

Submission of a DMF/ASMF via eGov Portal

DMF/ASMF should be submitted to Swissmedic electronically whenever possible. In order to enable an efficient and secure transfer, Swissmedic provides a special eGov service.

In order to enable the transfer of DMF/ASMF documents, the marketing authorization holder of the medicinal product provides by e-mail a transfer link to the DMF/ASMF holder that can be used only once. Using this transfer link, the DMF/ASMF holder can transfer the relevant documents to Swissmedic without the marketing authorization holder having access to these data.

This document describes the DMF/ASMF Holder's procedure for transferring documents to Swissmedic.

1. Establish connection via the transfer link

After loading the link sent by the marketing authorization holder, the following view appears (see picture). The following actions must be carried out:

Fill in the fields with * (mandatory fields, 1-3) and continue with "Choose File" (4).

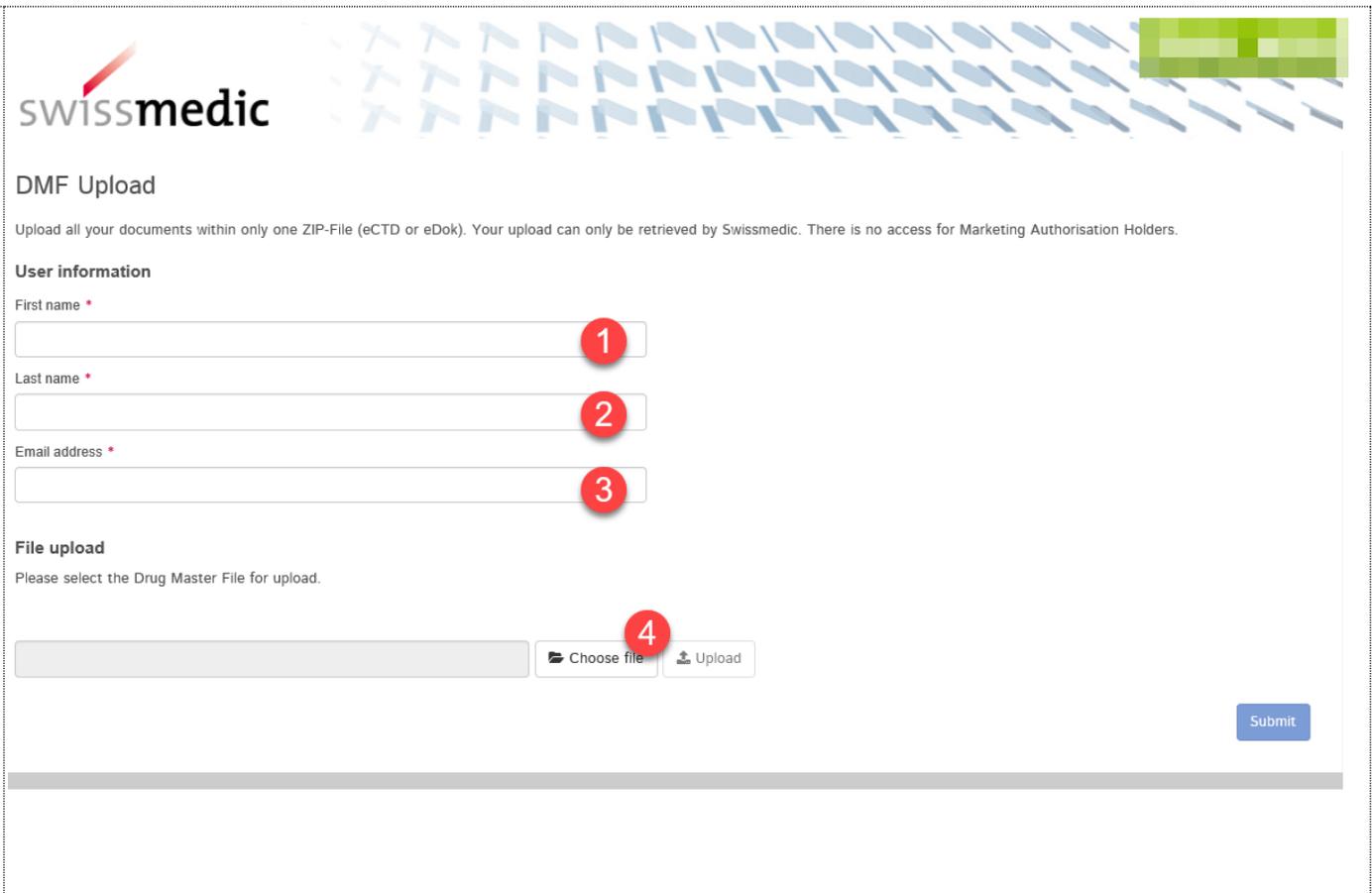
Select DMF/ASMF document on the PC.

ATTENTION: Only documents in eCTD or eDok format can be submitted!

Further information on both formats can be found under the following links:

<https://www.swissmedic.ch/swissmedic/en/home/services/submissions/ectd.html>

<https://www.swissmedic.ch/swissmedic/en/home/services/submissions/paper-submission---edok.html>



DMF Upload

Upload all your documents within only one ZIP-File (eCTD or eDok). Your upload can only be retrieved by Swissmedic. There is no access for Marketing Authorisation Holders.

User information

First name * 1

Last name * 2

Email address * 3

File upload

Please select the Drug Master File for upload.

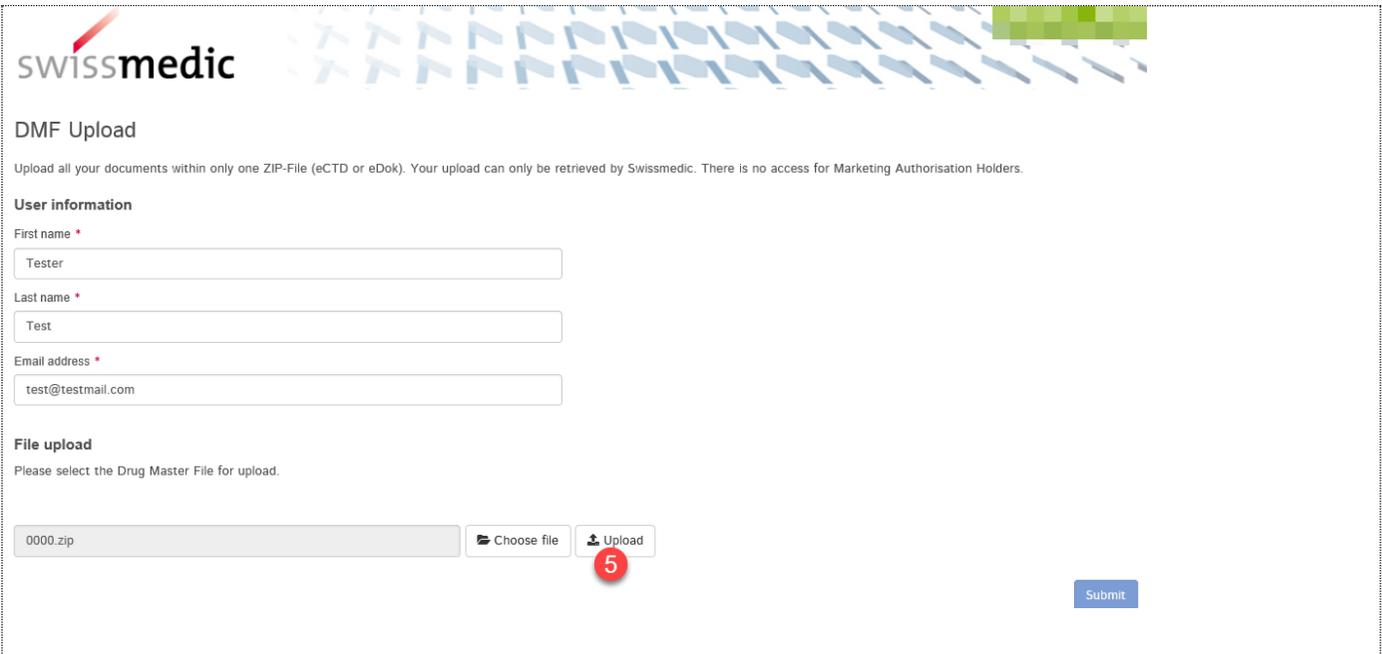
4 Choose file Upload

Submit

2. Upload and transfer of documents

Proceed with «Upload» (5).

As soon as the "Upload" is successfully completed, a green tick appears. With "Submit" (6) the submission can be completed.



SWISSmedic

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User information

First name *

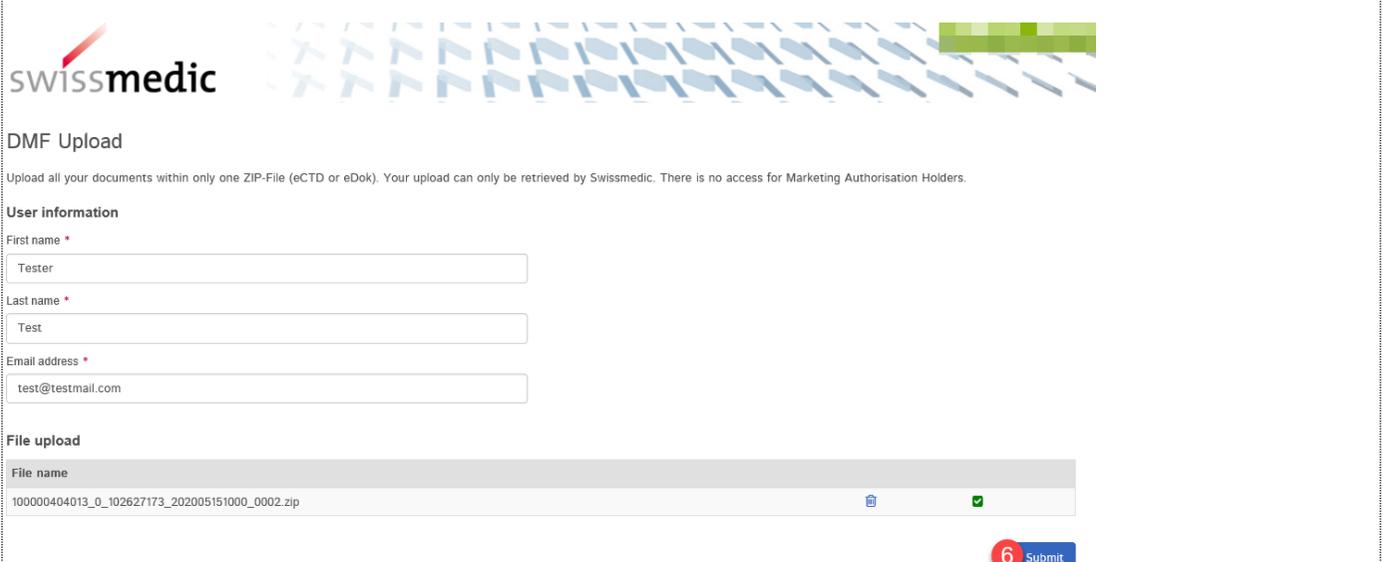
Last name *

Email address *

File upload

Please select the Drug Master File for upload.

5



SWISSmedic

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User information

First name *

Last name *

Email address *

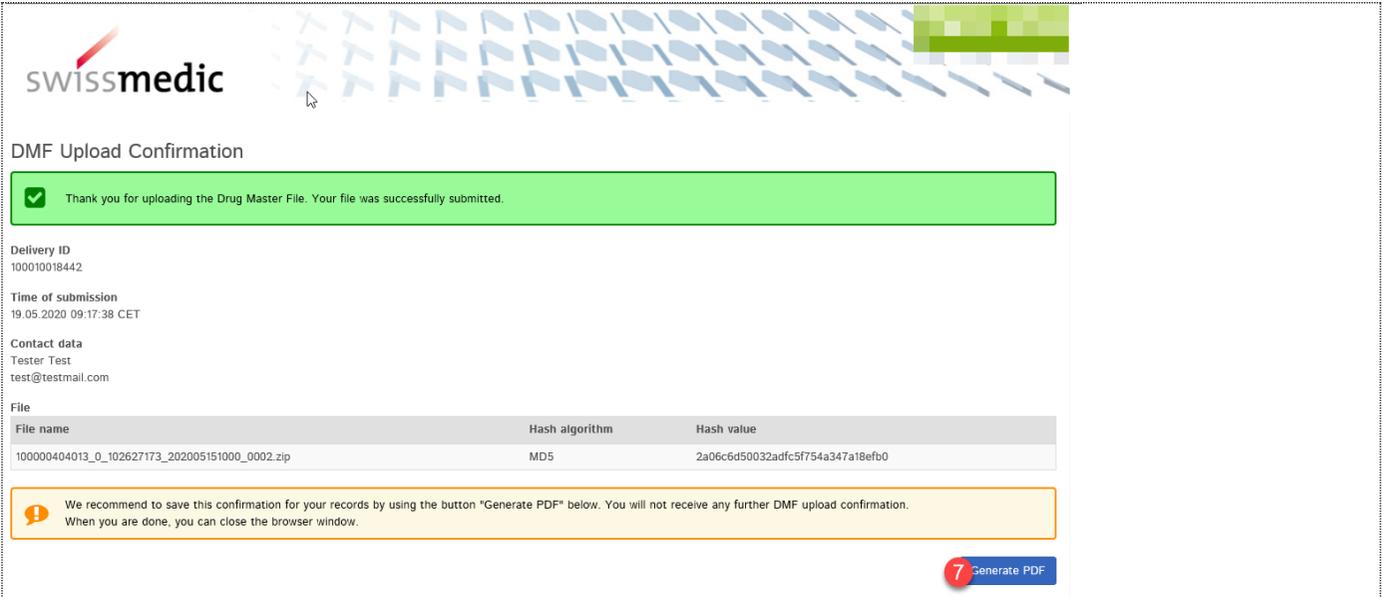
File upload

File name		
100000404013_0_102627173_202005151000_0002.zip	<input type="button" value="Delete"/>	<input checked="" type="checkbox"/>

6

3. Create an upload confirmation

Press "Generate PDF" (7) to receive a confirmation of the upload in PDF format.



The screenshot shows the SWISSmedic website interface for DMF Upload Confirmation. At the top left is the SWISSmedic logo. Below it, the text "DMF Upload Confirmation" is displayed. A green success message box contains a checkmark and the text: "Thank you for uploading the Drug Master File. Your file was successfully submitted." Below this, the following information is listed:

- Delivery ID:** 100010018442
- Time of submission:** 19.05.2020 09:17:38 CET
- Contact data:** Tester Test, test@testmail.com

A table titled "File" shows the following data:

File name	Hash algorithm	Hash value
100000404013_0_102627173_202005151000_0002.zip	MD5	2a06c6d50032adfc5f754a347a18efb0

Below the table, an orange information box with a speech bubble icon contains the text: "We recommend to save this confirmation for your records by using the button 'Generate PDF' below. You will not receive any further DMF upload confirmation. When you are done, you can close the browser window." At the bottom right of the page, there is a blue button with a red circle containing the number 7 and the text "generate PDF".