Guidance on the e-submission of Renewal of a national Marketing Authorisation

Tree structure - folder and file naming

Document	Directory	Proposed Filename[1]	Comments
Cover letter	m1/eu/10-cover/be	be-cover	
Table of content	m1/eu/11		
Renewal application form with the following annexes:	m1/eu/12-form/be	be-form	
A list of all authorised product presentations for which renewal is sought in tabular format	m1/eu/12-form/common	common-form-61authorisedpresentationsforrenewal	
Feeform	m1/eu/12-form/common	common-form-62proofpayment	
Details on contact persons	m1/eu/12-form/common	common-form-63detailsofcontactpersons	
• Qualified person in Belgium for Pharmacovigilance			
• Contact person in the EEA with overall responsibility for products defects and recalls			
• Contact person for scientific information in Belgium in charge of information about the medicinal product			
• List of EEA Member States where the product is on the market and indicating for each country which presentations are marketed and the launch date	m1/eu/12-form/common	common-form-64marketingstatusandstrenghts	
• Chronological list of all post-authorisation submissions since	m1/eu/12-form/common	common-form-65mahrequirements	

[1] File names in module 1 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).

grant of the Marketing authorisation or last renewal: a list of all approved or pending Type IA/IB and Type II variations, Extensions, Art 61(3) Notifications, USR, giving the procedure number (where applicable), date of submission, date of approval (if approved) and brief description of the change.			
• Revised list of all remaining Follow-up measures/post-authorization commitments	m1/eu/12-form/common	common-form-66chronologicallistoffollow-upletters	
• A statement, or when available, a certificate of GMP compliance (except for the products manufactured in Belgium), not more than three years old, for the manufacturer(s) of the medicinal product listed in the application issued by an EEA competent authority or MRA partner authority. A reference to the Community EudraGMP database will suffice, once this is available	m1/eu/12-form/common	common-form-67certificateofgmpcompliance	
• For manufacturing sites of the medicinal product not located in the EEA or in the territory of an MRA partner, a list of the most recent GMP inspections carried out by other authorities indicating the date, inspection team and outcome	m1/eu/12-form/common	common-form-68manufacturingsitesnotlocatedineea	
• A declaration by the Qualified Person (QP) of each of the manufacturing authorisation holders (i.e. located in the EEA) listed in the application form where the active substance(s) is (are) used as a starting material, that the active substance(s) is (are) manufactured in accordance with the guidelines on good manufacturing practice for starting materials.	m1/eu/12-form/common	common-form-69decqualifiedma	
Revised SPC, leaflet and labelling in case of modification	m1/eu/13-pi/131-spclabelpl/be/nl	be-spc-annotated and/or	“annotated” is a variable component. If necessary, the

	or m1/eu/13-pi/131-spclabelpl/be/fr or m1/eu/13-pi/131-spclabelpl/be/de	be-pl-annotated	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 quality expert (CV)	m1/eu/14-expert/141-quality	quality	
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).
Approved MA	m1/eu/additional-data/be	be-additionaldata-ammapproved	
New MA	m1/eu/additional-data/be	be-additionaldata-ammproposed	
Quality expert statement	m2/23-qos	quality-overall-summary	
Clinical expert statement and/or scientific evaluation by the responsible for pharmacovigilance in Belgium	m2/25-clin-over	clinical-overview	
Reports of Post-marketing experience (Periodic Safety Update	m5/53-clin-stud-rep/536-	*[variable]*	The file name is variable. We

Report and Summary Bridging Report if applicable)	postmark-exp		propose to start with “psur”, “sbr”, followed by the begin and end date (e.g. “psur2004-2005” or “sbr2000-2005”).