



WHO-UMC-HSA Inter-Regional Pharmacovigilance Training Workshop

Enhancing Preparedness for Pharmacovigilance

20 – 22 Sept 2021
Conducted via Zoom

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Day 1 – 20 September, Mon

Topic		
Day 1		
Pharmacovigilance in the COVID-19 Vaccine-era		
8.45am SGT 2.45am CEST	Registration and Briefing on use of Zoom	
9.00am SGT 3.00am CEST	Welcome	<p>Prof John Lim Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School</p> <p>Dr Mimi Choong Chief Executive Officer Health Sciences Authority (HSA) Singapore</p>
9.15am SGT 3.15 CEST	Opening remarks	<p>Dr Shanthy Pal Team Lead Pharmacovigilance Regulation and Safety World Health Organization (WHO)</p> <p>Ms Helena Sköld VigiBase Manager Uppsala Monitoring Centre (UMC) Sweden</p>
9.30am SGT 3.30am CEST	Global report on COVID-19 vaccines <ul style="list-style-type: none"> • WHO - Update on vaccine safety and key safety issues to date • Descriptive Analysis of COVID-19 Vaccines reporting in VigiBase 	<p>Mr Takahiro Goto Former Technical officer Pharmacovigilance (PVG) team World Health Organization (WHO)</p> <p>Dr Sara Vidlin Data Scientist UMC Sweden</p>
10.15am SGT 4.15am CEST	Break	
10.45am SGT 4.45am CEST	COVID-19 vaccination landscape in ASEAN Sharing by ASEAN regulators	From ASEAN regulators <ul style="list-style-type: none"> • Singapore • Brunei • Malaysia • Philippines • Thailand
12.00pm SGT 6.00am CEST	Lunch	
1.00pm SGT 7.00am CEST	Group Discussion Current areas for urgent intervention towards effective pharmacovigilance	
2.00pm SGT 8.00am CEST	CIOMS guide to active vaccine safety surveillance – Practical framework for implementation	<p>Dr Walter Straus Vice President Safety & Pharmacovigilance Moderna United States of America</p>

2.45pm SGT 8.45am CEST	WHO Listed Authorities (WLA) and Global Benchmarking Tool (GBT) for pharmacovigilance Adapting for COVID-19 situation	Mr Hiiti Sillo Team Lead Regulatory Systems Strengthening Regulation and Safety Unit Regulation and Prequalification Department WHO
3.30pm SGT 9.30am CEST	Break	
4.00pm SGT 10.00am CEST	Group Discussion <ul style="list-style-type: none"> Regulators' session: Applying GBT on local pharmacovigilance systems Industry session: Identifying strengths and opportunities for strengthening the ASEAN pharmacovigilance system 	<u>Regulators</u> WHO <u>Industry</u> CoRE <i>(a separate Zoom link will be used)</i>
5.30pm SGT 11.30am CEST	End	

Day 2 – 21 September, Tue

Topic		
Day 2		
Enhancing effective in PV		
8.45am SGT 2.45am CEST	Registration	
9.00am SGT 3.00am CEST	Risk Management Plan throughout the Product Lifecycle <ul style="list-style-type: none"> Objective and Principles of Risk Management Key Components of a Risk Management Plan HSA's RMP Requirements and Experiences 	Ms Christine Ho Regulatory Consultant Vigilance and Compliance Branch Health Sciences Authority Singapore
10.30am SGT 4.30am CEST	Break	
11.00am SGT 5.00am CEST	Group Discussion <ul style="list-style-type: none"> Regulators' session: Reviewing RMP for local population Industry session: Developing a RMP for the local NRA 	<u>Regulators</u> HSA <u>Industry</u> CoRE <i>(a separate Zoom link will be used)</i>
12.30pm SGT 6.30am CEST	Lunch	
2.00pm SGT 8.00am CEST	UMC's ecosystem of tools for National Pharmacovigilance Centres <ul style="list-style-type: none"> VigiFlow VigiBase 	Ms Helena Sköld VigiBase Manager Uppsala Monitoring Centre (UMC) Sweden
2.45pm SGT 8.45am CEST	Reliance in Pharmacovigilance <ul style="list-style-type: none"> Data sharing for decision support Applying reliance on WHO List of Authorities and other NRAs 	Dr Jean-Christophe Delumeau Head Pharmacovigilance Policy Strategy (Global) Bayer
3.30pm SGT 9.30am CEST	Break	
4.00pm SGT 10.00am CEST	Group Discussion <ul style="list-style-type: none"> Regulators' session: VigiLyze training Industry session: Facilitating reliance in PV – Challenges and Solutions from Industry 	<u>Regulators</u> Dr Elki Sollenbring Senior Pharmacovigilance Education Specialist Uppsala Monitoring Centre (UMC) Sweden Dr Mónica Tarapués UMC consultant Uppsala Monitoring Centre (UMC) Sweden <u>Industry</u> CoRE <i>(a separate Zoom link will be used)</i>
5.30pm SGT 11.30am CEST	End	

Day 3 – 22 September, Wed

Topic		
Day 3		
Pharmacovigilance in promoting public health		
8.45am SGT 2.45am CEST	Registration	
9.00am SGT 3.00am CEST	Leveraging digital innovations for early detection of Vaccine Related Events (VRE) <ul style="list-style-type: none"> Inform COVID-19 vaccine safety communications and interventions 	Ms Isabelle Sahinovic Technical Officer Pharmacovigilance (PVG) Team Regulation and Safety (REG) Unit Regulation and Prequalification (RPQ) Department Access to Medicines and Health Products (MHP) Division World Health Organization (WHO)
		Mr Brian Yau VSN Promotion & Engagement Lead Pharmacovigilance (PVG) Team Regulation and Safety (REG) Unit Regulation and Prequalification (RPQ) Department Access to Medicines and Health Products (MHP) Division World Health Organization (WHO)
9.30am SGT 3.30 CEST	Patients' role in pharmacovigilance communications	Ms Nidhi Swarup Founder & President Crohn's & Colitis Society of Singapore (CCSS)
10.00am SGT 4.30am CEST	Break	
11.00am SGT 5.00am CEST	Role of pharmacovigilance in digital health	Mr Rajesh Ghosh Senior Director Digital Safety and Decision Support PV Scientific Development Roche
11.30pm SGT 6.00am CEST	Closing remarks	Dr Mimi Choong Chief Executive Officer Health Sciences Authority (HSA) Singapore
11.45pm SGT 6.15am CEST	End of Workshop	
Regulators' Session		
2.00pm SGT 8.00am CEST	EUL (Emergency Use Listing) and RMP (Risk Management Plan) for COVID-19 vaccines	Dr Carmen Rodriguez-Hernandez Team Lead, Vaccines PQ Regulation and Prequalification Department World Health Organization
3.00pm SGT 9.00am CEST	End of Regulators' Session	