EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Electronic Application Forms

eAF Pilot Phase Training

Presented by: Gabriel Boronat
Business Analyst, eSubmissions Programmme

An agency of the European Union

Overview

1. Introduction
2. Scope of pilot phase
3. Navigation & data entry
4. Known issues/operational constraints

Introduction

- eAF project background
- Notice to Applicants Group
- Project milestones
- Pre-requisites
- Additional sources of information

Scope of Pilot Phase

Included in pilot phase 1:

- Human Product Authorisations: Renewals & Variations
- Human Product Initial Authorisation Applications [*2008 rev.9*]

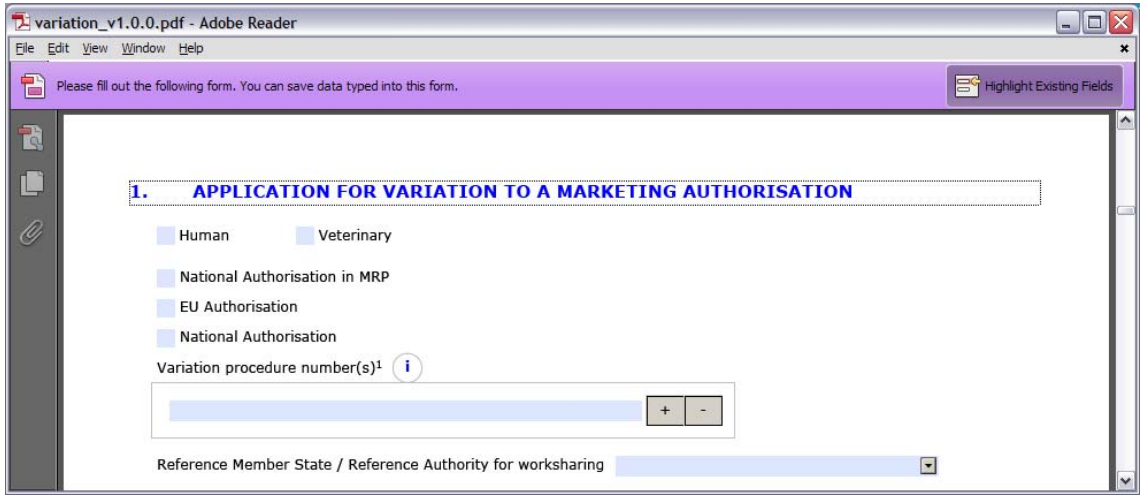
To follow in pilot phase 2:

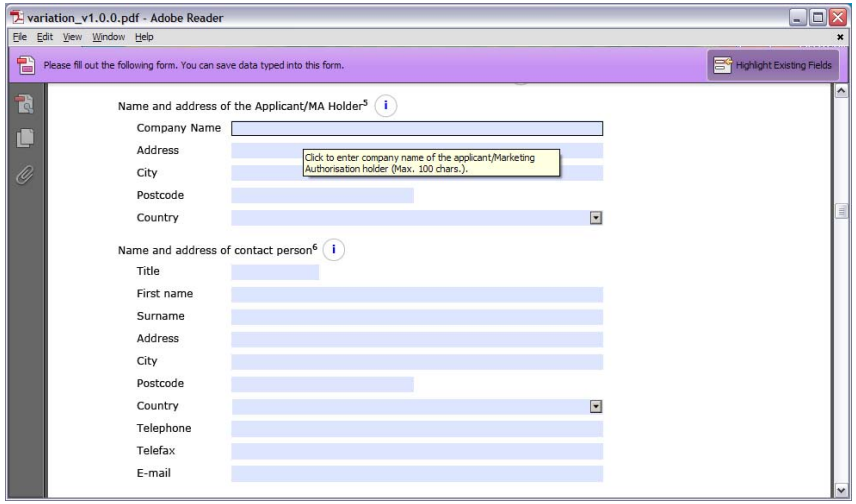
- Veterinary product-related applications

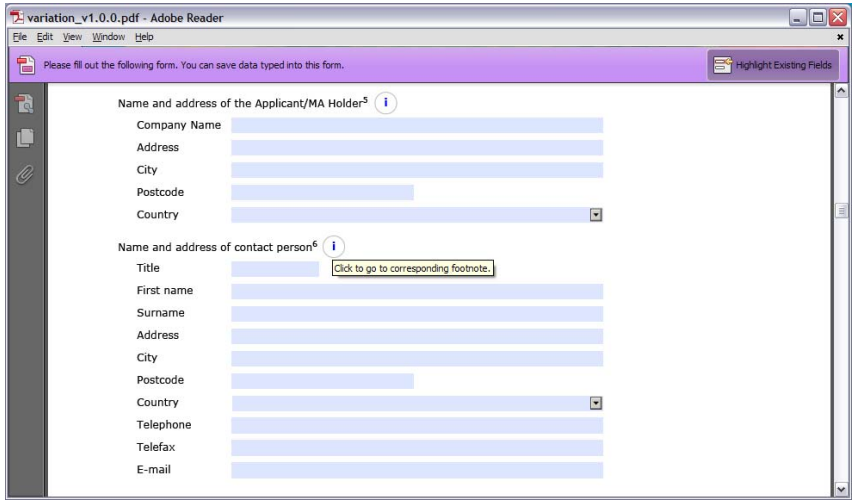
Navigation

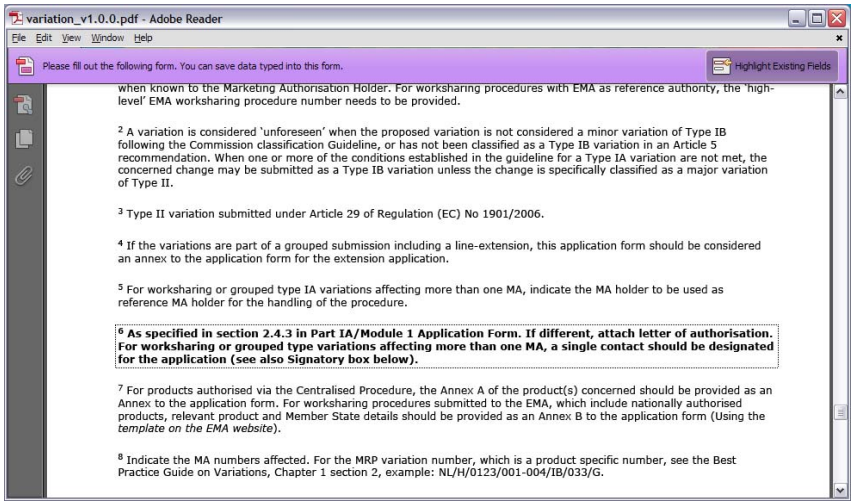
- Table of contents
- Hyperlinks
- Tooltips & footnotes
- Dynamic business rules


variation_v1.0.0.pdf - Adobe Reader
File Edit View Window Help
Please fill out the following form. You can save data typed into this form.
Highlight Existing Fields
TABLE OF CONTENTS
1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION
2. PRODUCTS CONCERNED BY THIS APPLICATION7
3. TYPES OF CHANGE(S)
ANNEXED DOCUMENTS (WHERE APPROPRIATE)
DECLARATION OF THE APPLICANT
SIGNATURE
NOTES
FORM VALIDATION

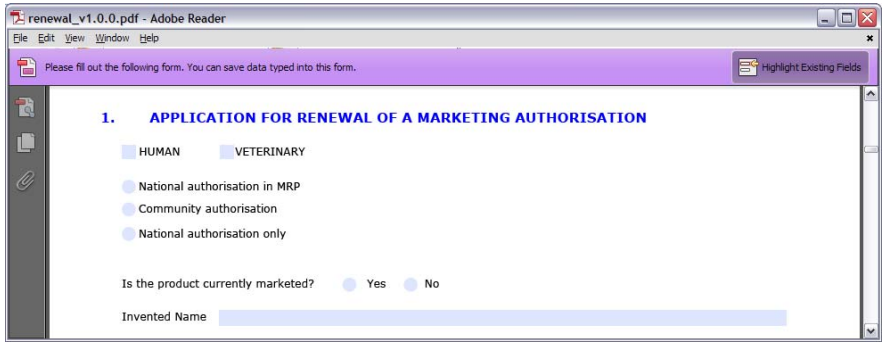

variation_v1.0.0.pdf - Adobe Reader
File Edit View Window Help
Please fill out the following form. You can save data typed into this form.
Highlight Existing Fields
1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION
Human
Veterinary
National Authorisation in MRP
EU Authorisation
National Authorisation
Variation procedure number(s)1
+
-
Reference Member State / Reference Authority for worksharing


variation_v1.0.0.pdf - Adobe Reader
File Edit View Window Help
Please fill out the following form. You can save data typed into this form.
Highlight Existing Fields
Name and address of the Applicant/MA Holder[5]
Company Name
Address
City
Postcode
Country
Click to enter company name of the applicant/Marketing Authorisation holder (Max. 100 chars.).
Name and address of contact person[6]
Title
First name
Surname
Address
City
Postcode
Country
Telephone
Telefax
E-mail

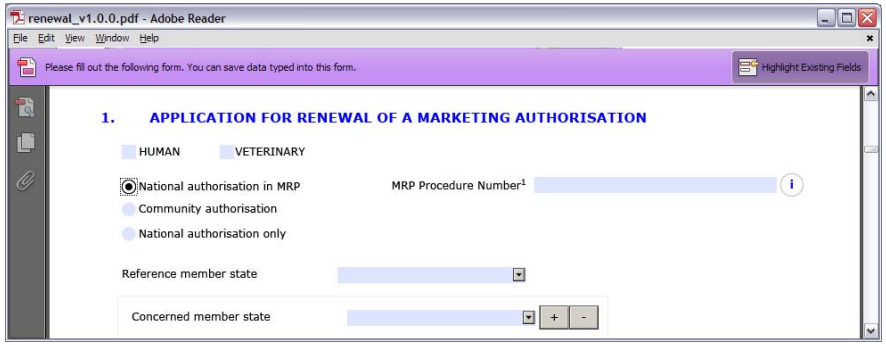

variation_v1.0.0.pdf - Adobe Reader
File Edit View Window Help
Please fill out the following form. You can save data typed into this form.
Highlight Existing Fields
Name and address of the Applicant/MA Holder[5]
Company Name
Address
City
Postcode
Country
Name and address of contact person[6]
Click to go to corresponding footnote.
Title
First name
Surname
Address
City
Postcode
Country
Telephone
Telefax
E-mail


variation_v1.0.0.pdf - Adobe Reader
File Edit View Window Help
Please fill out the following form. You can save data typed into this form.
Highlight Existing Fields
when known to the Marketing Authorisation Holder. For worksharing procedures with EMA as reference authority, the 'high-level' EMA worksharing procedure number needs to be provided.
[2] A variation is considered 'unforeseen' when the proposed variation is not considered a minor variation of Type IB following the Commission classification Guideline, or has not been classified as a Type IB variation in an Article 5 recommendation. When one or more of the conditions established in the guideline for a Type IA variation are not met, the concerned change may be submitted as a Type IB variation unless the change is specifically classified as a major variation of Type II.
[3] Type II variation submitted under Article 29 of Regulation (EC) No 1901/2006.
[4] If the variations are part of a grouped submission including a line-extension, this application form should be considered an annex to the application form for the extension application.
[5] For worksharing or grouped type IA variations affecting more than one MA, indicate the MA holder to be used as reference MA holder for the handling of the procedure.
[6] As specified in section 2.4.3 in Part IA/Module 1 Application Form. If different, attach letter of authorisation. For worksharing or grouped type variations affecting more than one MA, a single contact should be designated for the application (see also Signatory box below).
[7] For products authorised via the Centralised Procedure, the Annex A of the product(s) concerned should be provided as an Annex to the application form. For worksharing procedures submitted to the EMA, which include nationally authorised products, relevant product and Member State details should be provided as an Annex B to the application form (Using the template on the EMA website).
[8] Indicate the MA numbers affected. For the MRP variation number, which is a product specific number, see the Best Practice Guide on Variations, Chapter 1 section 2, example: NL/H/0123/001-004/IB/033/G.

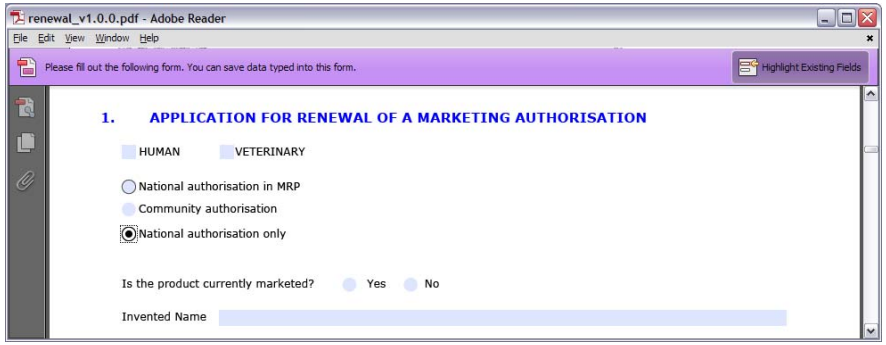
Navigation


renewal_v1.0.0.pdf - Adobe Reader
File Edit View Window Help
Please fill out the following form. You can save data typed into this form.
Highlight Existing Fields
1. APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION
HUMAN
VETERINARY
National authorisation in MRP
Community authorisation
National authorisation only
Is the product currently marketed?
Yes
No
Invented Name

Navigation


renewal_v1.0.0.pdf - Adobe Reader
File Edit View Window Help
Please fill out the following form. You can save data typed into this form.
Highlight Existing Fields
1. APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION
HUMAN
VETERINARY
National authorisation in MRP
MRP Procedure Number[1]
Community authorisation
National authorisation only
Reference member state
Concerned member state
+
-

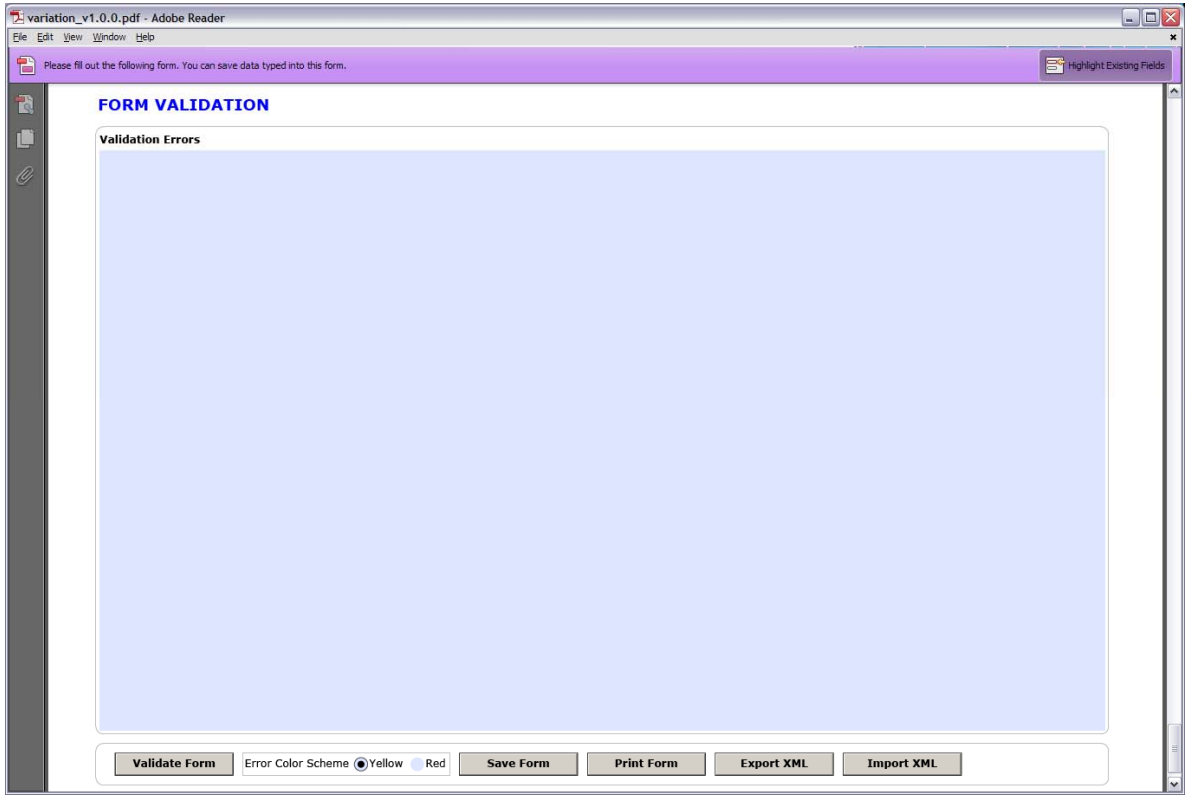
Navigation


renewal_v1.0.0.pdf - Adobe Reader
File Edit View Window Help
Please fill out the following form. You can save data typed into this form.
Highlight Existing Fields
1. APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION
HUMAN
VETERINARY
National authorisation in MRP
Community authorisation
National authorisation only
Is the product currently marketed?
Yes
No
Invented Name

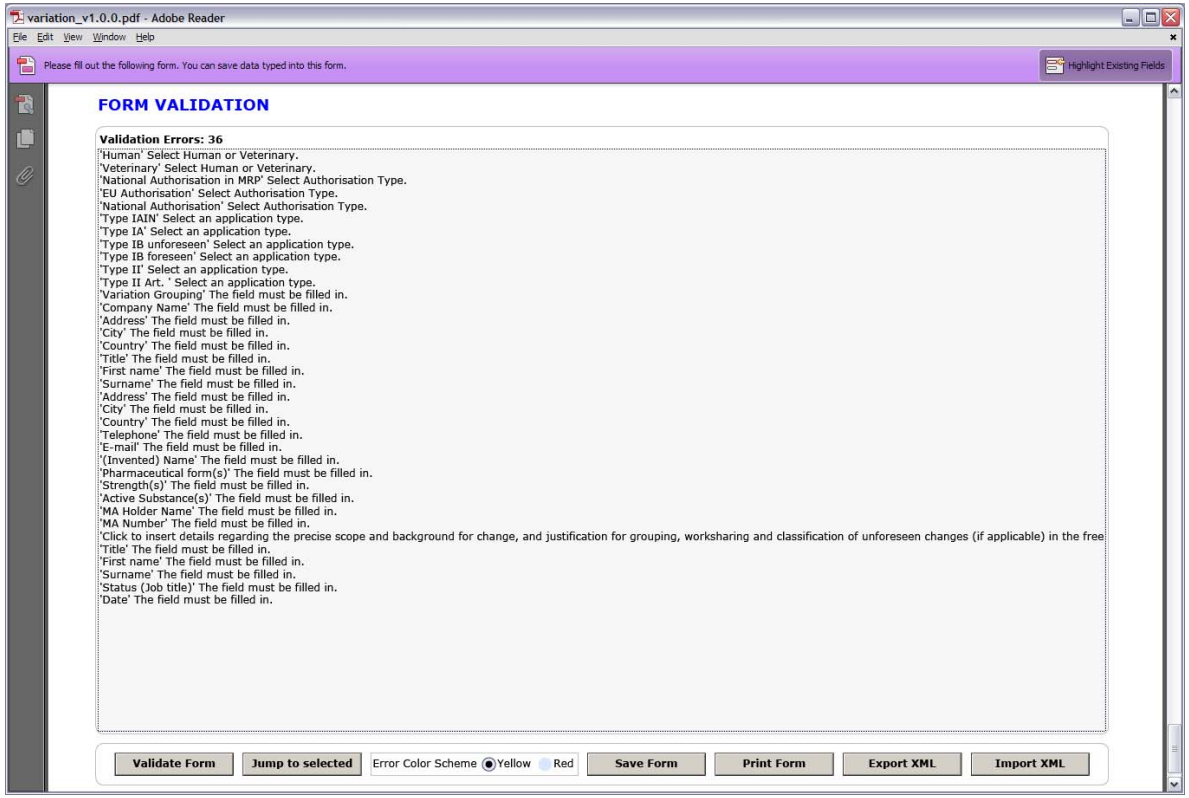
Data Entry

- Mandatory fields & validation
- Radio buttons & check boxes
- Additional groups
- Controlled terminology lists
- Dates
- Email addresses
- Signatures
- Currency amounts

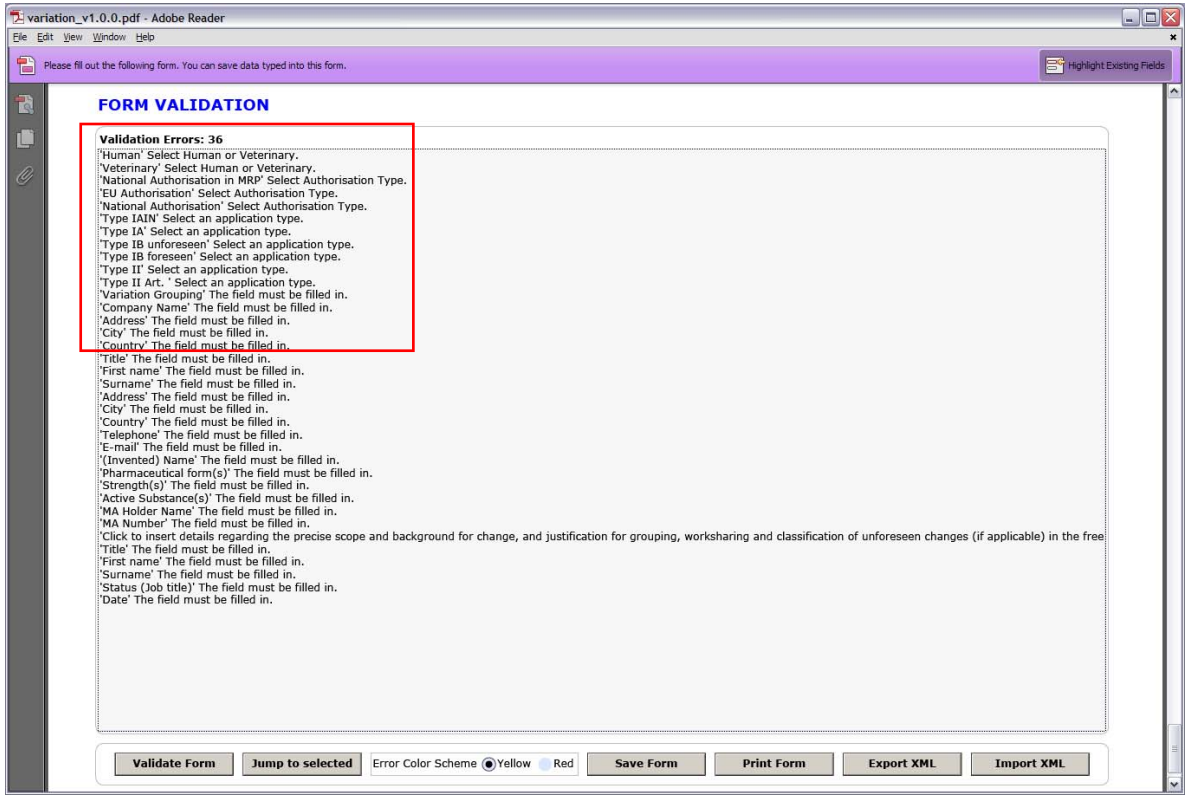
Mandatory Fields & Validation



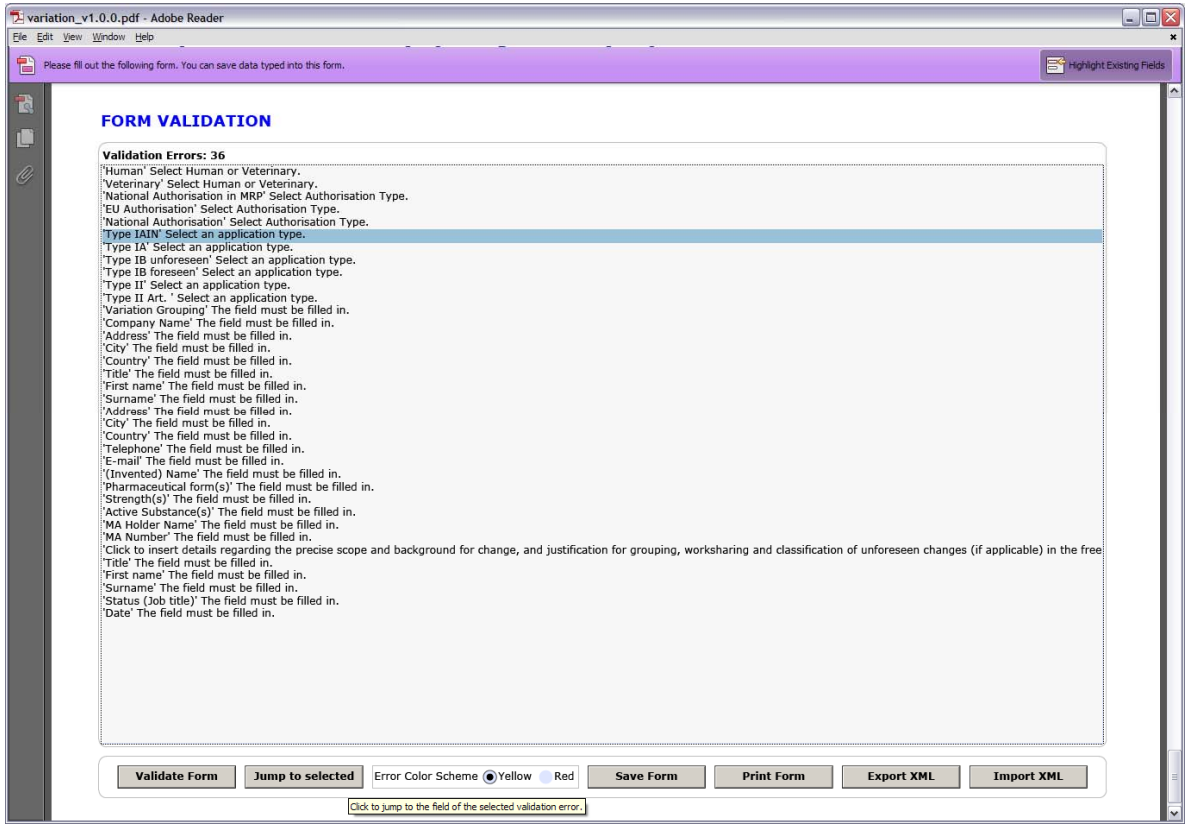
Mandatory Fields & Validation



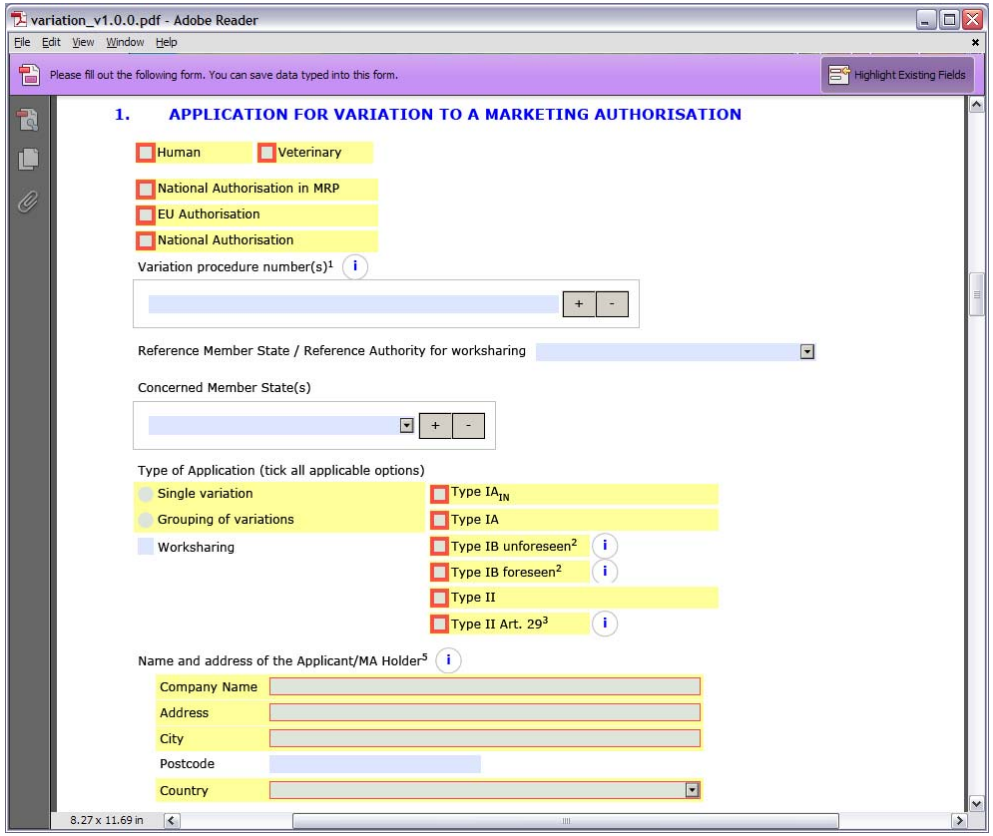
Mandatory Fields & Validation



Mandatory Fields & Validation

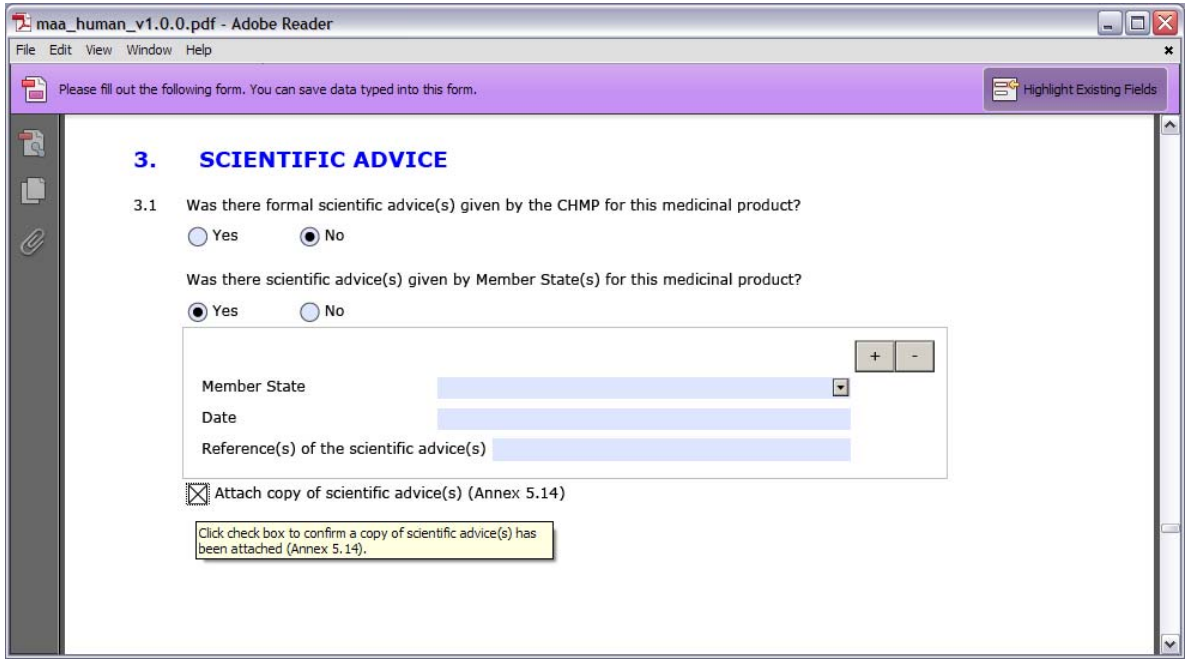


Mandatory Fields & Validation

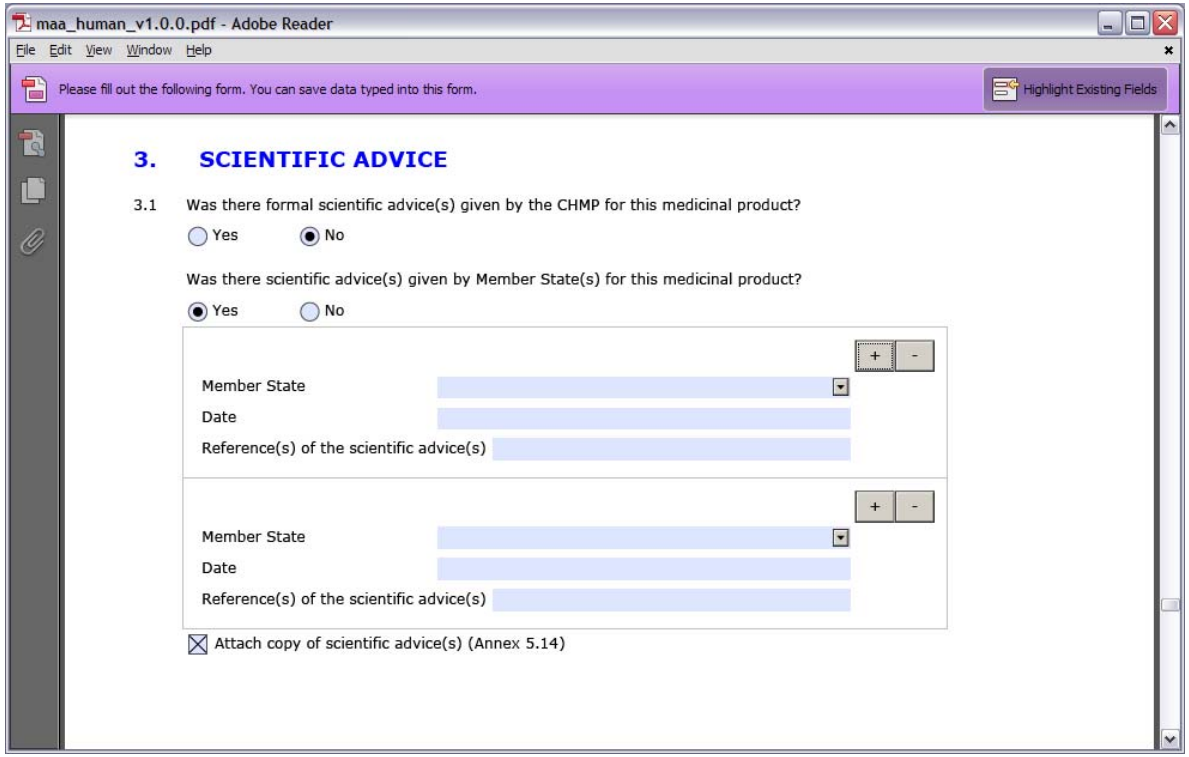


Radio Buttons & Check Boxes

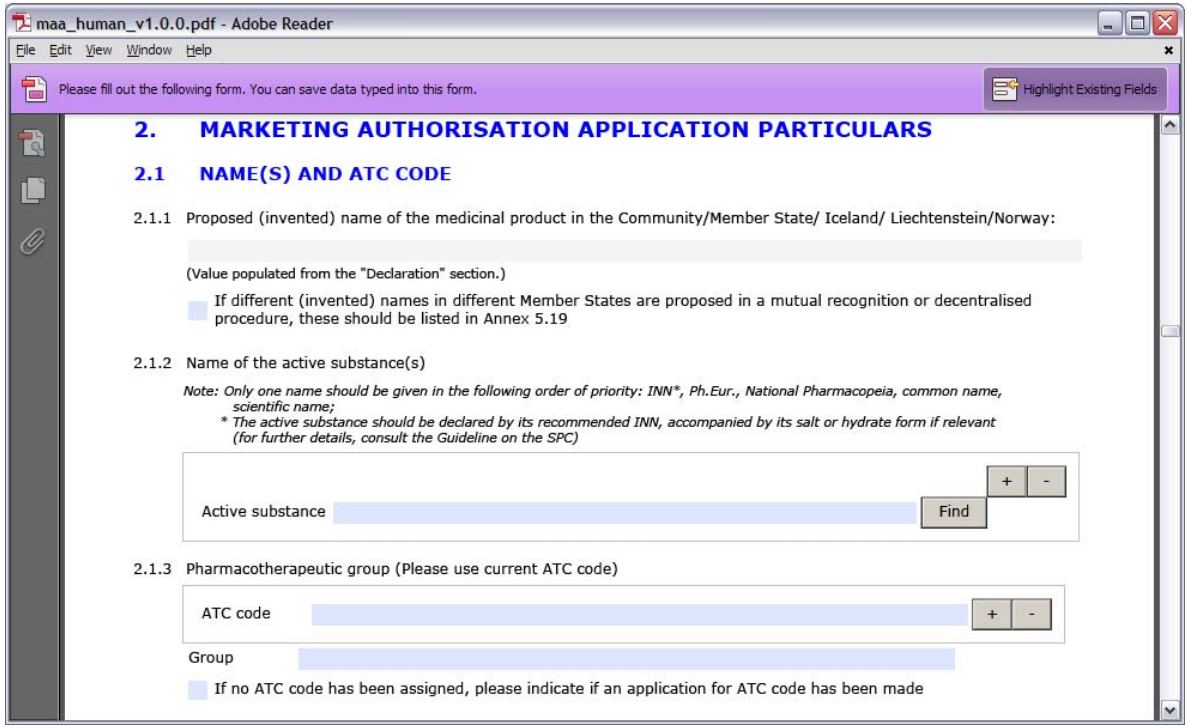
Radio Buttons & Check Boxes



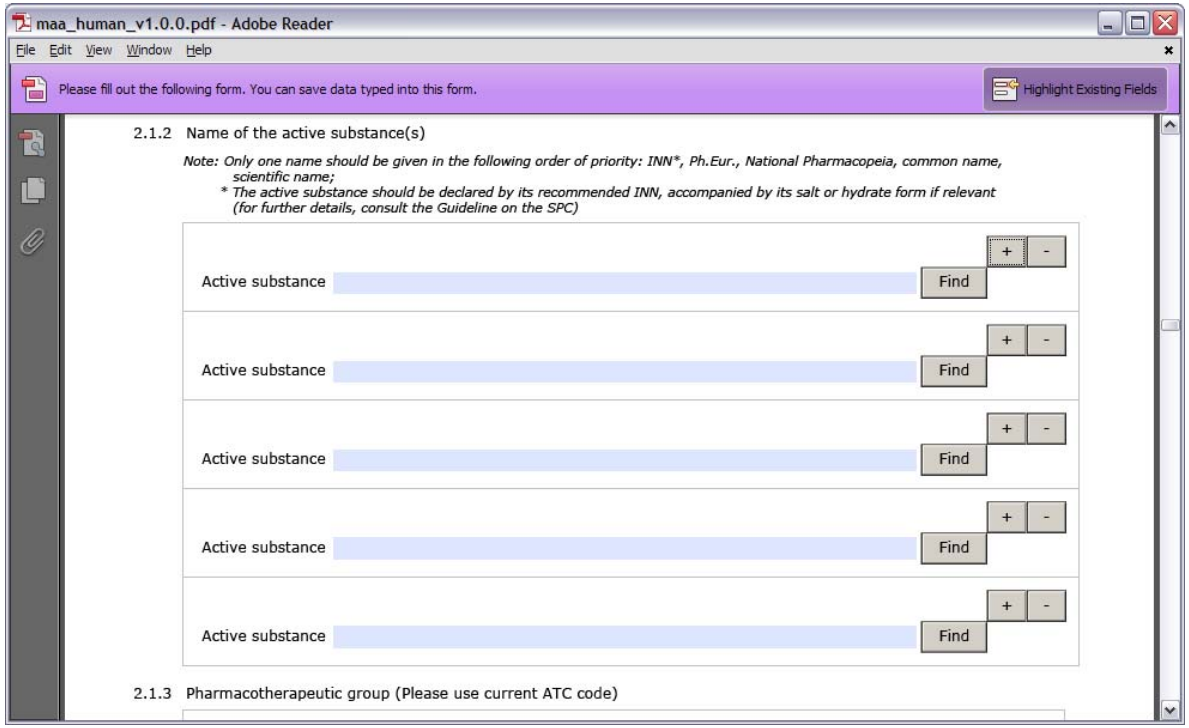
Additional Groups



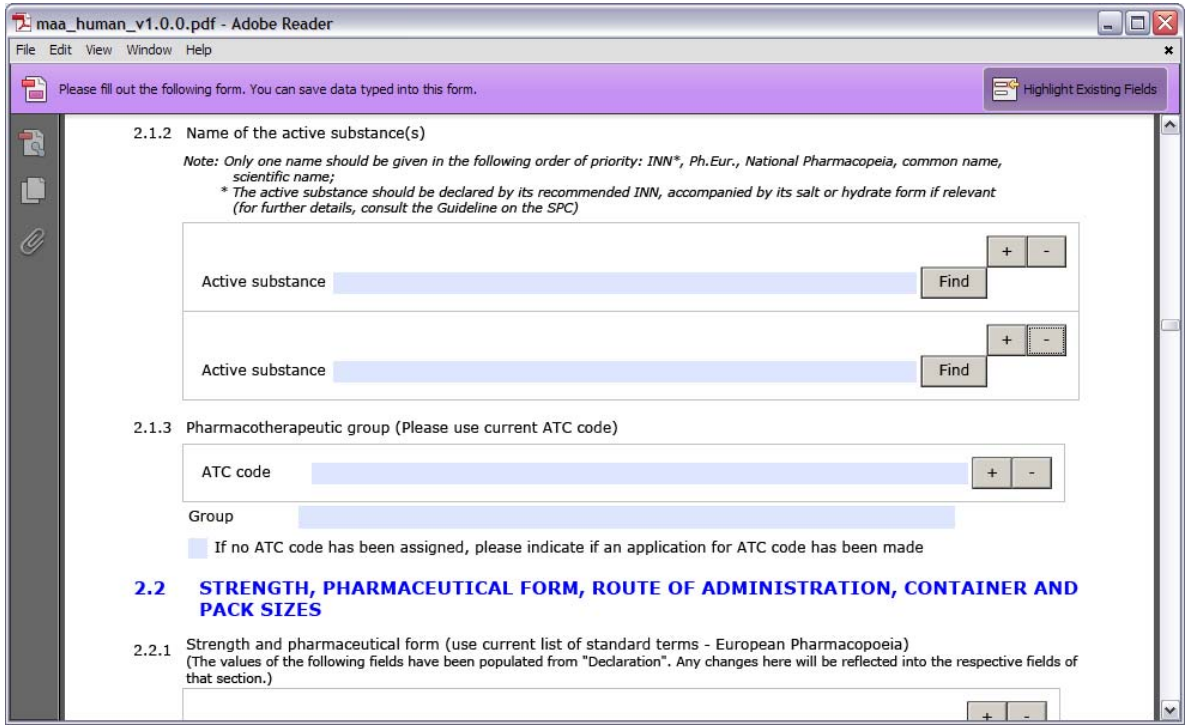
Additional Groups



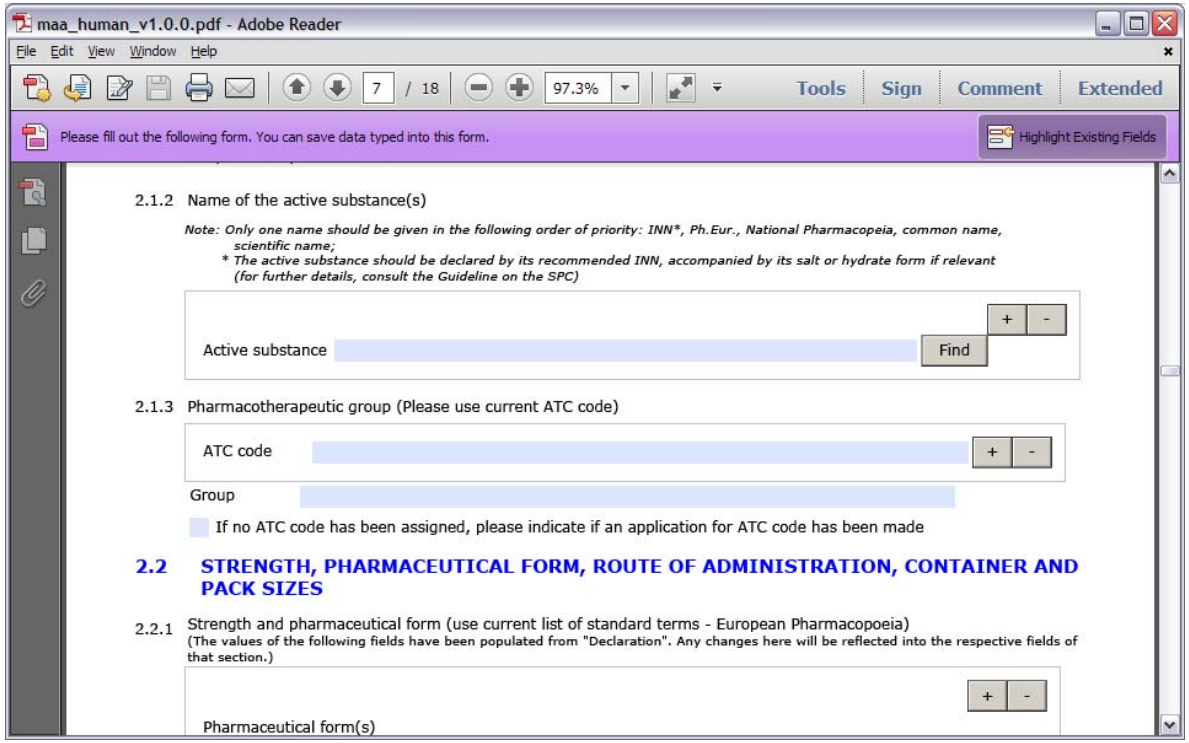
Additional Groups



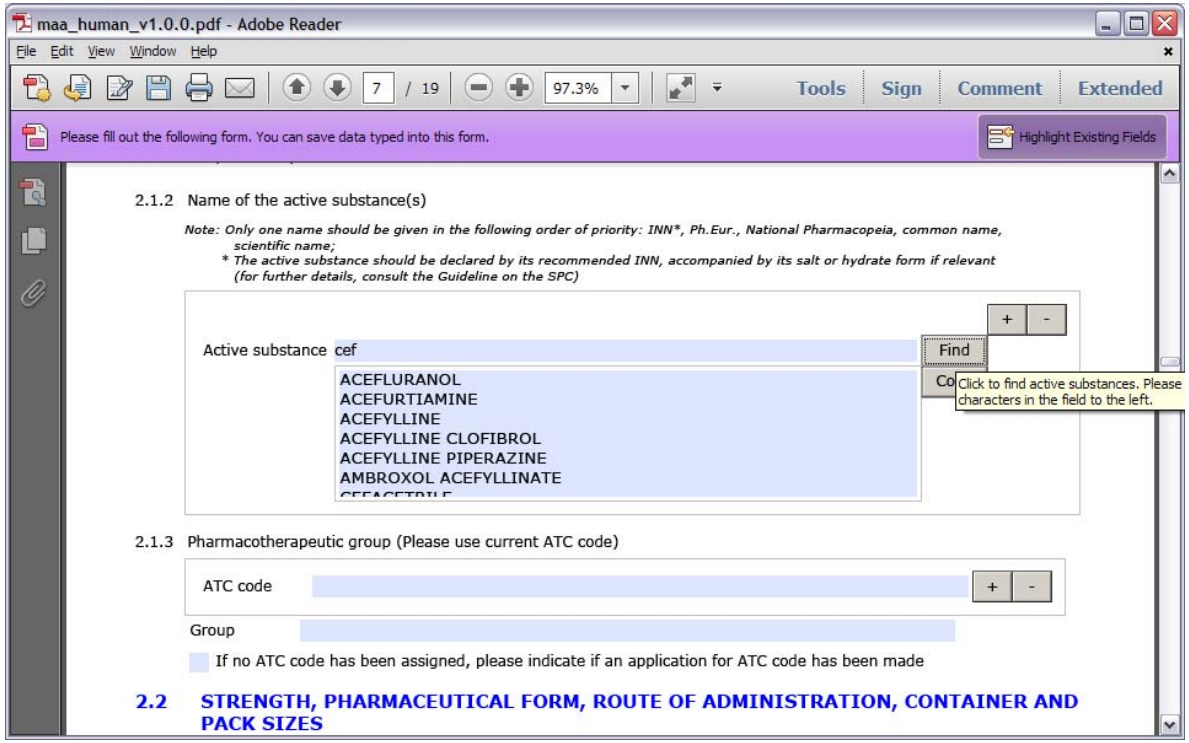
Additional Groups



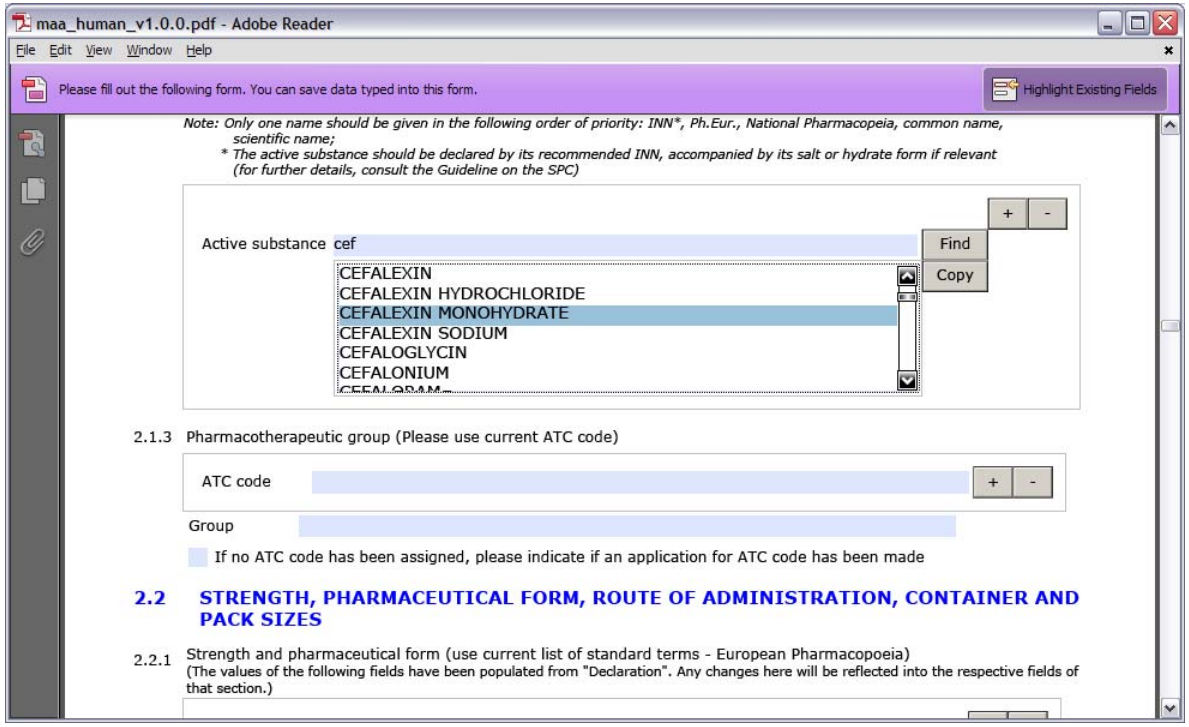
Controlled Terminology Lists



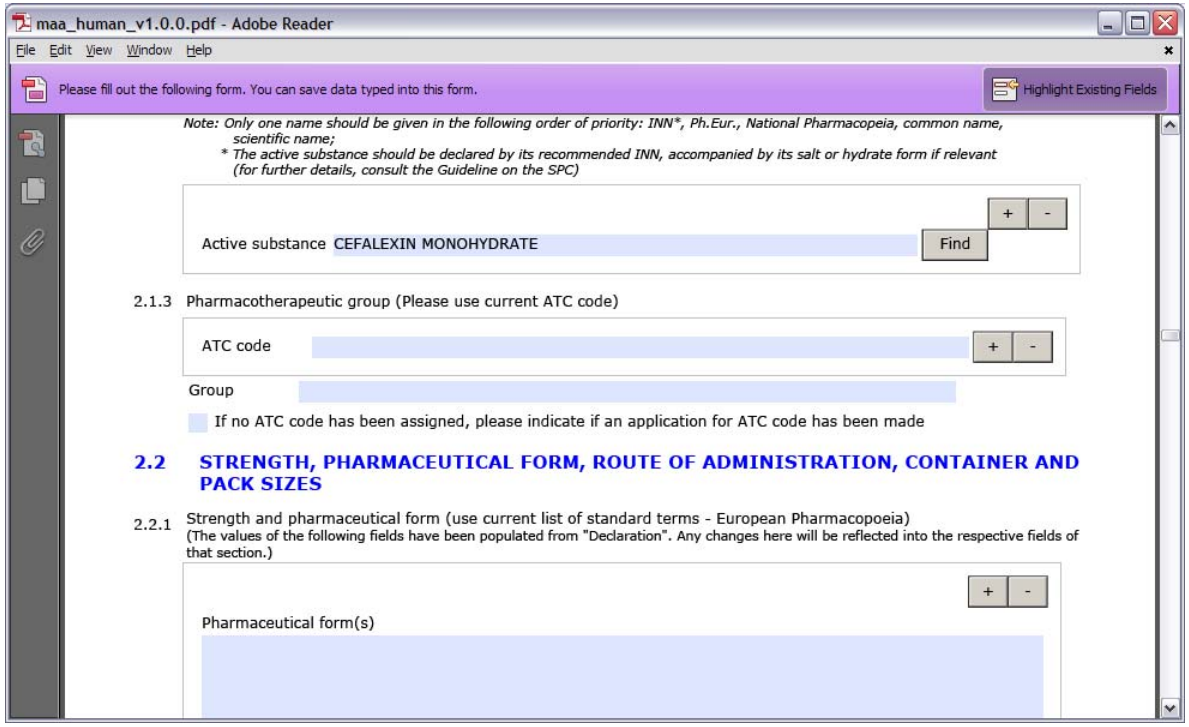
Controlled Terminology Lists



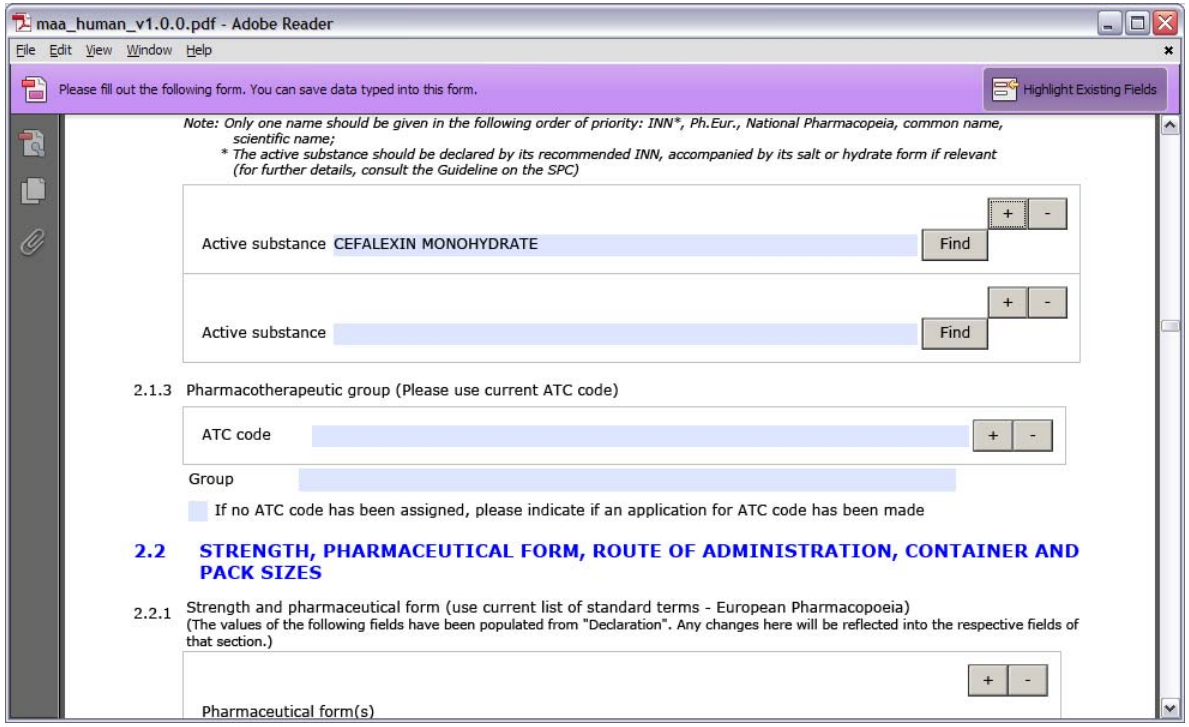
Controlled Terminology Lists



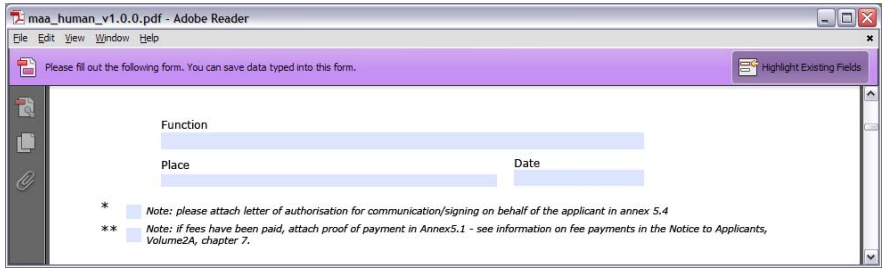
Controlled Terminology Lists

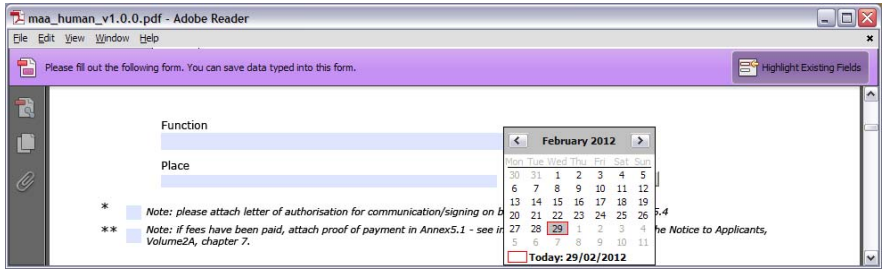


Controlled Terminology Lists



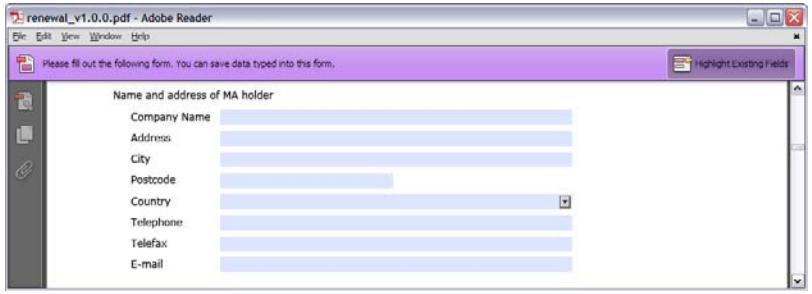
Dates

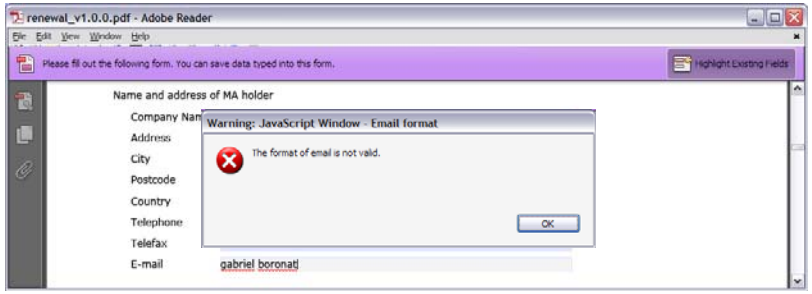

maa_human_v1.0.0.pdf - Adobe Reader
File Edit View Window Help
Please fill out the following form. You can save data typed into this form.
Highlight Existing Fields
Function
Place
Date
* Note: please attach letter of authorisation for communication/signing on behalf of the applicant in annex 5.4
** Note: if fees have been paid, attach proof of payment in Annex5.1 - see information on fee payments in the Notice to Applicants, Volume2A, chapter 7.

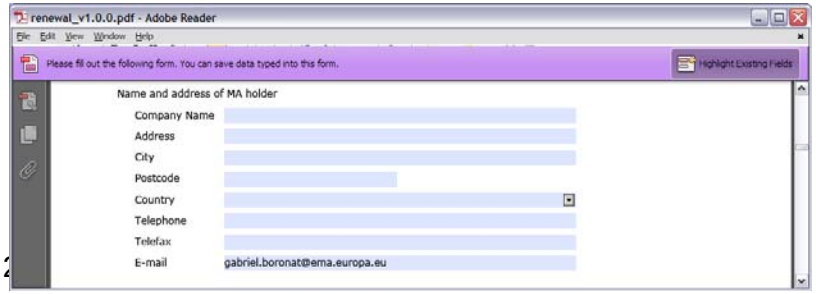

maa_human_v1.0.0.pdf - Adobe Reader
File Edit View Window Help
Please fill out the following form. You can save data typed into this form.
Highlight Existing Fields
Function
Place
February 2012
Today: 29/02/2012
* Note: please attach letter of authorisation for communication/signing on b
** Note: if fees have been paid, attach proof of payment in Annex5.1 - see i
Volume2A, chapter 7.


maa_human_v1.0.0.pdf - Adobe Reader
File Edit View Window Help
Please fill out the following form. You can save data typed into this form.
Highlight Existing Fields
Function
Place
Date
2012-02-29
* Note: please attach letter of authorisation for communication/signing on behalf of the applicant in annex 5.4
** Note: if fees have been paid, attach proof of payment in Annex5.1 - see information on fee payments in the Notice to Applicants, Volume2A, chapter 7.

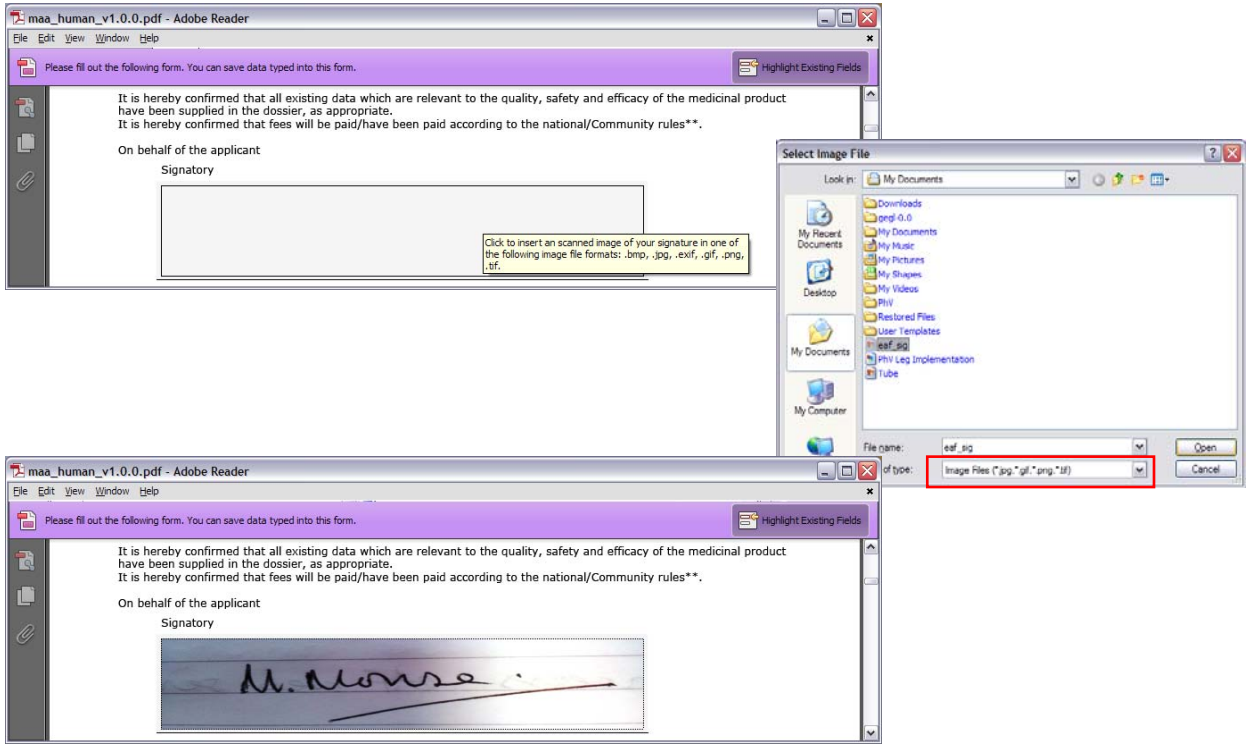
Email Addresses



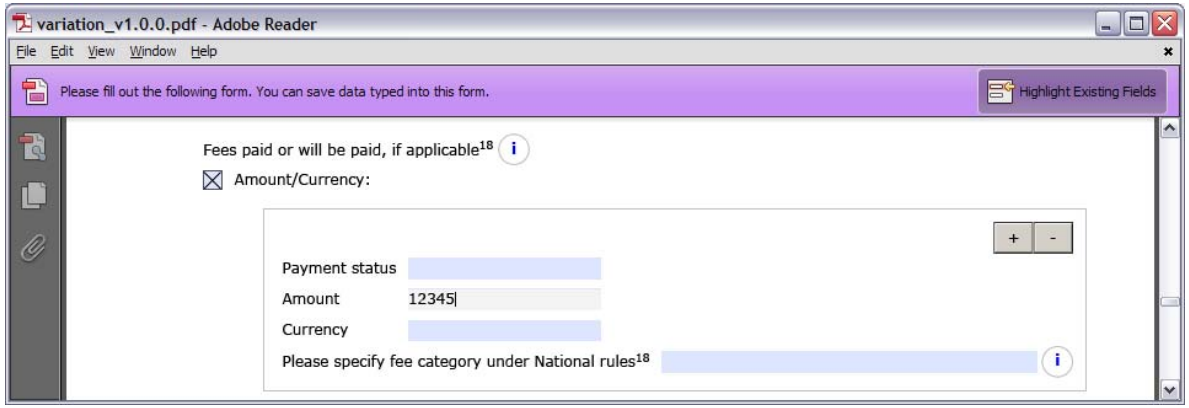




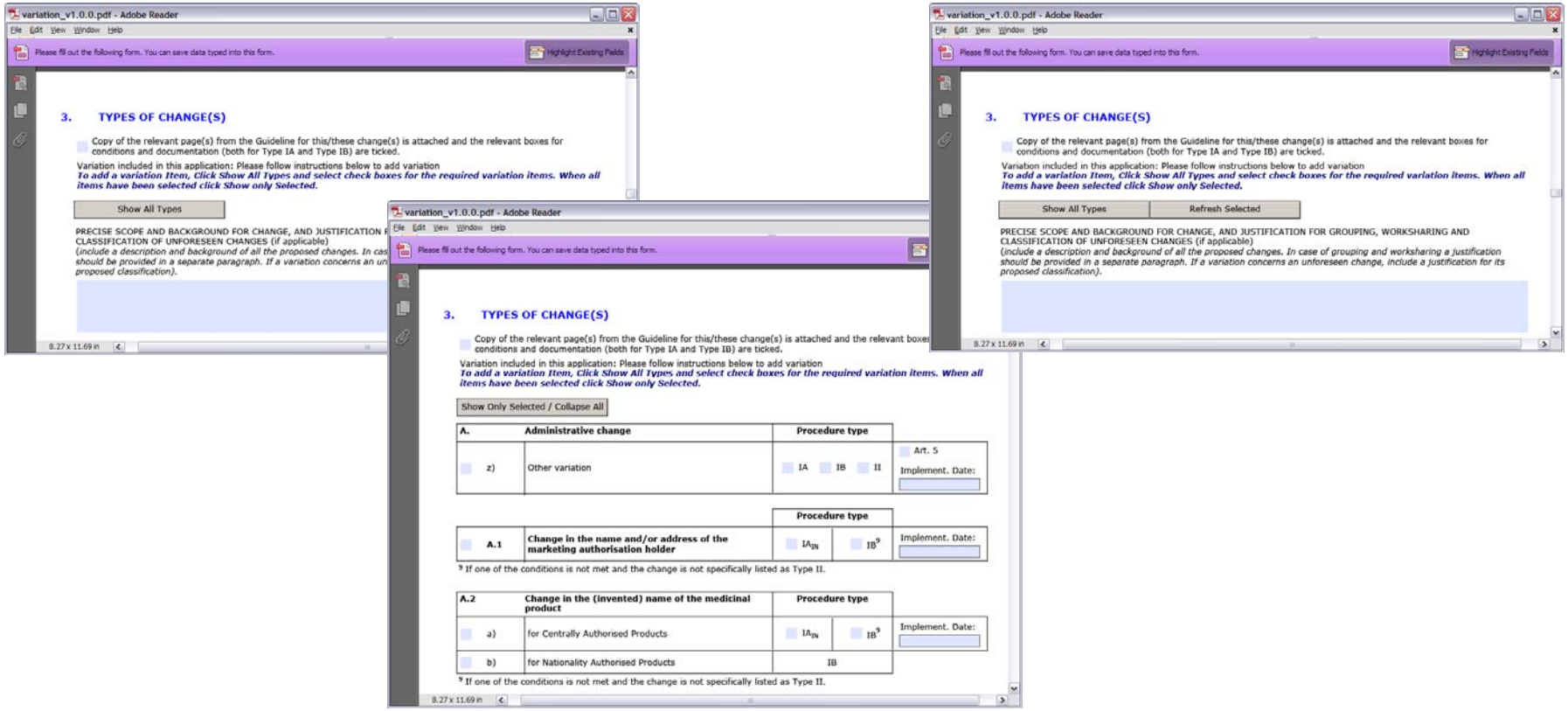
Signatures


maa_human_v1.0.0.pdf - Adobe Reader
File Edit View Window Help
Please fill out the following form. You can save data typed into this form.
Highlight Existing Fields
It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the medicinal product have been supplied in the dossier, as appropriate.
It is hereby confirmed that fees will be paid/have been paid according to the national/Community rules**.
On behalf of the applicant
Signatory
Click to insert an scanned image of your signature in one of the following image file formats: .bmp, .jpg, .exif, .gif, .png, .tif.
Select Image File
Look in: My Documents
Downloads
gegl-0.0
My Documents
My Music
My Pictures
My Shapes
My Videos
PhV
Restored Files
User Templates
eaf_sig
PhV Leg Implementation
Tube
My Recent Documents
Desktop
My Documents
My Computer
File name: eaf_sig
Files of type: Image Files (*.jpg,*.gif,*.png,*.tif)
Open
Cancel
maa_human_v1.0.0.pdf - Adobe Reader
File Edit View Window Help
Please fill out the following form. You can save data typed into this form.
Highlight Existing Fields
It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the medicinal product have been supplied in the dossier, as appropriate.
It is hereby confirmed that fees will be paid/have been paid according to the national/Community rules**.
On behalf of the applicant
Signatory

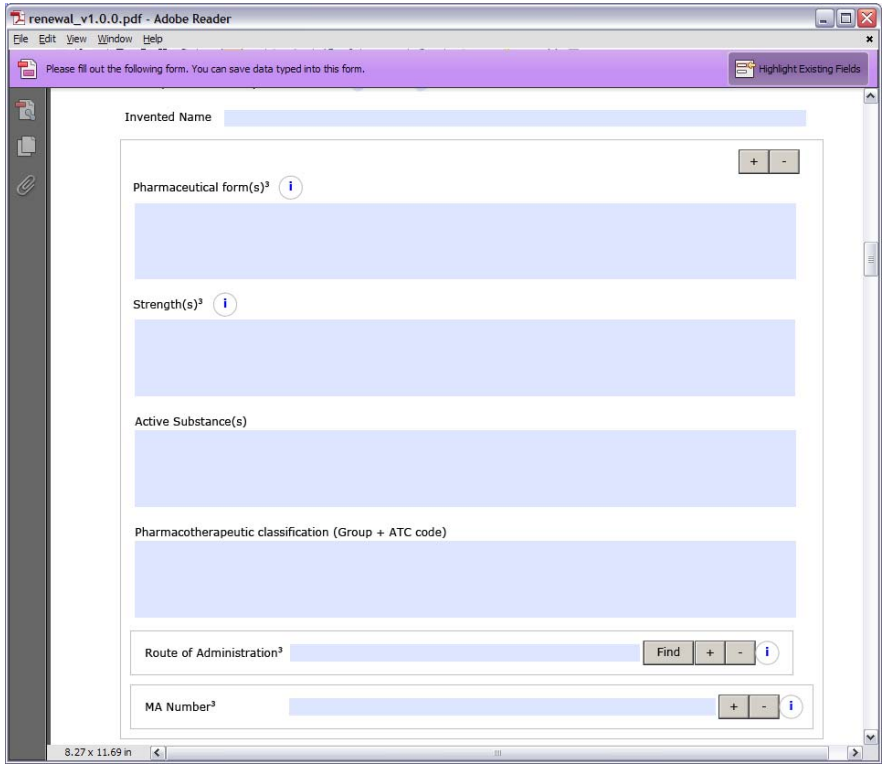
Currency Amounts



Variation Scopes



Substances, Forms & Strengths



Operational Constraints

Attachments – do not use.

Import/export XML – final step in processing only.