Guidance on the e-submission of PSURs / ASRs
Tree structure - folder and file naming

The following table gives an overview of documents which <u>can</u> be present in the CTD related to PSUR/ASR submissions. Please note that this is a <u>maximum</u> list, and that not all these documents have to be present in the CTD. However, documents with an asterisk (*) are mandatory.

1. National procedure

Document	Directory	Proposed Filename[1]	Comments
Cover letter*	m1/eu/10-cover/be	be-cover	
Proof of payment	m1/eu/12-form/be	be-proof-of-payment	See circular letter 530
Revised SPC, leaflet[2]	m1/eu/13-pi/131-spclabelpl/be/nl or m1/eu/13-pi/131-spclabelpl/be/fr or m1/eu/13-pi/131-spclabelpl/be/de	be-spc-annotated and/or be-pl-annotated	"annotated" is a variable component. If necessary, the variable part can be extended to clearly identify the document (e.g. be-spc-tablet10mgannotated)
Currently approved SPC, leaflet*	m1/eu/13-pi/135-approved/be	be-approved-spc and/or be-approved-pl	"spc" and "pl" are variable components. If necessary, the variable part can be extended to clearly identify the document (e.g. be-approved-tablet10mgspc)
Information about the clinical expert (CV)	m1/eu/14-expert/143-clinical	clinical	If more than one CV is present in this folder, a variable component can be added to the file name to clearly identify the document (e.g. "clinical-qpbelgium).

---

[1] <u>File names in module 1</u> have a fixed and a variable component. The fixed component is mandatory. The variable component is optional and should be used only if necessary. The variable component, if used, should be a logical name and should be kept as brief and descriptive as possible (without capital letters, separation or hyphens). The first component in the file name is the country code. For documents only applicable for Belgium, the country code will be "be". For documents that apply to more than one member state (in MRP), the country code will be "common".

[2] If a <u>revision of the SPC / leaflet</u> is necessary, arising from the PSUR evaluation, the markting authorisation holder should submit a separate variation application at the same time as the PSUR. If this is not possible, a timetable for submission should be given. This should be clearly mentioned in the cover letter.

Template* PSUR/ASR[3]	m1/eu/additional-data/be	be-additionaldata-template	
Scientific evaluation of the PSUR by the responsible for pharmacovigilance in Belgium*	m1/eu/additional-data/be	be-additionaldata-qpphvigbe	
Responses to questions following the evaluation of previous PSURs/ASRs	m1/eu/responses/be	be-responses	If more than one response document is present in this folder, a variable component can be added to the file name to clearly identify the document (e.g. "be-responses-previouspsur).
Clinical expert statement	m2/25-clin-over	clinical-overview	
PSUR*, ASR*, Summary Bridging Report, line listing, summary tabulation	m5/53-clin-stud-rep/536-postmark-exp	[variable[4]]	The file name is variable. We propose to start with "psur", "asr", "sbr", "ll", "st" followed by the begin and end date (e.g. "psur2004-2005" or "sbr2000-2005").
Literature references	m5/54-lit-ref	[variable[4]]	The file name is variable. The applicant should give a logical name, which allows to easily identify the document.

---

[3] This template can be found on the website of the FAMHP (www.fagg-afmps.be)
[4] File names in module 5: The variable component should be a logical name and should be kept as brief and descriptive as possible (without capital letters, should not start/end with a hyphen and should not contain two successive hyphens)

2. Mutual Recognition Procedure / Decentralised procedure/PSUR work sharing procedure

Document	Directory	Proposed Filename[1]	Comments
Cover letter*	m1/eu/10-cover/common	common-cover	
Table with overview of Marketing Authorisations[5]	m1/eu/10-cover/common	common-cover-overviewma	"overviewma" is a variable component.
Proof of payment	m1/eu/12-form/be	be-proof-of-payment	See circular letter 530
Revised SPC, leaflet[2]	m1/eu/13-pi/131-spclabelpl/common	common-spc-annotated and/or common-pl-annotated	"annotated" is a variable component. If necessary, the variable part can be extended to clearly identify the document (e.g. common-spc-tablet10mgannotated)
Proposed Core Safety Profile[5]	m1/eu/13-pi/131-spclabelpl/common	common-spc-csp	"csp" is a variable component. If necessary, the variable part can be extended to clearly identify the document
Currently approved SPC, leaflet*	m1/eu/13-pi/135-approved/be	be-approved-spc and/or be-approved-pl	"spc" and "pl" are variable components. If necessary, the variable part can be extended to clearly identify the document (e.g. be-approved-tablet10mgspc)
	m1/eu/13-pi/135-approved/common	common-approved-spc and/or common-approved-pl	
Information about the clinical expert (CV)	m1/eu/14-expert/143-clinical	clinical	If more than one CV is present in this folder, a variable component can be added to the file name to clearly identify the document (e.g. "clinical-qpbelgium").
Template* PSUR/ASR[3]	m1/eu/additional-data/be	be-additionaldata-template	
Scientific evaluation of	m1/eu/additional-data/be	be-additionaldata-	

---

[5] Documents requested as part of the PSUR work sharing procedure.

the PSUR by the responsible for pharmacovigilance in Belgium*		qpphvigbe	
Responses to questions following the evaluation of previous PSURs/ASRs	m1/eu/responses/common	common-responses	If more than one response document is present in this folder, a variable component can be added to the file name to clearly identify the document (e.g. "common-responses-previouspsur).
Clinical expert statement	m2/25-clin-over	clinical-overview	
PSUR*, ASR*, Summary Bridging Report, line listing, summary tabulation	m5/53-clin-stud-rep/536-postmark-exp	[variable[4]]	The file name is variable. We propose to start with "psur", "asr", "sbr", "ll", "st" followed by the begin and end date (e.g. "psur2004-2005" or "sbr2000-2005").
Literature references	m5/54-lit-ref	[variable[4]]	The file name is variable. The applicant should give a logical name, which allows to easily identify the document.