

## SAAPI CONFERENCE 2022 | Programme

WEDNESDAY 3 AUGUST		
Session 1		Pandora 1 & 2
08h30 – 08h45	Welcome – <b>Gina Partridge</b> (SAAPI President/Conference Committee Co-Chair)	
08h45 – 09h30	Keynote - navigating the new normal – <b>Aki Kalliatakis</b> (Managing Partner, The Leadership LaunchPad)	
09h30 – 10h00	Africa Medicines Agency - unpacked – <b>Judy Coates</b> (Senior Manager Regulatory Affairs, Government Affairs & Value & Access Amgen SA)	
10h00 – 10h30	Refreshments	Exhibition Area
Session 2	Virtual session	Pandora 1 & 2
10h30 – 10h40	The benefits of labelling harmonisation – <b>Speaker</b>	
10h40 – 11h05	The status of labelling harmonisation in Africa - Zimbabwe – <b>Grace Matimba</b> (Senior Regulatory Officer, Medicines Control Authority of Zimbabwe)	
11h05 – 11h35	The status of labelling harmonisation in Africa - Tanzania – <b>Alex Juma</b> (DRO, Tanzania Medicines & Medical Devices Authority)	
11h35 – 12h00	The status of labelling harmonisation in Africa – Ghana - <b>Nana Afrakom Ashia</b> (Principal Regulatory Officer, Drug & Nutraceuticals Department, FDA, Ghana)	
12h00 – 12h30	WHO global benchmarking tool and regulatory agency maturity levels– <b>Andrea Julsing Keyter</b> (Technical Officer, RSS/REG/RPQ/WHO)	
12h30 – 13h30	Lunch	Exhibition Area
Session 3		Pandora 1 & 2
13h30 – 13h40	Marketing Code Authority of South Africa - <b>Video</b>	
13h40 – 14h00	ISPE - women in pharma – <b>Lizette Janse van Rensburg</b> (General Manager, eurolab ASU)	
14h00 – 14h30	eLabelling – <b>Torkil Fredborg</b> (Associate Vice President, Global Regulatory Affairs, International Regions, Eli Lilly & Company)	
14h30 – 15h00	Cultivating ethical and responsible leadership – <b>Aldrin Beyer Founder</b> (Lead Coach, Aldrin Beyer Coaching & Facilitation)	
15h00 – 15h30	Use of digital platforms in the marketing of medicines – <b>Mohammed Dalwai</b> (Chief Product Officer, EMGuidance)	
15h30 – 16h00	Refreshments	Exhibition Area
Session 4		Pandora 1 & 2
16h00 – 16h30	Data integrity in a digital environment – <b>Nick Armstrong &amp; Jonathan Thompson</b> (ISPE)	
16h30 – 17h00	Accelerating digital transformation with Pharma 4.0 - <b>Jonathan Thompson</b> (ISPE)	
17h00 – 19h30	Trade Preview & Networking Evening	Exhibition Area

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THURSDAY 4 AUGUST		
Session 5		Pandora 1 & 2
08h30 – 08h40	Welcome – <b>Patrick Demana</b> (SAAPI Vice-President)	
08h40 – 09h10	The seamless transition from eSubmission to eCTD – <b>Kent Briggs</b> (Managing Director, Vector Life Sciences)	
09h10 – 09h35	Quality by design - aniIntroduction – <b>Mbonisi Ncube</b> (Lead Consultant, Pharma Operations, Phed Pharma)	
09h35 – 10h00	Quality by design – ISPE – <b>Alice Redmond or alternate</b> (ISPE)	
10h00 – 10h45	Regulators perspective on navigating the new normal - <b>Boitumelo Semete</b> (CEO,SAPHRA)	
10h45 – 11h15	Refreshments	Exhibition Area
Session 6		Pandora 1 & 2
11h15 – 12h00	SAHPRA's approach to prevention, detection and response to Substandard and/or Falsified Medicines – <b>Daphney Fafudi</b> (Regulatory Compliance, SAHPRA)	
12h00 – 12h45	SAHPRA Digital Systems – <b>Christelna Reyneke</b> (Chief Operating Officer, SAPHRA)	
12h45 – 13h45	Lunch	Exhibition Area
Session 7		Pandora 1 & 2
13h45 – 14h15	Cybercrime- how your company can avoid becoming a victim – <b>Musa Wenkosi Khumalo</b> (Cyberinsurance Underwriter, ITOO Specials Risks Ltd)	
14h15 – 14h40	Key considerations in risk management plans for medicines – <b>Maarten Lagendijk</b> (Deputy Qualified Person, Pharmacovigilance (deputy EU QPPV), MSD)	
14h40 – 15h00	SAHPRA pharmacovigilance update – <b>Florah Matlala</b> (SAPHRA)	
15h00 – 15h30	Refreshments	Exhibition Area
Session 8		Pandora 1 & 2
15h30 – 16h00	Quality risk management to address impurities – <b>Alice Redmond</b> (ISPE)	
16h00 – 16h45	Nitrosamines - A regulator's perspective and next steps - <b>Mphako Ratlabiyana</b> (Head of Nitrosamines Working Group, SAPHRA)	
16h45 – 17h00	ISPE - benefits of being an ISPE member – <b>Edyna Miguez</b> (Membership Growth Manager, ISPE)	
	Free Evening	

FRIDAY 5 AUGUST		
Session 9		Pandora 1 & 2
08h20 – 08h30	Welcome – <b>Minoka Maharaj</b> (SAAPI Conference Committee Co-Chair)	
08h30 – 09h00	Medical device regulation – an update and roadmap for the future – <b>Dimakatso Mathibe</b> (Senior Manager, Medical Devices, SAPHRA)	
09h00 – 09h30	Harmonising medical device regulation to benefit patients – <b>Avanthi Bester</b> (Associate Director, Regulatory Affairs & Quality, Alcon)	
09h30 – 10h00	Navigating the SAHPRA website & a brief introduction to the online OTC directory – <b>Ntokozi Msiza</b> (Web Designer, SAPHRA)	
10h00 – 10h30	Refreshments	Exhibition Area
Session 10		Pandora 1 & 2
10h30 – 11h00	Understanding pricing regulations and SEP – <b>Ntobeko Mpanza</b> (Director, Pharmaceutical Economic Evaluations, NDOH)	
	<b>Access to medicines (11h00 – 12h00)</b>	
11h00 – 11h20	A managed care's perspective on access to medicines – <b>Susan Lin</b> (Senior Manager, Health Policy Development, Medicine I Support, Health Policy Unit)	
11h20 – 11h40	An industry perspective on access to medicines – <b>Vuyo Mjekula</b> (Director External Affairs (Policy and Market Access), Sub Saharan Africa, MSD)	
11h40 – 12h00	A legal perspective – patent law and access to medicines, where do we stand in SA - <b>John McKnight</b> (Patent Attorney, Spoor & Fisher)	
12h00 – 12h30	Complementary medicines regulation – navigating the path forward – <b>Deepa Maharaj</b> (Africa Science Affairs Head, Sanofi, Chairperson of ITG)	
12h30 – 12h50	Veterinary medicine regulation - An update and roadmap for the future – <b>Alice Sigobodhla</b> (Veterinary Scientist, SAPHRA)	
12h50 – 13h00	Conference close - <b>Gina Partridge</b> (SAAPI President)	
13h00 – 14h00	Lunch on departure	Exhibition Area