World Health Organization

Covid-19 Vaccine Safety Ecosystem workshop

Support document

Sept. 9th, 15:00-18:00 CET

Agenda – Covid-19 Vaccine Safety Ecosystem workshop (Sept. 9th, 15:00-18:00 CET)

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	15:10-15:15	Housekeeping & Meeting logistics	Pierre Vigin (McKinsey)	5 min
Setting the scene	15:15-15:30	ACT-A and COVAX	Kate O'Brien (WHO)	15 min
	15:30-15:50	Covid-19 vaccine safety monitoring: Challenges & Opportunities	Shanthi Pal (WHO); Dicky Akanmori (WHO)	20 min
	15:50-16:00	Discussion	**Emer Cooke (WHO) - Chair**	10 min
Landscape of Covid-19 vaccine safety activities	16:00-16:15	Developers' needs (Report from the Aug. 31 workshop)	Ajoke Sobanjo-ter Meulen (BMGF)	15 min
	16:15-16:40	Regulatory and Programme Perspectives	Agnes Saint-Raymond (ICMRA) Philip Bryan (MHRA); Gagandeep Kang	25 min
	16:40-16:55	Safety Platform for Emergency vACcines (SPEAC)	Robert Chen (Brighton Collaboration)	15 min
	16:55-17:15	Covid-19 vaccine safety & WHO Global Advisory Committee	Christine Guillard (WHO); Madhav Balakrishnan (WHO); Ananda Amarasinghe (WHO)	20 min
	17:15-17:30	Synergies and unmet needs for Covid-19 vaccine safety	Sten Olsson	15 min
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Introduction and background

- **Unprecedented time in the vaccine development world**
  - New platforms
  - New actors, developers, companies
  - Different populations
  - **Topic of vaccine safety has never been more important**
  - Alignment from clinical trial phase to post deployment is a must
- Large number of WHO and international initiatives focused on ensuring vaccine safety – connecting the dots is a must
- **WHO's mandate and lead role in global vaccine safety – 20 years of experience**
- **COVAX SWAT teams – the new kid on the block**

Objectives of today's workshop

1. **Review the challenges** faced in addressing the end to end safety of new COVID19 vaccines
2. **Map current international efforts** in addressing those challenges
3. **Identify overlaps, gaps and potential synergies**
4. **Specify lead organizations, roles and responsibilities**
5. **Agree on the way forward** for effective collaboration

This workshop was designed as part of a stepwise approach to best organize the safety discussions within COVAX. A proposal had been made to set up a Safety Taskforce and it is now crucial to create transparency on potential overlaps and gaps in terms of vaccine safety activities.

This workshop will contribute to two main outcomes

- **A high level roadmap** with activities, leads, roles, responsibilities and timelines on Covid-19 vaccine safety management across the product lifecycle

- **An agreement on how to best coordinate and leverage existing activities and address unmet needs**

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Housekeeping & Meeting logistics: Ground rules for today's meeting

Ask your questions on the chat or keep questions for the discussion sessions – There are a lot of topics to cover

"Raise your hand" if you want to say something during the two discussion sessions

Let's respect the allocated time – Additional sessions will be scheduled for further discussions

No criticizing or blaming, all ideas count – The objective is to improve together

Flat hierarchy within the group – everyone's point-of-view matters

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Planning for the pharmacovigilance of Covid-19 vaccines (1/8)

PHASE: prior to licencing

	Global (Lead (L) or Support (S))	Regional (Lead (L) or Support (S))	National (Lead (L) or Support (S))
Clinical trials protocol, critical safety endpoints, registry	• **Brighton Collab** (L) • **CIOMS** WG VI 2005, WG VII (DSUR) 2006 (S) • **WHO** (Solidarity Trials, ECBS guidance) (L) • **PATH** (L)	• **WHO** (S) (AVAREF) • **HPRA** (L) scientific advice/protocol assistance/assessment of centralised EU applications	• **Butantan** On-going (BRA) (L) • **TGA** (Therapeutic Goods Administration, Australia (L) • **HPRA** (L) • **HC** (CAN) (L)
Risk Management Plans	• **CDC** • **CIOMS** WG IX (2014) (S) • **WHO PQ** (L) • **PATH** (S)	• **CDC** • **EMA** (EU) Regulatory approval of RMPs of vaccines centrally authorized in the EU (L) • **HPRA** (S) • **WHO** (S) (AVAREF)/RO	• **Butantan** On-going (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (L) • **HPRA (S)** • **Swissmedic (S)** • **HC** (CAN) (L)
Identify AESI, priority criteria and background rate	• **Brighton Collab (L)** • **CIOMS**/WHO Working Group on vaccine PV (2012) (S) • **UMC** (MIS-C case definition) (S) • **WHO** (S) (GACVS) • **PATH** (S)	• **EMA** Provision of AESI list (continuously updated), background rates provided by EMA funded project ACCESS (EU) (L) • **HPRA** (S) • **WHO** (S) thru RO to adopt/background rates	• **Butantan** On-going (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (L) • **HPRA** (S) • **WHO/CO** (S) to adopt • **HC** (CAN) (S)

Planning for the pharmacovigilance of Covid-19 vaccines (2/8)

	Global (Lead (L) or Support (S))	Regional (Lead (L) or Support (S))	National (Lead (L) or Support (S))
Templates for Benefit – risk evaluation per vaccine product (e.g. using Brighton Collaboration Benefit-Risk Assessment of Vaccines by Technology (BRAVATO))	• **Brighton Collab** (L) • **WHO** (S) (GACVS, ECBS endorsements/advice • **PATH** (S)	• **HPRA (L)** • **WHO** (S) thru RO to adopt/implement	• **Butantan** On-going (BRA) (S) • **TGA** (AUS) (L) • **WHO** (S) to adopt/implement thru WCO • **HC** (CAN) (S)
Data sources and networks to study background AESI rates	• **Brighton Collab** (S) • **WHO (L)** with guidance on data sources, methods	• **EMA** Provided by EMA funded project ACCESS, available data sources and establish a network for vaccines monitoring for studying safety, effectiveness and coverage (EU) (L) • **HPRA** (S) • **WHO** (S) thru RO to adopt/train	• **Butantan** On-going (BRA) (S) • **CDC** (USA) • **TGA (AUS) (L)** • **WHO** (S) thru WCO to implement/estimate background rates
PV Requirements for pandemic preparedness (checklists, guidance)	• **Brighton Collab** (S) • **WHO (L)**, to prepare checklists, guidance • **PATH** (S)	• **EMA** GVP guidance applies, EU network COVID-19 vaccines monitoring preparedness plan in preparation (L) • **HPRA** (S) • **WHO** (L) through RO, to promote, train	• **Butantan** On-going (BRA) (S) • **TGA** (AUS) (L) • **HPRA** (L) • **WHO** (L) through WCO, to apply, determine preparedness • **Swissmedic (L)** • **HC** (CAN) (L)
Contributions to Strategies on injury- compensation policies	• **Brighton Collab** (S) • **WHO** (S) through COVAX Task Force on liability, indemnification and compensation • **PATH** (S)	• **WHO** (S) through RO, with AEFI regional data	• **WHO/WCO** (S) with AEFI national data

Planning for the pharmacovigilance of Covid-19 vaccines (3/8)

PHASE: licensing

	Global (Lead (L) or Support (S))	Regional (Lead (L) or Support (S))	National (Lead (L) or Support (S))
Safety specification per vaccine product	• **WHO/PQ & R&D** (S) • **PATH** (S)	• **EMA** – Regulatory approval for vaccines centrally authorized in the EU (L) • **HPRA** (S)	• **Butantan** Planned (BRA) (S) • **TGA** (AUS) (L) • **Swissmedic (L)** • **HC** (CAN) (L/S)
Pharmacovigilance plan per vaccine product	• **WHO/PQ** (S) • **PATH** (S)	• **EMA** Regulatory approval for vaccines centrally authorized in the EU (L) • **HPRA (S)** • **WHO/RO** (S) through platforms such as AVAREF	• **Butantan** Planned (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (L) • **Swissmedic (L)** • **HC** (CAN) (L)
Risk minimization plan per product with annex by country	• **WHO/PQ** (S) • **PATH** (S)	• **EMA** Regulatory approval for vaccines centrally authorized in the EU (L) • **HPRA (S)** • **WHO/RO** (S) through platforms such as AVAREF	• **Butantan** Planned (BRA) (L) • **TGA** (AUS) (L) • **Swissmedic (L)** • **HC** (CAN) (L)

Planning for the pharmacovigilance of Covid-19 vaccines (4/8)

PHASE: Early post-licensing/general use

1. Active Vaccine Safety Surveillance (AVSS)

	Global (Lead (L) or Support (S))	Regional (Lead (L) or Support (S))	National (Lead (L) or Support (S))
Establishment of preferred design and standard study protocol	• **Brighton Collab** (S) • **CDC** • **CIOMS** (L) • **WHO** (S) (work with CIOMS, to develop guidance); **PATH** (L)	• **CDC** • **EMA** For studies included in the RMP as category 1 and 2 in vaccines centrally authorized in the EU (L) • **WHO/RO** (S), to train	• **Butantan** On-going (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (S) • **WHO/CO (S)**, to train, implement AVSS • **HC** (CAN) (S)
Decision on number, size, location and responsible investigator of AVSS	• **Brighton Collab** (L) • **WHO (S)**, coordinate • **PATH** (S)	• **EMA** - For studies included in RMP as category 1 & 2 vaccines centrally authorized in EU (L) • **WHO/RO (S)**, to identify participating countries and study sites	• **Butantan** Planned (BRA) (L) • **TGA** (AUS) (S) • **WHO/CO**, to coordinate with MoH/EPI • **Swissmedic (S)**
Establishment of a global office to coordinate operations of local safety follow-up studies and data streams	• **Brighton Collab** (S) • **WHO** (L)	• **WHO/RO** (L)	• **Butantan** Planned (BRA) (L) • **TGA** (AUS) (S) • **WHO/CO** (L)
Ethical clearance for collecting personal and clinical information in countries	• **Brighton Collab** (S) • **CIOMS/WHO** International ethical guidelines for health-related research (2016) (S); **PATH** (L)	• …	• **Butantan** Planned (BRA) (L) • **TGA** (AUS) (S)
Develop information material for vaccine recipients taking part in AVSS	• **PATH** (L)	• …	• **Butantan** Planned (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (S)
Software for recording of vaccine details and contact details of recipient	• **Brighton Collab** (S) • **WHO/IVB?** (S)	• …	• **Butantan** Planned (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (S); **Swissmedic (L/S)**
Training of staff to carry out follow-up interviews	• **PATH** (L)	• …	• **Butantan** Planned (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (S)

Planning for the pharmacovigilance of Covid-19 vaccines (5/8)

	Global (Lead (L) or Support (S))	Regional (Lead (L) or Support (S))	National (Lead (L) or Support (S))
Software (E2b) for recording of AEFIs by investigator	• **Brighton Collab** (L) • **WHO/UMC** (S) by participating in ICH	• **WHO/RO (S)**, to adopt E2b standards/bridge with EPI	• **Butantan** On-going (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (L) • **WHO/UMC (S), to implement E2b compatible tools** • **HC** (CAN) (L)
Communication facilities for transmission of collected data to national, regional and global data analysis centre	• **UMC** (S) • **WHO** (S)	• **WHO/RO** (S)	• **Butantan** On-going (BRA) (L) • **TGA** (AUS) (L) • **WHO/CO** (S) • **Swissmedic (L)** • **HC** (CAN) (L)
Statistical package for near real-time screening for AESI reports	• **Brighton Collab** (S) • **PATH** (L)	• **EMA** in the EU using the Eudravigilance database	• **Butantan** On-going (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (L)
Establishment of safety data review committees with Standard Operating Procedures for their activities	• **WHO (S)** through guidance docs, facilitating joint reviews between groups of countries • **PATH** (L)	• **WHO/RO (S)** by convening platforms and supporting joint reviews	• **Butantan** Planned (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (L) • **WHO/CO (S)** to train/implement committees; **Swissmedic (S)** • **HC** (CAN) (L/S)
Establishment of communications policy and plan for interaction with regulatory authorities, the scientific community, media and the public	• **CDC** • **WHO (L)** to develop guidance • **PATH** (S)	• **CDC** • **HPRA** (S) (Chair at Vx Working Party) • **WHO/RO (S)** to adopt	• **Butantan** On-going (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (L) • **HPRA** (S) (through national cross-organizational teams on Vx) • **WHO/CO** (S) to implement; **Swissmedic (S)** • **HC** (CAN) (L/S)

Planning for the pharmacovigilance of Covid-19 vaccines (6/8)

2. System for spontaneous reporting of individual case safety reports.

	Global (Lead (L) or Support (S))	Regional (Lead (L) or Support (S))	National (Lead (L) or Support (S))
Establishing Centres for management of the safe introduction of Covid-19 vaccines with relevant competencies and resources	• **Brighton Collab** (S) • **UMC** support/training to NRA (S) • **HPRA** (S) • **WHO** (L) through PIDM and GVSI • **PATH** (S)	• **HPRA (S)** • **WHO/RO (L)** Training and coordination between countries in regions	• **HPRA (L)** • **UMC** (S) • **TGA** (AUS) (L) • **WHO/CO** (L) in liaising between NRA and EPI in country; **PATH** (S); **Swissmedic (L)**
Information material developed for target groups, explaining the different routes for AEFI reporting and what to report	• **UMC** (S) • **HPRA** (S) • **WHO/HQ** (L) with guidance, training • **PATH** (S)	• **HPRA (S)** • **WHO/RO** (S) with coordination in region, training	• **TGA** (AUS) (L) • **HPRA** (L) • **WHO/CO** (S) with implementation in countries; **PATH** (S); **HC** (CAN) (S)
AEFI Reporting tools developed / made available (paper based, phone, e-mail, web, reporting-apps)	• **Brighton Collab** (L) • **UMC** (L) • **HPRA** (S) • **WHO (S)** by coordinating • **PATH** (S)	• **HPRA (S)** • **WHO/RO** (S) by advocating, training	• **UMC** (S) • **TGA** (AUS) (L) • **HPRA** (L) • **WHO/CO (S)** in implementing, feedback on tools; **PATH** (S); **Swissmedic (L) ; HC** (CAN) (S)
Systems for confirmation/ acknowledgement of receipt of AEFI reports	• **HPRA** (S) • **PATH** (S)	• **HPRA** (S)	• **Butantan** On-going (BRA) (S) • **CDC** (USA) • **TGA** (AUS) (L) • **HPRA** (L); **PATH** (S); **HC** (CAN) (L/S)
Pooling of data through the different reporting routes	• **UMC** (L) • **HPRA** (S) • **WHO (S)** by coordinating • **PATH** (S)	• **HPRA (S)** • **WHO/RO** (S) by convening/facilitating platforms for data sharing/pooling	• **Butantan** On-going (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (L) • **HPRA** (L); **PATH** (S); **TGA** (AUS) (L/S)
Reconciling data from AVSS and the spontaneous reporting systems	• **UMC** (S) • **PATH** (S)	• …	• **Butantan** On-going (BRA) (L) • **CDC (USA); TGA** (AUS) (L); **PATH** (S); **HC** (CAN) (L/S)

Planning for the pharmacovigilance of Covid-19 vaccines (7/8)

	Global (Lead (L) or Support (S))	Regional (Lead (L) or Support (S))	National (Lead (L) or Support (S))
Vaccine safety expert panels for continuous review of safety data	• **Brighton Collab** (L) • **CIOMS** WG X (2016) (S) • **UMC** (L) • **HPRA** (S) • **WHO** (L) GACVS • **PATH** (S)	• **EMA** – Signal detection for vaccines that are centrally authorised in the EU (L) • **HPRA** (S) • **WHO/RO** (S) in establishing regional committees	• **Butantan** Planned (BRA) (S) • **CDC (USA)** • **TGA** (AUS) (L) • **HPRA** (L) • **WHO/CO** (S) in establishing/training etc • **PATH** (S) • **HC** (CAN) (L/S)
Collating distribution statistics by product and geographic region with batch numbers	• **HPRA** (S) • **WHO** (IVB) S	• **EMA** -In collaboration with ECDC and member states in the EU (L) • **HPRA** (S)	• **Butantan** On-going (BRA) (L) • **TGA** (AUS) (L) • **HPRA** (L) • **HC** (CAN) (S)
Communications policy and plan	• **CIOMS** Guide to Vaccine Safety Communication (2018) (S) • **HPRA** (S) • **PATH** (S)	• **EMA** – Communications at EU level (L) • **HPRA** (S)	• **Butantan** On-going (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (L) • HPRA (L) • **PATH** (S) • **Swissmedic** (S) • **HC** (CAN) (L/S)

Planning for the pharmacovigilance of Covid-19 vaccines (8/8)

	Global (Lead (L) or Support (S))	Regional (Lead (L) or Support (S))	National (Lead (L) or Support (S))
PHASE: Later stage activities following general use			
Verification and characterization of identified new safety signals/clusters	• **Brighton Collab** (S) • **CIOMS** WG VIII (2010) (S) • **UMC** (L) • **HPRA** (S) • **WHO** (GACVS) (L); **PATH** (S) (to manufacturers)	• **EMA** – Signal management for vaccines centrally authorised in the EU (L) • **HPRA** (S)	• **Butantan** On-going (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (L) • **HPRA** (L) • **Swissmedic (L); HC** (CAN) (L/S)
Additional Verification/signal characterization studies	• **Brighton Collab** (S) • **HPRA** (S) • **WHO** GACVS (L) • **PATH** (S) (to manufacturers)	• **EMA** - As part of signal management for vaccines centrally authorised in the EU (L) • **HPRA** (S)	• **Butantan** On-going (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (L) • **HPRA** (L); **Swissmedic (S); HC** (CAN) (L/S)
Publication of results (scientific journal, general media)	• **Brighton Collab** (S) • **UMC** (L) • **HPRA** (S) • **WHO** GACVS (L); **PATH** (S) (to manufacturers)	• **EMA** Publication of the outcome of signals assessed by PRAC and the regulatory actions to be taken by the MAH (L) • **HPRA** (S)	• **Butantan** Planned (BRA) (L) • **CDC** (USA) • **TGA** (AUS) (L) • **HPRA** (L); **HC** (CAN) (L/S)
Updating of Summary of Product Characteristics (product labelling) based on outcome of study.	• **Brighton Collab** (S) • **HPRA** (S) • **WHO/PQ** (S)	• **EMA** – For the SmPC and PL of vaccines centrally authorised in the EU (L) • **HPRA** (S)	• **Butantan** Planned (BRA) (L) • **TGA** (AUS) (L) • **HPRA** (L) • **Swissmedic (S); HC** (CAN) (L/S)
PHASE: Periodic reporting by MAH			
Periodic Benefit Risk Evaluation Report (PBRER) Legislations, Guidelines, Records etc	• **Brighton Collab** (S) • **HPRA** (S) • **WHO PQ and** GACVS (S); **PATH** (S)	• **EMA** For vaccines centrally authorised in the EU (L) • **HPRA** (S)	• **Butantan** On-going (BRA) (L) • **TGA** (AUS) (L) • **Swissmedic (L)** • **HC** (CAN) (L)

Safety monitoring – some of the challenges we need to solve – what, who and how we work together

- End to end process from product development to post deployment monitoring
- Consistent approach to risk management plans
- Alignment on post deployment safety and effectiveness studies
- What to monitor?
- Who monitors at country level?
- Transparency and interconnectivity across different systems
- Enabling rapid feedback from national to global
- Connectivity of public health and regulatory processes
- Authority to make this happen

Proposed next steps (for discussion)

- Start developing high level roadmap
- Consolidate and share workshop results
- Set up coordination mechanism
- (If gaps are identified) Convene working groups to further explore focus topics/develop solutions
- …