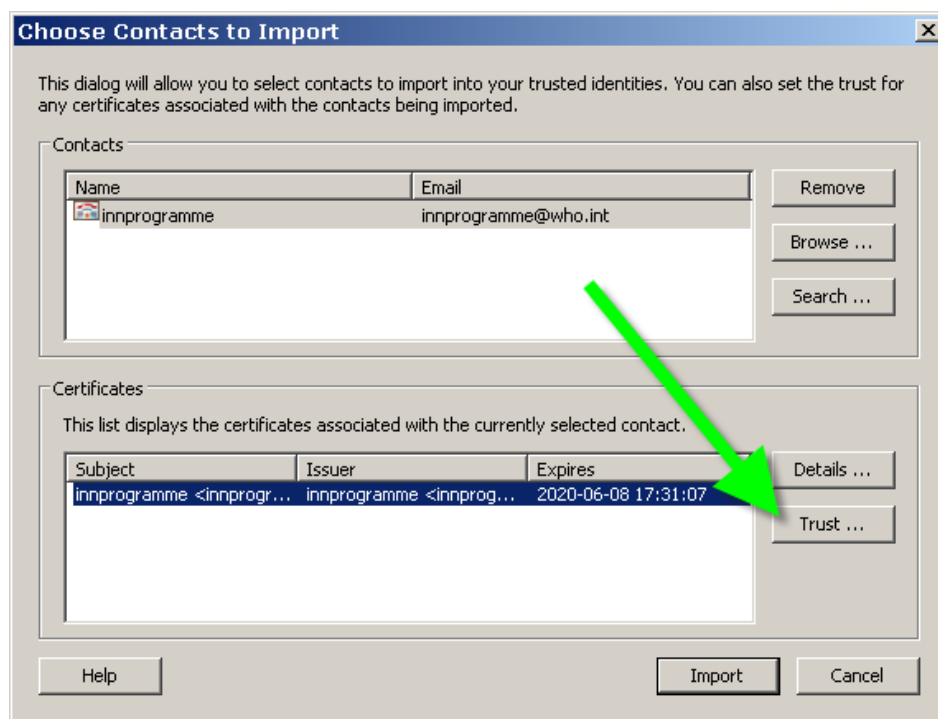


Figure 6 "Add Contacts..." dialog box "Trust..." command

In the "Import Contact Settings" window that will be opened, select the box pointed to by the red arrow and the green arrows (see Figure 7) to assign rights.

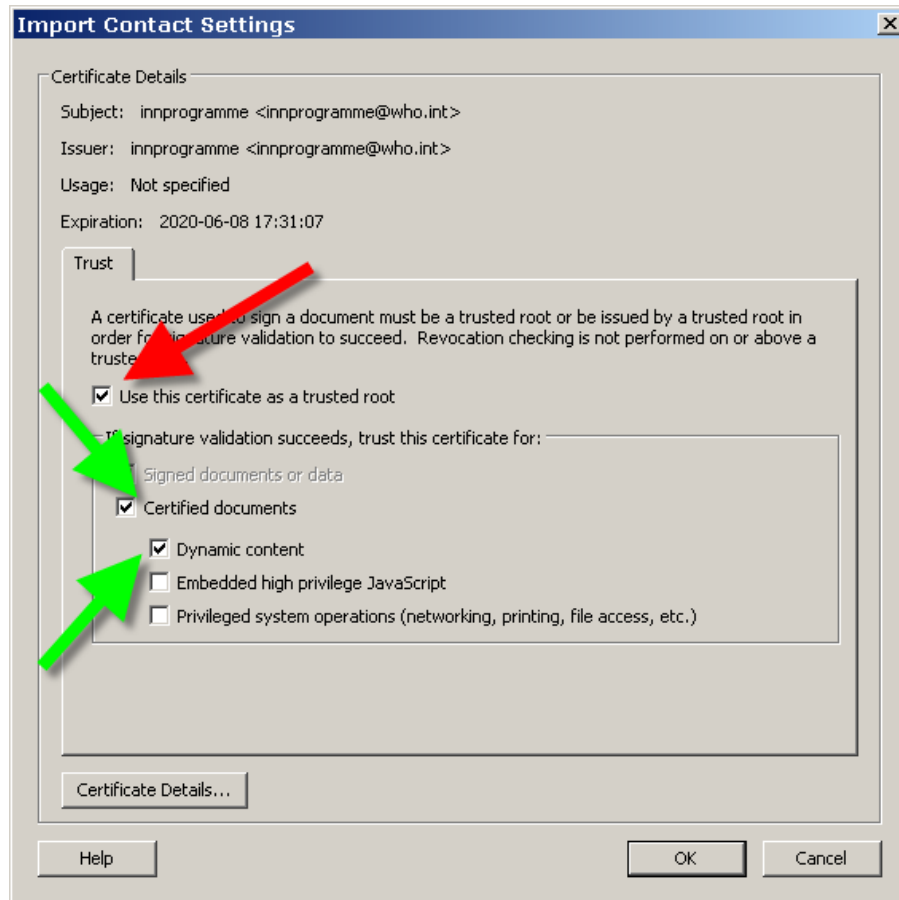


Figure 7 "Import Contact Settings" window

Click on the button "OK" and then click on the "Import" button in Figure 8. The succeeded operation will be confirmed by the box in Figure 9.

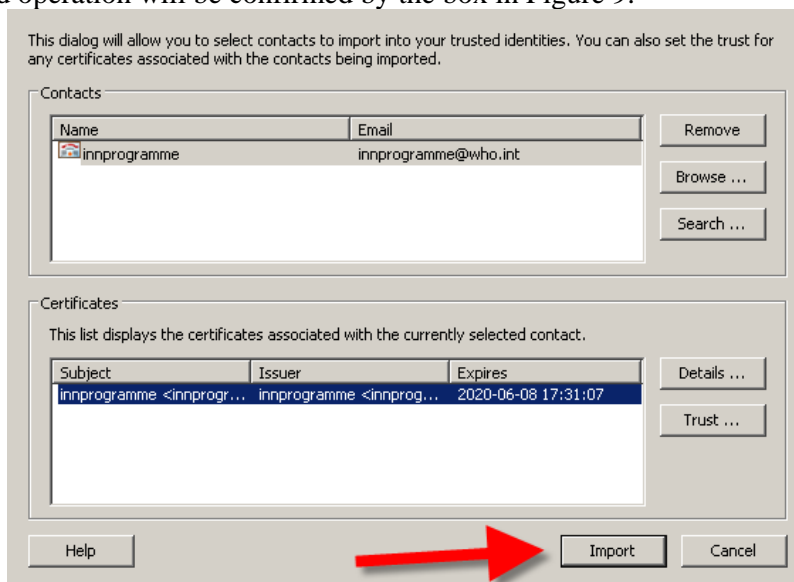


Figure 8 "Add Contacts..." dialog box "Import" command

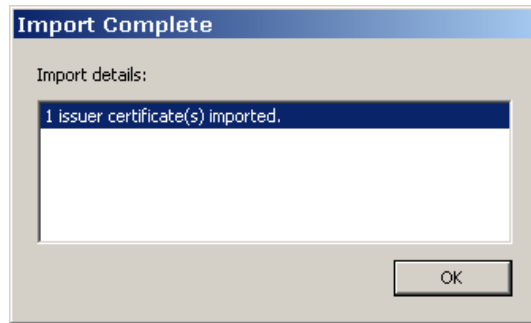


Figure 9 INN Certificate imported

2.2 Opening the INN PDF form

Download the PDF file from the INN site (see 1.1 or click [here](#)). For your security, please, do not use other PDF files coming from different sources.

In order to authenticate and to trust the PDF file, after the execution of the steps described in 2.1, click on the icon pointed to by the red arrow in Figure 10

The screenshot shows the 'Request for an international nonproprietary name (INN)' form. The form is titled 'WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE'. It includes a 'Reset' button and a 'Verify' button. The 'Verify' button is highlighted with a red arrow. The form contains several sections: 'Manufacturer / Fabricant', 'Address / adresse', 'SUGGESTED NAMES (in order of preference)', 'CHEMICAL NAME OR DESCRIPTION (INCLUDING STEREOCHEMICAL INFORMATION)', and 'GRAPHIC FORMULA (INCLUDING AMINO ACID OR DNA SEQUENCES IN ELECTRONIC FORMAT)'. The 'Verify' button is located in the top right corner of the form.

Figure 10 Verify signature on PDF

The icon on the left pointed to by the red arrow in Figure 11 shows if the PDF document has been validate or not.

The validation process allows you to verify if changes have been done on the document and/or if the author of the document is an authorized one.

Clicking on the "Validate All" item (green arrow in Figure 11) the Acrobat Reader will verify the integrity and the author identity of the PDF document.

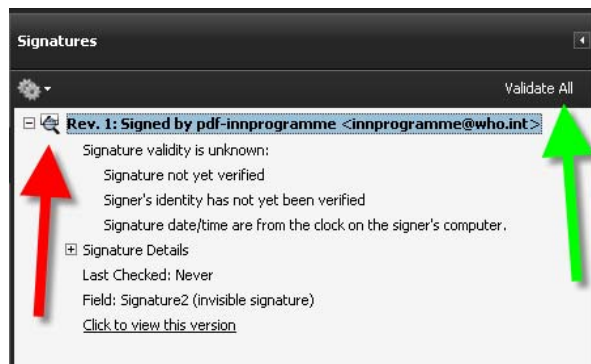


Figure 11 Signature status on PDF

If the signature is valid you will see messages on the top bar and on the icon showed in Figure 12 (green arrows).

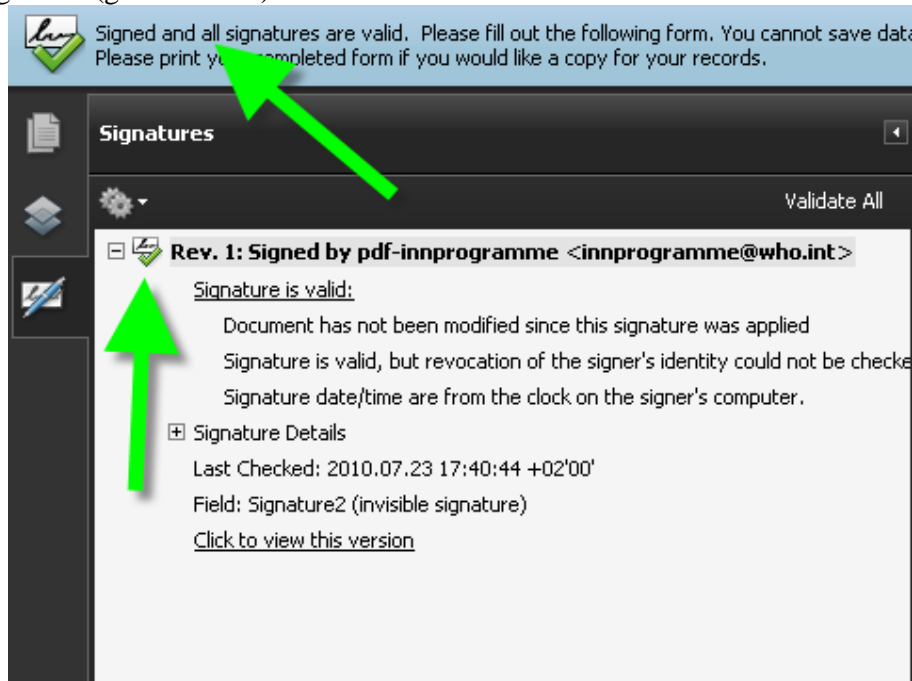


Figure 12 Successful Verify signature

If you see messages like in Figure 13 (red arrows) you missed these steps in the phase before. Please verify all the steps in 2.1. If the warning message persists please contact the INN secretariat. In fact, the document could be corrupted or it could contain links to malicious sites, please, do not use this PDF document to send sensible information.

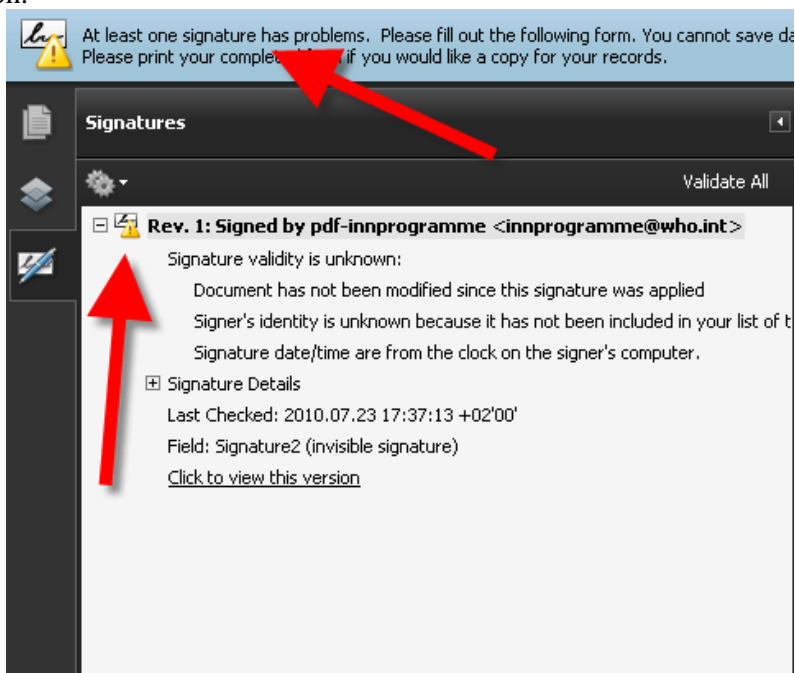


Figure 13 Mistrusted PDF author

Another kind of warning message could be the one shown in Figure 14. The green arrow points to the succeeded trusted process for author, but, on the other hand the red arrow shows that one of the fields has been changed. In this case, please verify the changed field, if it is an update of date (like this case) do not worry. If the changes are related to the java scripts embedded into the PDF, please do not use the PDF document and contact the INN secretariat

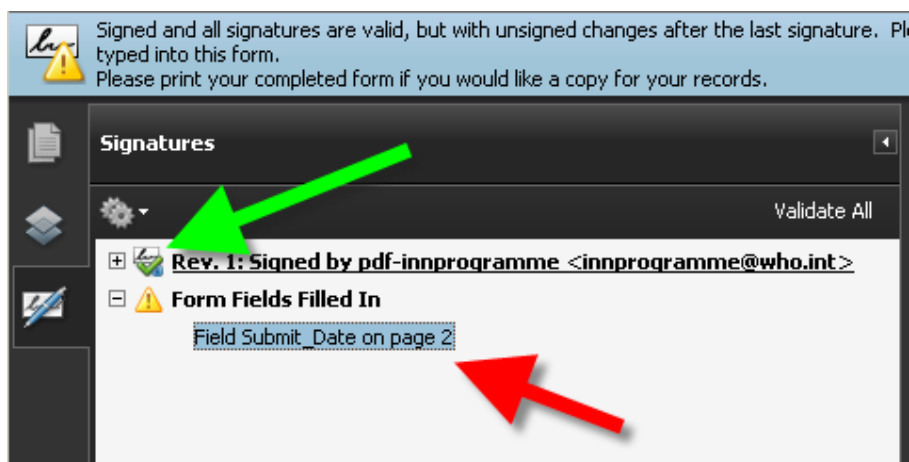


Figure 14 Warning integrity message

3. Filling the INN PDF form

The INN on-line application uses the Adobe Reader software as user interface. Opening the PDF file, the user will see a PDF document in Figure 15.

WORLD HEALTH ORGANIZATION
ORGANISATION
MONDIALE DE LA SANTE

Request for an international nonproprietary name (INN)
Demande de dénomination commune internationale (DCI)
Fee: US\$ 8000 (for details see overleaf)

Reset **Verify**

Manufacturer / Fabricant ☒ **Manufacturer Name**
First Name of responsible officer / Premier du responsable
Address / adresse:
Street
Zip Code
City - State
Country
Organization name **Department name**
Telephone No/No. de téléphone **Fax No./No. de fax**
Email Address

For completion by WHO
Request No:
Date:
Copies forwarded:
Date:
Payment received:
Date of cheque:
Acknowledged:

SUGGESTED NAMES (in order of preference):
1st suggested name **2nd suggested name** **3rd suggested name** **4th suggested name** **5th suggested name** **6th suggested name** ☐ **Biological**

CHEMICAL NAME OR DESCRIPTION (INCLUDING STEREOCHEMICAL INFORMATION):
Chemical Name

GRAPHIC FORMULA (ONLY RENEWABLE ACTS ON DNA RESEQUENCES IN ELECTRONIC FORMAT):
FORMULE GRAPHIQUE (SEULEMENT LES SEQUENCES D'ACIDES AMINES OU D'ADENINES FORMATS ELECTRONIQUES):
Add SMILES structure image

MOLECULAR FORMULA: **Molecular Formula**
FORMULE BRUTE

CHEMICAL ABSTRACTS SERVICE (CAS) REGISTRY NUMBER: **CAS Registry Number**
NUMERO DE REGISTRE CAS

TRADE NAME (NAME OF COMMERCE): **Trade Name**
NOM COMMERCIAL (NOM DE COMMERCE)

ANY OTHER NAME OR CODE: **Manufacturer Code**
AUTRE NOM OU CODE

PRINCIPAL THERAPEUTIC USES AND PHARMACOLOGY; PHARMACOLOGICAL ACTION:
USAGES THERAPEUTIQUES ET PHARMACOLOGIE; ACTION PHARMACOLOGIQUE
Pharmacological Action

Additional Files: **Add a small summary of the INN** **ADD**

1. The process of selecting an INN should be initiated during that period of investigation when the compound is undergoing clinical study in human subjects. Please indicate the date when clinical trials began. (year) **1900-1999**

2. This proposal is made on the understanding that neither as is known, nor of the suggested names is either registered or pending registration. (In proceeding with this proposal, the signatory declares that he has no knowledge of any other names already registered or pending registration.)

3. Permission is granted to the WHO Secretariat to include a Chemical Abstracts Name and registry number for the compound in corresponding line acid, base or alcohol. N.B.: A letter from Chemical Abstracts Service confirming the CAS Registry Number and the CA Index Name needs to be submitted by requesters together with the INN application form. (L'autorisation est accordée à l'OMS, par la présente, d'inclure le nom et le numéro attribué par le Chemical Abstracts Service à la substance faisant l'objet de la demande ou à l'acide libre, base ou alcool correspondant. N.B.: Une lettre du Chemical Abstracts Service confirmant le numéro de registre de CAS et le nom de CAS doit être présentée par le demandeur pour chaque demande de DCI en même temps que la soumission de la demande.)

ADDITIONAL COMMENTS:
REMARQUES

Date: 2010-07-26 **Signature:**

ADDITIONAL INSTRUCTIONS FOR APPLICATIONS RELATED TO BIOLOGICAL AND BIOTECHNOLOGICAL SUBSTANCES
Information also needs to be provided:

1. For a protein substance, the complete mature amino acid sequence, using the one-letter code, in a format that can be copied for analysis (Word or in the text of an e-mail) and with spaces between groups of ten characters, and the sequence length, the positions of the disulfide bridges and all post-translational modifications.
For a glycoprotein/glycopeptide, the glycosylation pattern (site, the type of sugar, etc.).
For a monoclonal antibody, the precursor nucleotide sequence with spaces between codons and translation and with numbers per line, CDS-INGT, the origin of each chain, sites of disulfide-bridges, Ig class and subclass, amino structure of the antigen against which the monoclonal antibody is directed.
For a recombinant DNA protein, expression system, comparison with the native sequence.

2. For a substance comprising nucleic acid (e.g. a DNA vaccine, oligonucleotide, gene therapy product), the full nucleotide sequence of the nucleic acid with the pertinent regions (e.g. reading frame) delineated.

Please be aware that sequence information will be published either electronically (Molbase) or in both print and electronic format, depending on the size of the structure.

The processing of a request for an International Nonproprietary Name (INN) is subject to the payment of a fixed fee of US\$ 8000. (No other currency is accepted). Payment by bank transfer or by bankers certified cheque must be included with each request and should be made payable to:

Bank transfer: **UBS AG**
C.P. 8000
CH - 1211 Geneva 2, Switzerland
USD Account: **240 00 188 800 0**
USD Account IBAN: **CH51 0004 0040 010000000**
Swift code: **UBSWCH33HAN**

Cheque payable to: **World Health Organization**
Avenue Appia
CH-1211 Geneva 27
Switzerland

To avoid delays in processing, the accompanying cheque should be sent by regular mail or special delivery to the INN programme, via Quality Assurance & Safety: Medicines (QAS&S/EMP) at the above address.

Please send a copy of the bank transfer by fax to QSM (0041 22 791 47 30, which will enable us to timely validate receipt of your payment.

PLEASE ENSURE OUR REFERENCE NUMBER IS QUOTED ON PAYMENT:
EDMINN26FT010000022

No request for an INN will be processed without payment having been received by WHO.
This request form must be completed and sent to the WHO INN Secretariat both in hard copy and electronic format.

Figure 15 INN PDF document

The yellow fields are the required information (see Figure 16) in order to start the INN process. For details about the INN process please refer to the INN web site (<http://www.who.int/medicines/services/inn/en/>). The fields contain, as default values, information about the content to submit.

WORLD HEALTH ORGANIZATION
ORGANISATION
MONDIALE DE LA SANTE

Reset

Manufacturer / Fabricant ☒ **Manufacturer Name**
First Name of responsible officer / Prenom du responsable
Family name of responsible officer / Nom du responsable

Address / adresse:
Street
Zip Code
City - State
Country
Organization name **Department name**
Telephone No/No. de téléphone **Fax No./No. de fax**
Email Address

We hereby request the World Health Organization to establish a free substance described below.
L'OMS est priée de bien vouloir établir une DCI à usage libre pour la

Figure 16 INN PDF fields

If the content is correct the field becomes green, if there are some format problems the field becomes red (see Figure 17).

The screenshot shows a form titled "MONDIALE DE LA SANTE" with a "Fee: US\$" field. The form contains several input fields: "Manufacturer Fabricant" (checked), "Authority Autorité" (unchecked), "Coccio sa", "Prof" (dropdown), "Antonio", "Romero", "Address / adresse", "Rue des ains", "12091", "Geneve", "Switzerland", "GSM", "INN", "+41 22 554558", "+41 22 85855", and "thename@domain". The "thename@domain" field is highlighted in red, while all other fields are green. A tooltip "First Name" is visible over the "Antonio" field. Below the form, there is a statement: "We hereby request the World Health Organization to establish a free and unrestricted INN for the substance described below." and its French equivalent.

Figure 17 INN PDF correct fields(green) and wrong field (red)

In order to obtain information about the field move the mouse over the field and wait few seconds until the field label appears (see "First Name" label in Figure 17).

Therefore, yellow fields are for the default values, green fields are for correct content and red fields are for wrong content or format (see arrows in Figure 18)

The screenshot shows the same form as Figure 17, but with additional elements. At the top, there is a "Reset" button (red) and a "Submit" button (green). Below the form, there is a section for "SUGGESTED NAMES (in order of preference):" with a table of six suggested names. The first suggested name is "Swissina" (green), the second is "Second suggested name" (yellow), the third is "Third suggested name" (yellow), the fourth is "Fourth suggested name" (yellow), the fifth is "Fifth suggested name" (yellow), and the sixth is "Sixth suggested name" (yellow). There is also a "Biological" checkbox. Arrows indicate the field status: a green arrow points to the "Antonio" field, a red arrow points to the "thename@domain" field, and a yellow arrow points to the "Fourth suggested name" field.

Figure 18 Correct fields(green), wrong fields (red) and default values (yellow)

In order to see the mandatory fields for the INN process click on the button on the top right corner on Acrobat Reader (see red arrow in Figure 19)

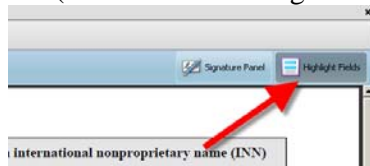


Figure 19 INN PDF show mandatory fields

The fields with the red border are mandatory (see Figure 20) the fields without the red border are optional but encouraged (green arrows in Figure 20).

WORLD HEALTH ORGANIZATION
ORGANISATION
MONDIALE DE LA SANTE

Reset

Manufacturer *Fabricant* ☒ A

Manufacturer Name

Other ☐ First Name of responsible officer / *Prenom du responsable*
Family name of responsible officer / *Nom du responsable*

Address / *adresse:*

Street

Zip Code

City - State

Select country

Organization name Department name

Telephone No./No. de telephone Fax No./No. de fax

Email Address

We hereby request the World Health Organization to establish a free an
substance described below.

Figure 20 INN PDF mandatory fields (red border)

Some of the fields are hidden, they will appear only if selected. For instance fields for authority details will appear after the selection of the box pointed to by the green arrow in Figure 21.

Verify

Demande de dénomination co
Fee: US\$ 9000 (for details see

Authority *Autorité* ☒ For

Choose...

Other ☐ First Name of responsible officer / *Prenom* Rec
Family Name of responsible officer / *Nom d* Dat

Address / *adresse:*

Street

Zip Code

City - State

Select country

Organization name Department name

Telephone No./No. de télé Fax No./No. de fax

Email Address

free and unrestricted INN for the pharmaceutical

Pay
Dat
Acl

Figure 21 Hidden fields (e.g. Authority details)

3.1 Submit files using INN PDF form

There are also fields to submit files (chemical structure and annex files).

The chemical structures files are mandatory.

Clicking on the button showed in Figure 22 (green arrow) a "Browse" window will be opened enabling you to select the BMP image of the chemical structure. After this an optional button will appear for CDX file (Chemdraw file format).

Figure 22 INN Chemical Structure Files

The same behaviour for biological. MS Word file or a txt file is mandatory (see Figure 23)

Figure 23 INN Chemical Structure Files (MS word doc or txt)for biological

Moreover, the user can add until four annex files (see red arrow in Figure 23) putting also information about the content of the files (see green arrow in Figure 23).

Clicking on the "Add" button the standard dialog box to browse file should appear.

If you need to add more the four files please, compress them using software compressor (e.g. zip)

Figure 24 INN Annex Files

3.2 INN PDF form advance editing functions

Some of the fields require some advance editing capabilities.

Chemical name, molecular formula and additional comment can contain formatted text. The "copy and paste" command works according the Acrobat capabilities. Problems rise for sub script and super script numbers or letters.

To open the advance editing dialog box, select the field and press "CTRL+E", the bar in Figure 25 will be showed.

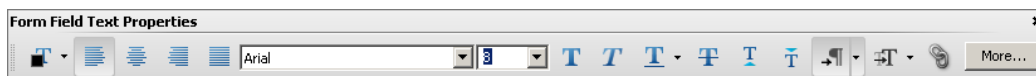


Figure 25 Acrobat advance editing dialog box

To write chars as super script you have to click on the button pointed to by the red arrow in Figure 26. For sub script click on the button pointed to by the green arrow.



Figure 26 Super script and sub script on Acrobat advance editing

Some chemical names need chars written as small caps.

The function small caps does not exist on acrobat. For this reason the user has to select the chars and to click on the font menu (see red arrow in Figure 27). Selecting the Arno Pro SC font the chars will be transformed as small caps.



Figure 27 Small-caps on acrobat advance editing

If you need to add Greek chars use the char map of your system. Please, use chars encoded UTF-8.

3.3 INN PDF form submit data

In order to submit the data the user has to click on the "Verify" button (see red arrow in Figure 28) on the top of the PDF document.



Figure 28 Verify data

If the verification process is right the "Submit" button will appear (see green arrow in Figure 29).

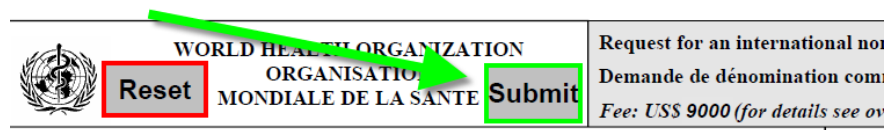


Figure 29 Submit data

Clicking it, the window message in Figure 30 will warn you about an internet connection to the https://extranet.who.int/inn_online_application domain. In this case click on "Allow" (see green arrow in Figure 30).

The submit process status will be display through the status bar showed in Figure 31. If the warning message shows a different internet domain (e.g. <http://182.0.24.23/xxx>) please, click on "Block" and contact the INN secretariat

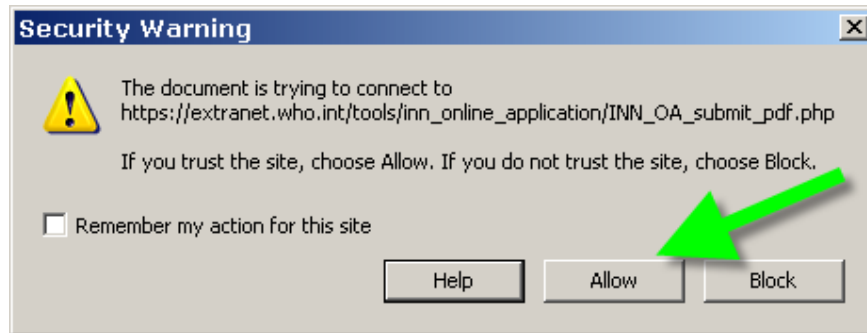


Figure 30 Warning submit window

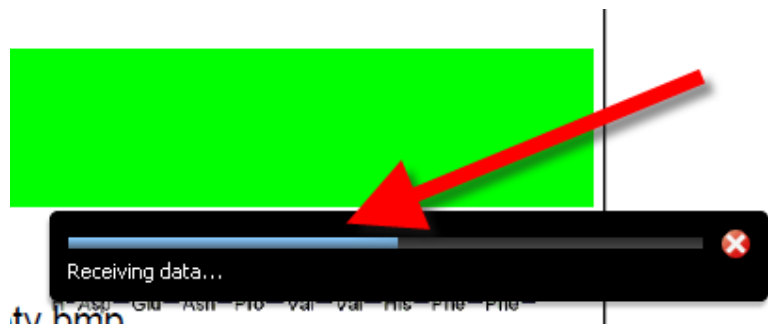


Figure 31 Submit process bar

4. The INN PDF receipt

The submit process will end with a new PDF document (the INN PDF receipt) containing the submitted data.

The receipt contains hyperlinks, for this reason as first step, verify the integrity of the document.

In an authenticated INN PDF receipt on the top of the PDF document you will see the icon pointed to by the green arrow in Figure 32.

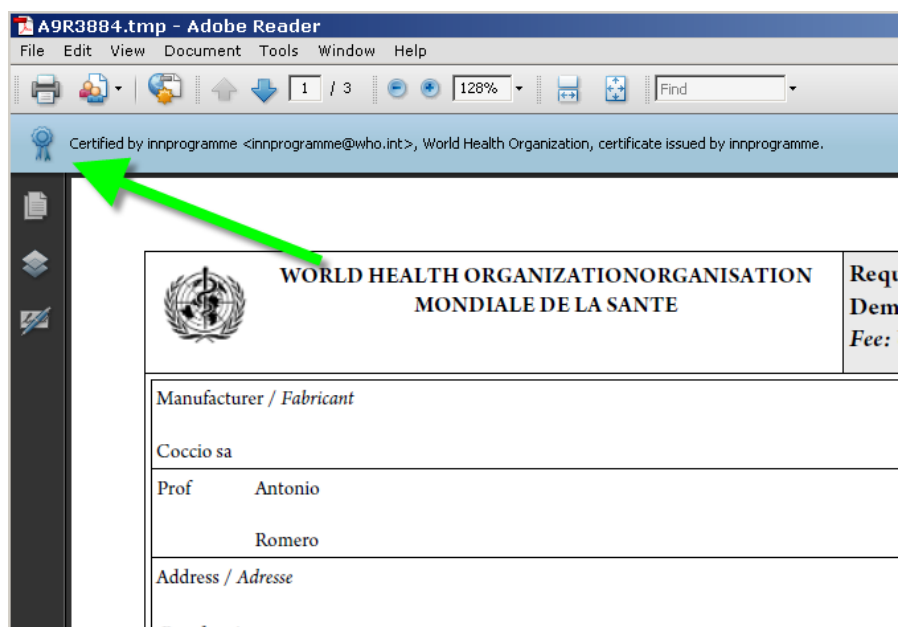


Figure 32 INN PDF receipt

After this first step, you MUST verify the correctness of the content.

On the right of each files (chemical structure and/or annex files) an hash code will be readable (see red arrow in Figure 33).

The hash code is used to verify the integrity of files or data (see for more information and tools <http://en.wikipedia.org/wiki/Md5sum>)

For chemical structure submitted as BMP file, the image will be present. On the other hand for the Chemdraw file, the name and the hash code will be visible.

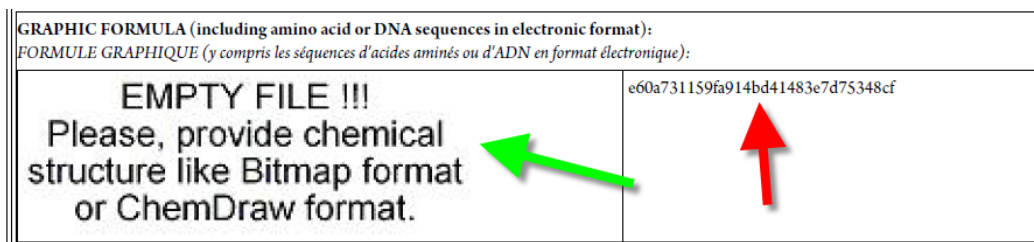


Figure 33 Chemical structure details on the INN PDF receipt

The same will be showed for the annex files, but the added information will be visible (see Figure 34, yellow arrow for the file name, red arrow for added information, green arrow for the hash verification code)

Additional Files:		
9256_fas.doc	comment	7fc14a1db4e41f527caae7592c936dd

Figure 34 Annex files details on the INN PDF receipt

At the end of the INN PDF receipt a summary of the previous needed steps and two links (see Figure 35) are readable.

If you agree to the data in this receipt please save (see Figure 38) and click on the "Approve" link in Figure 35 (green arrow).

An Acrobat message will warn you that you are connecting to an external internet site (see Figure 36). Please verify the domain before clicking the "Allow" button.

If there are some errors, "Reject" the document (red arrow in Figure 35) and then please, fill the PDF document with the right data.

"Approve" and "Reject" command will be confirmed opening on your browser one of the two pages showed in Figure 37.

If editing errors persist please contact the INN secretariat.

Steps to follow

Follow the steps below to finalized the submit process.

On the INN site you can find more details if needed.

1. Verify pdf electronic signature
2. Verify content
 1. Verify fields content
 2. Verify files integrity code (see how to verify on the web)
3. ["Click here to approve your data"](#) or ["Click here to reject your data"](#)

If you reject the pdf please click on the link and correct the wrong information on the original pdf, if the error persist please contact the WHO INN Secretariat
4. If you approve the pdf click on the link and after go to step 4.
4. Save this PDF document on your computer
5. Print the pdf file without the instructions pages
6. Sign it (by hand)
7. Send the pdf file to WHO INN Secretariat both in hard copy and electronic format (innprogramme@who.int)

Please be aware that the application process will be finished only with a proof of payment

Figure 35 INN PDF receipt (Approve or Reject)

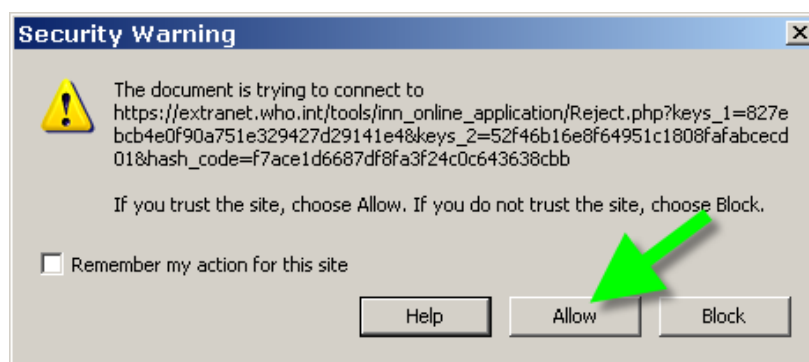


Figure 36 Warning message for external links in INN PDF receipt

Reject command OK Approve command OK

Figure 37 Reject and Approve browser pages

In case of successful verification process, you must save the receipt (see green arrow in Figure 40) and send it by email to innprogramme@who.int.

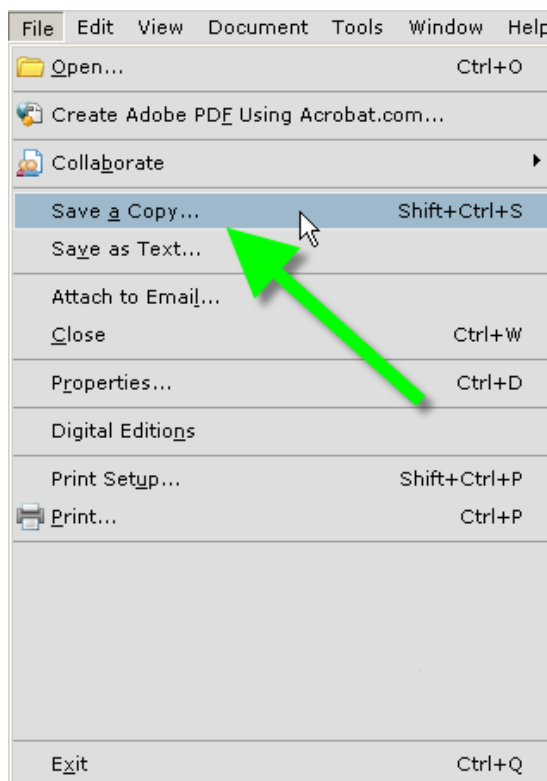


Figure 38 Save and send the INN PDF receipt

Do not worry about the warning message showed in Figure 39 and click on the button aimed by the green arrow.

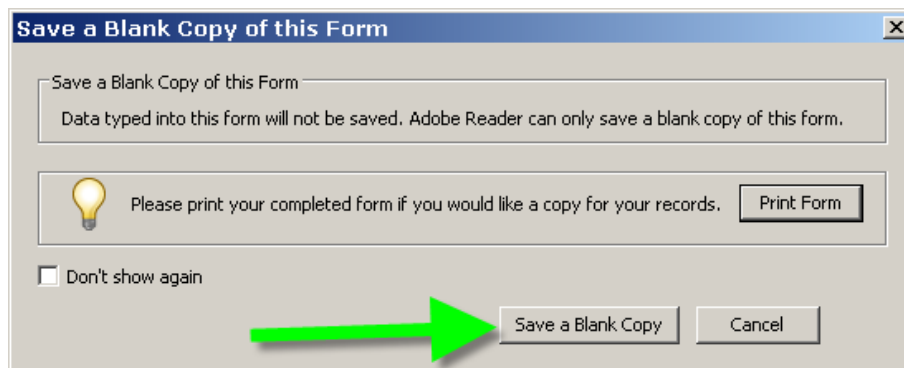
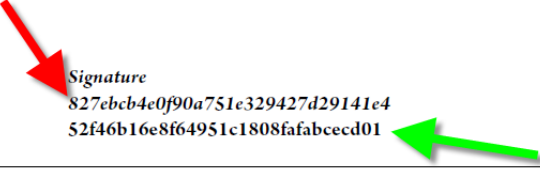


Figure 39 Save a Blank Copy

Moreover, print the INN PDF receipt and sign it by hand on the zone in Figure 40 and sent it, with a proof of payment, to:

World Health Organization
International Nonproprietary Names
(HSS/EMP/INN)
20 Avenue Appia
1211, Geneva 27
Switzerland

*et le numéro attribué par le Chemical Abstracts Service à la substance faisant l'objet de la
lettre du Chemical Abstracts Service confirmant le numéro de registre du CAS et le
mandat de DCI en même temps que la soumission de la demande.*



Signature
827ebcb4e0f90a751e329427d29141e4
52f46b16e8f64951c1808fafabcecd01

TO BIOLOGICAL AND BIOTECHNOLOGICAL SUBSTANCES

Figure 40 Signature in the INN PDF receipt

5. Conclusions

In order to finalize the INN application process three documents are mandatory:

1. the signed (by hand) hard copy of the INN PDF receipt,
2. the electronic copy of the INN PDF receipt sent by email,
3. the proof of payment

Without these documents the process **cannot** be finalized.