SAHPRA Section 21 Named Patient Application Checklist

Section	Field	Mandatory?	If not applicable to my situation what should I do?	
A. Particulars of the Applicant	Title	Mandatory		☐
A. Particulars of the Applicant	Full Name and Initials	Mandatory		☐
A. Particulars of the Applicant	Surname	Mandatory		☐
A. Particulars of the Applicant	HPCSA Registration Number	Mandatory	Please enter the registration number applicable to your professional board or council. If none, please enter 'N/A' only as a last resort.	☐
A. Particulars of the Applicant	HPCSA Registration Certificate (File upload)	Mandatory	Please upload any applicable proof of profession or registration with a council	☐
A. Particulars of the Applicant	Registered Qualifications	Mandatory		☐
A. Particulars of the Applicant	Registered Specialty	Mandatory	If none, please enter 'N/A' only as a last resort.	☐
A. Particulars of the Applicant	Practice Number (BHF No)	Mandatory	If none, please enter 'N/A' only as a last resort.	☐
A. Particulars of the Applicant	Cellular Phone Number	Mandatory		☐
A. Particulars of the Applicant	Site Address (1)	Mandatory		☐
A. Particulars of the Applicant	Add Address	Optional		☐
A. Particulars of the Applicant	Contact Person(s) (1)	Mandatory		☐
A. Particulars of the Applicant	Cellular Phone Number (Contact)	Mandatory	Please enter applicants details again if no other contacts required	☐
A. Particulars of the Applicant	Email Address (Contact)	Mandatory	Please enter applicants details again if no other contacts required	☐
A. Particulars of the Applicant	Add Contact	Optional		☐
B. Licensed Importer and Distributor Details	Select Licensed Importer	Mandatory	Select options or please type the missing importer in text only as a last resort.	☐
B. Licensed Importer and Distributor Details	Status (read-only)	Auto-filled		☐
B. Licensed Importer and Distributor Details	SAHPRA License Number	Optional (if applicable)		☐
B. Licensed Importer and Distributor Details	SMF Number	Mandatory	Select options or please type the missing number in text only as a last resort.	☐
B. Licensed Importer and Distributor Details	Physical Site Address	Mandatory		☐

Section	Field	Mandatory?	If not applicable to my situation what should I do?	
B. Licensed Importer and Distributor Details	Select Licensed Distributor	Optional (if applicable)		☐
B. Licensed Importer and Distributor Details	Select Name (Distributor)	Optional (if applicable)		☐
B. Licensed Importer and Distributor Details	Status (Distributor)	Optional (if applicable)		☐
B. Licensed Importer and Distributor Details	SAHPRA License Number (Distributor)	Optional (if applicable)		☐
B. Licensed Importer and Distributor Details	SMF Number (Distributor)	Optional (if applicable)		☐
B. Licensed Importer and Distributor Details	Physical Site Address (Distributor)	Optional (if applicable)		☐
C. Particulars of the Patient	Title	Mandatory		☐
C. Particulars of the Patient	First Name	Mandatory		☐
C. Particulars of the Patient	Surname	Mandatory		☐
C. Particulars of the Patient	Age	Mandatory		☐
C. Particulars of the Patient	Gender	Mandatory		☐
C. Particulars of the Patient	Weight (Kg)	Mandatory		☐
C. Particulars of the Patient	Height (Cm)	Mandatory		☐
C. Particulars of the Patient	Residential Address	Mandatory		☐
C. Particulars of the Patient	Occupation	Mandatory		☐
C. Particulars of the Patient	Telephone Number (Office)	Mandatory	If none enter Cellular Number	☐
C. Particulars of the Patient	Cellular Number	Mandatory		☐
C. Particulars of the Patient	Proof of Identification (File upload)	Optional (if applicable)	Any proof of identification of person	☐
C. Particulars of the Patient	Diagnosis (ICD-11)	Mandatory	Select XS5P - 9 Not applicable	☐
C. Particulars of the Patient	Severity	Mandatory	Select Not Known or N/A	☐

Section	Field	Mandatory?	If not applicable to my situation what should I do?	
C. Particulars of the Patient	Staging	Mandatory	Select Not Known or N/A	☐
C. Particulars of the Patient	Prognosis	Mandatory	Select Not Known or N/A	☐
C. Particulars of the Patient	Treatment Regimen	Mandatory	Select any	☐
C. Particulars of the Patient	Details of Current Treatment	Mandatory	If unknown, please enter 'N/A' only as a last resort.	☐
C. Particulars of the Patient	Add Diagnosis/Treatment	Optional		☐
C. Particulars of the Patient	- Concomitant Disease/s Diagnosis (ICD-11)	Mandatory	Select XS5P - 9 Not applicable	☐
C. Particulars of the Patient	- Severity	Mandatory	Select Not Known or N/A	☐
C. Particulars of the Patient	- Staging	Mandatory	Select Not Known or N/A	☐
C. Particulars of the Patient	- Prognosis	Mandatory	Select Not Known or N/A	☐
C. Particulars of the Patient	- Treatment Regimen	Mandatory	Select any	☐
C. Particulars of the Patient	- Details of Current Treatment	Mandatory	If unknown, please enter 'N/A' only as a last resort.	☐
C. Particulars of the Patient	Informed Consent (File upload)	Mandatory		☐
D. Unregistered Medicine	INN Name	Mandatory	If not found select 'Manual Override' as the option	☐
D. Unregistered Medicine	Manufacturer	Optional (if applicable)		☐
D. Unregistered Medicine	API Manufacturer Number Type	Optional (if applicable)		☐
D. Unregistered Medicine	Number	Optional (if applicable)		☐
D. Unregistered Medicine	Search Name (Manufacturer)	Optional (if applicable)		☐
D. Unregistered Medicine	SMF Number	Optional (if applicable)		☐
D. Unregistered Medicine	GMP Approval Number	Optional (if applicable)		☐
D. Unregistered Medicine	Approval Date	Optional (if applicable)		☐

Section	Field	Mandatory?	If not applicable to my situation what should I do?	
D. Unregistered Medicine	Regulatory Body Name	Optional (if applicable)		☐
D. Unregistered Medicine	Upload GMP Certificate	Optional (if applicable)		☐
D. Unregistered Medicine	Proposed Name	Mandatory		☐
D. Unregistered Medicine	Strength	Mandatory	For unfinished products imported please list all strengths with a'/' separating them	☐
D. Unregistered Medicine	Unit of Measurement	Mandatory	Of the final product	☐
D. Unregistered Medicine	Route of Administration	Mandatory	Of the final product	☐
D. Unregistered Medicine	Dosage Form	Mandatory	Of the final product	☐
D. Unregistered Medicine	Pack Size	Mandatory		☐
D. Unregistered Medicine	Patient Pack Selling Price	Mandatory	If No selling price or unknown enter '0.00'	☐
D. Unregistered Medicine	Upload Prescription	Mandatory		☐
D. Unregistered Medicine	Upload PI/PIL	Mandatory		☐
D. Unregistered Medicine	Dosage Unit	Mandatory		☐
D. Unregistered Medicine	Dosage Interval	Mandatory		☐
D. Unregistered Medicine	Duration of Treatment	Mandatory	If there is no duration of treatment and should be given immediately, please select the 'Stat' option in Dosage Interval	☐
D. Unregistered Medicine	Registered / Unregistered	Optional (if applicable)		☐
D. Unregistered Medicine	Select Country	Optional (if applicable)		☐
D. Unregistered Medicine	Registered Country	Optional (if applicable)		☐
D. Unregistered Medicine	NRA Name	Optional (if applicable)		☐
D. Unregistered Medicine	NRA Full Name	Optional (if applicable)		☐
D. Unregistered Medicine	Search SAHPRA Medicines Registry	Mandatory		☐

Section	Field	Mandatory?	If not applicable to my situation what should I do?	
D. Unregistered Medicine	Reason for Not Using SAHPRA Product	Mandatory		☐
D. Unregistered Medicine	Upload Supporting Docs	Optional (if applicable)		☐
Additional Supporting Documents (Attach in Supporting Documents section based on application)	Additional Supporting Documents (Attach in Supporting Documents section based on application)	Additional Supporting Documents (Attach in Supporting Documents section based on application)	Additional Supporting Documents (Attach in Supporting Documents section based on application)	
E. Supporting Documentation	Manufacturing License	Optional (if applicable)		☐
E. Supporting Documentation	GMP Certificate	Optional (if applicable)		☐
E. Supporting Documentation	Product Insert (PI)	Optional (if applicable)		☐
E. Supporting Documentation	Motivation Letter	Optional (if applicable)		☐
E. Supporting Documentation	Peer-Reviewed Articles	Optional (if applicable)		☐
E. Supporting Documentation	Dosing Evidence	Optional (if applicable)		☐
E. Supporting Documentation	MC & S Reports	Optional (if applicable)		☐
E. Supporting Documentation	Out-of-stock Letter	Optional (if applicable)		☐
E. Supporting Documentation	Discontinuation Letter	Optional (if applicable)		☐
E. Supporting Documentation	Cultivation Licence	Optional (if applicable)		☐
E. Supporting Documentation	COA / Professional Info	Optional (if applicable)		☐
E. Supporting Documentation	PIL	Optional (if applicable)		☐
E. Supporting Documentation	Target Product Profile	Optional (if applicable)		☐
E. Supporting Documentation	Investigational Product Brochure	Optional (if applicable)		☐
E. Supporting Documentation	Clinical Study Reports	Optional (if applicable)		☐
E. Supporting Documentation	Clinical Development Plan	Optional (if applicable)		☐
E. Supporting Documentation	Meta-analyses	Optional (if applicable)		☐

Section	Field	Required?	If not applicable to my situation what should I do?	
E. Supporting Documentation	Risk Management Plan	Optional (if applicable)		☐
E. Supporting Documentation	Public Assessment Reports	Optional (if applicable)		☐
E. Supporting Documentation	Country-specific Documents	Optional (if applicable)		☐
E. Supporting Documentation	Access Program Pre-Approval Form	Optional (if applicable)		☐