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Section	Section Title	Element	Comments
1.0	Correspondence	m1-0-application-letter	Changed to Parent-element
1.0.1	Letter of Application	m1-0-1-application-letter	Moved to Sub-element
1.0.2	Note to Evaluator	m1-0-2-note-to-evaluator	New
1.0.3	Correspondence from SAHPRA	m1-0-3-correspondence-from-authority	New
1.0.4	Response to SAHPRA Request	m1-0-4-response-to-authority	New
1.0.5	Meeting Information	m1-0-5-meeting-info	New
1.2	**Application**	**m1-2-application**	**Unchanged**
1.2.1	Application Form	m1-2-1-application-form	Unchanged
1.2.2	Annexes	m1-2-2-annexes	Unchanged
1.2.2.1	Proof of Payment	m1-2-2-1-proof-of-payment	Unchanged
1.2.2.2	Letter of Authorisation	m1-2-2-2-letter-of-authorisation	Unchanged
1.2.2.3	Dossier Product Batch Information	m1-2-2-3-dossier-product-batch-information	Unchanged
1.2.2.4	Electronic Copy Declaration	m1-2-2-4-electronic-copy-declaration	Unchanged
1.2.2.5	Curriculum Vitae of the Person Responsible for Pharmacovigilance	m1-2-2-5-cv-pharmacovigilance	Unchanged
1.2.2.6	API Change Control	m1-2-2-6-api-change-control	Unchanged
1.2.2.7	EMA Certificate for a Vaccine Antigen Master File (VAMF)	m1-2-2-7-vamf-certificate	Unchanged
1.2.2.8	EMA Certificate for a Plasma Master File (PMF)	m1-2-2-8-pmf-certificate	Unchanged
1.2.2.9	Declaration of Sameness for Replicas and Clones	m1-2-2-9-declaration-sameness	New
1.2.2.10	Letter of Permission from HCR for Replica	m1-2-2-10-letter-permission-hcr	New
1.2.2.A	Additional Annexes	m1-2-2-a-additional-annexes	New
1.2.3	Change in Applicant	m1-2-3-change-in-applicant	New
1.2.3.1	Letter of Authorisation from Product Owner to New Registrant	m1-2-3-1-loa-from-prod-owner	New
1.2.3.2	Written Confirmation of Hand-over of Dossier	m1-2-3-2-confirmation-of-hand-over	New
1.2.4	Patent Declaration	m1-2-4-patent-declaration	New
1.2.5	Checklists, Validation Templates	m1-2-5-checklists-val-templates	Moved from former 1.8
1.2.A	Additional Administrative Information	m1-2-a-additional-admin-info	New
1.3	**South African Product Information**	**m1-3-za-labelling-packaging**	**Change in Title**
1.3.1	South African Professional Information	m1-3-1-sapi	Change in Title
1.3.1.1	Professional Information (PI)	m1-3-1-1-pi	Change in Title
1.3.1.1.1	PI - Approved	m1-3-1-1-1-pi-approved	Moved to Sub-element
1.3.1.1.2	PI - Clean	m1-3-1-1-2-pi-clean	Moved from former 1.5
1.3.1.1.3	PI - Annotated	m1-3-1-1-3-pi-annotated	Moved from former 1.5
1.3.1.2	Standard References	m1-3-1-2-stdrefs	Changed to Parent-element
1.3.1.2.1	Reference Product - Local	m1-3-1-2-1-ref-prod-local	New
1.3.1.2.2	Other References	m1-3-1-2-2-other-refs	Moved to Sub-element
1.3.2	Patient Information Leaflet (PIL)	m1-3-2-pil	Changed to Parent-element
1.3.2.1	PIL - Approved	m1-3-2-1-pil-approved	Moved to Sub-element
1.3.2.2	PIL - Clean	m1-3-2-2-pil-clean	Moved from former 1.5
1.3.2.3	PIL - Annotated	m1-3-2-3-pil-annotated	Moved from former 1.5

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1.3.3	Labels	m1-3-3-labels	Changed to Parent-element
1.3.3.1	Labels - Approved	m1-3-3-1-labels-approved	Moved to Sub-element
1.3.3.2	Labels - Clean	m1-3-3-2-labels-clean	New
1.3.3.3	Labels - Annotated	m1-3-3-3-labels-annotated	New
1.3.4	Braille	m1-3-4-braille	Unchanged
1.3.5	Foreign Prescribing and Patient Information	m1-3-5-foreign-prescribing-pat-info	Moved from 1.10.3
1.3.6	Artwork and Samples	m1-3-6-artwork-samples	New
1.3.6.1	Statement Confirming Submission of Samples	m1-3-6-1-statement-of-samples	New
1.3.6.2	Artwork and Pictures of Samples	m1-3-6-2-artwork-pics-of-samples	New
1.3.6.3	Batch Manufacturing Record of the Sample	m1-3-6-3-batch-of-samples	Moved from 1.7.10.2
1.3.6.4	CoA of the Sample	m1-3-6-4-coa-samples	Moved from 1.7.10.3
1.4	**Information about the Experts**	**m1-4-expert-information**	**Unchanged**
1.4.1	Quality	m1-4-1-quality	Unchanged
1.4.2	Nonclinical	m1-4-2-non-clinical	Unchanged
1.4.3	Clinical	m1-4-3-clinical	Unchanged
1.5	**Specific Requirements for different Types of Applications**	**m1-5-specific-requirements**	**Unchanged**
1.5.1	Literature Based Submissions	m1-5-1-literature-based	Unchanged
1.5.2	Amendments/Variations	m1-5-2-amendment	Unchanged
1.5.2.1	Tabulated Schedule of Amendments	m1-5-2-1-amendment-schedule	Unchanged
1.5.2.2	Medicines Register Details	m1-5-2-2-medicine-register	Changed to Parent-element
1.5.2.2.1	Medicines Register Details	m1-5-2-2-1-medicine-register	Moved to Sub-element
1.5.2.2.2	Registration Certificates	m1-5-2-2-2-registration-certificates	New
1.5.2.3	Affidavit by Responsible Pharmacist	m1-5-2-3-affidavit	Unchanged
1.5.3	Proprietary Name Applications and Changes	m1-5-3-proprietary-name	Unchanged
1.5.4	Genetically Modified Organisms	m1-5-4-gmo	Unchanged
1.5.5	PI and PIL amendments/updates	m1-5-5-pi-amendment	Moved to 1.3.1.1 and 1.3.2
1.5.6	Bioequivalence Trial Information	m1-5-6-btif	Moved from 1.11
1.5.6.1	Generic Applications (BTIF)	m1-5-6-1-btif	New
1.5.6.2	Biowaiver	m1-5-6-2-biowaiver	New
1.5.7	Abridged Applications (Abridged/Verified Review Document)	m1-5-7abridged-apps	New
1.5.A	Additional Types of Applications Specific Requirements	m1-5-a-additional-types-applications	New
1.6	**Environmental Risk Assessment**	**m1-6-environ-risk-assessment**	**Unchanged**
1.6.1	Non-GMO (Genetically Modified Organisms)	m1-6-1-nongmo	Unchanged
1.6.2	GMO (Genetically Modified Organisms)	m1-6-2-gmo	Unchanged
1.7	**Good Manufacturing Practice**	**m1-7-gmp**	**Unchanged**
1.7.1	Date of Last Inspection of each Site	m1-7-1-last-inspection	Unchanged
1.7.2	Inspection Reports or Equivalent Document	m1-7-2-inspection-report-or-equivalent	Unchanged
1.7.3	Latest GMP Certificate or a Copy of theAappropriate Licence	m1-7-3-gmp-certificate	Unchanged
1.7.4	Release	m1-7-4-release	Unchanged

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Section	Section Title	Element	Comments
1.7.4.1	API	m1-7-4-1-api	Unchanged
1.7.4.2	IPIs	m1-7-4-2-ipi	Unchanged
1.7.4.3	Finished Product Release Control (FPRC) Tests	m1-7-4-3-fprc-tests	Unchanged
1.7.4.4	Finished Product Release Responsibility (FPRR) Criteria	m1-7-4-3-fprr-criteria	Unchanged
1.7.5	Confirmation of Contract	m1-7-5-contract-confirmation	Unchanged
1.7.6	CPP (WHO Certification Scheme)	m1-7-6-cpp	Moved to 1.10.6
1.7.7	SAPC Registration	m1-7-7-sapc-reg	Unchanged
1.7.8	Registration with Registrar of Companies	m1-7-8-comp-reg	Unchanged
1.7.9	Other Documents Relating to the Applicant/PHCR	m1-7-9-docs-phcr	Unchanged
1.7.10	Sample and Documents	m1-10-sample-documents	Moved to 1.3.6
1.7.10.1	Confirmation of submission of sample	m1-7-10-1-sample-submission-confirmation	Moved to 1.3.6.1
1.7.10.2	Batch manufacturing record of the sample	m1-7-10-2-sample-bmr	Moved to 1.3.6.3
1.7.10.3	CoA of the sample	m1-7-10-3-sample-coa	Moved to 1.3.6.4
1.7.11	Manufacturing Permits	m1-7-11-manufacturing-permit	Change in Title
1.7.12	Inspection Flow Diagram	m1-7-12-inspection-flow-diagram	Unchanged
1.7.13	Organogram	m1-7-13-organogram	Unchanged
1.7.14	PQR	m1-7-14-pqr	New
1.7.A	Additional GMP Documents	m1-7-a-additional-gmp-documents	New
1.8.	Details of Compliance with Screening Outcomes	m1-8-compliance-screening	Moved to 1.2.5
1.8	**Information Relating to Pharmacovigilance**	**m1-8-info-relating-pv**	**New**
1.8.1	Pharmacovigilance Systems	m1-8-1-pv-systems	New
1.8.2	Risk Management Plan	m1-8-2-risk-management-plan	Moved from 1.13
1.9	**Individual Patient Data - Statement of Availability**	**m1-9-indiv-patient-data**	**Unchanged**
1.10	**Foreign Regulatory Status**	**m1-10-foreign-reg-status**	**Unchanged**
1.10.1	Tabulated List of Foreign Regulatory Status	m1-10-1-countries-same-appl	Change in Title
1.10.2	Registration Certificate or Marketing Authorisation	m1-10-2-foreign-reg-certif-or-ma	Unchanged
1.10.3	Foreign Prescribing and Patient Information	m1-10-3-foreign-pi	Moved to 1.3.5
1.10.4	Data Set Similarities	m1-10-4-data-set-similarities	Changed to Parent-element
1.10.4.1	Data Set Similarities	m1-10-4-1-data-set-similarities	Moved to Sub-element
1.10.4.2	Declaration of Sameness	m1-10-4-2-declaration-sameness	New
1.10.5	RRA Reports	m1-10-5-rra-reports	New
1.10.6	CPP (WHO certification scheme)	m1-10-6-cpp	Moved from 1.7.6
1.11	**Bioequivalence Trial Information**	**m1-11-be-trial-info**	**Moved to 1.5.6.1 and Biowaver**
1.12	**Paediatric Development Programme**	**m1-12-paediatric-dev-program**	**Unchanged**
1.13	Risk Management Plan	m1-13-risk-management-plan	Moved to 1.8.2
1.A	**Additional Data**	**m1-a-additional-data**	**New**