



EVALUATIONS AND REGISTRATION DIVISION

DOCUMENT SUBMISSION CHECKLIST

A completed copy of this checklist should be included in the dossier. All PDF documents should be in text selectable format.

1.0 Application Information (this should be completed for all applications)

Type of application (new application/ response/ variation/ Zazibona)	
Nature of medicine (human allopathic/ veterinary/ complementary)	
Proprietary / Product Name	
INN, strength, dosage form	
Applicant	

2.0 New application checklist should be included in Module 1

Complete the relevant sections below.

	Submitted? <i>Please tick if submitted</i>	
	Applicant	MCAZ
Cover letter which should include: i. Evaluation pathway (Zazibona, expedited, normal or WHO CRP) ii. Name and contact details of local representative/ contact person		
Letter of authorization to be the local representative for the applicant. <i>Letter should specify whether you are representing the applicant for that specific product, a specified product range or all products from that applicant.</i> This letter is to be submitted when the communication concerning the local representative is being made for the first time.		
Signed and dated MC8 Form/ CM1		
EVRF 32 Quotation Form		
Proof of payment		
QIS in word format (CD/ USB stick) *		
QOS in word format (CD/ USB stick) *		
CD/ USB stick		

3.0 Variation applications checklist

	Submitted	
	Applicant	MCAZ
Cover letter which should include: <ul style="list-style-type: none"> i. File number ii. Nature of variation iii. Name and contact details of local rep/ contact person 		
Signed and dated MC8 Form		
EVRF 32 Quotation Form		
Proof of payment		
EVRF56 Variation application form**		
QIS in word format (CD/ USB stick) *		
CD/ USB stick		

4.0 Response to applications checklist

	Submitted	
	Applicant	MCAZ
Cover letter which should include: <ul style="list-style-type: none"> i. Evaluation pathway for new apps ii. Nature of variation for variation applications iii. Name and contact details of local rep/ contact person iv. Application number 		
MCAZ query letter the response is addressing		
Signed and dated MC8 Form		
CD/ USB stick		

**This should be provided in word format in the CD/ USB Stick. Not Applicable for complementary medicines.*

*** Applicable for human allopathic medicines*