SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Road
Arcadia
0083

SAHPRA & INDUSTRY WORKSHOP

21st July 2022

NO	ITEM	PRESENTER	TIME
1.	Opening and Welcome Confirming logistical arrangements for the session		08h30 - 08h40 08h40 - 08h45
2.	**Matters for Discussion**		
	2.1 Renewals Guideline - Industry Comments		
2.1.1	Application Form and format (eCTD)		08h45 - 09h00
2.1.2	Application Process		
2.1.3	Inactive Products/Un-marketed products		09h00 - 09h30
2.1.4	Product registered before 2017 and not yet registered (old medicines)		
2.1.5	Variations review during Renewal		09h30 - 09h45
2.1.6	HCR transfer to be completed before renewal due		
2.1.7	PI/PIL		09h45 - 10h00
2.1.8	Batches Manufactured at a lower scale		
2.1.9	GMP approval of manufacturing sites		
2.1.10	CPP		10h00 - 10h15
2.1.11	Copies of relevant licenses		
2.1.12	PQR - for the SPECIFIC PRODUCT UNDER REVIEW		
2.1.13	QOS and QIS - templates		10h15 - 11h00
2.1.14	Risk Benefit Assessment Report		
2.1.15	Process Timeline		11h00 - 11h15
2.1.16	Screening Checklist - Pilot Review output		11h15 - 11h20
2.1.17	Renewals Workstream structure		11h20 - 11h35
2.1.18	Product Status during renewals process - temporary approval pending outcome of renewal review		11h35 - 11h45
2.1.19	Renewal Schedule - by applicant		11h45 - 12h00
2.1.20	Terminology clarification		12h00 - 12h15
	2.2 Renewals Roadmap		
2.2.1			12h15 - 12h30

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	2.3 Pilot		
2.3.1 2.3.2 2.3.3	Communication with indentified pilot participants Individual pre-submsission meetingings Communicating results and further refinement to guideline		12h30 - 12h45
3.	**3.1 Other**		12h45 - 13h00