Introduction

This document is the synthesis of a survey on Covid-19 vaccine safety activities (planned and ongoing), at global, regional and national levels. The collected information will help understand the synergies and opportunities to collaborate, and to plan a strategy for addressing the unmet needs in Covid-19 vaccine safety requirements.

In the table below, organization have indicated the nature of their role in the various Vaccine Safety and Pharmacovigilance requirements: (L) for Lead role and (S) for supportive role.

More context and insights will be shared during the Vx safety ecosystem workshop (Sept. 9th, 15:00-18:00 CET)

ESSENTIAL REQUIREMENTS FOR VACCINE SAFETY AND PHARMACOVIGILANCE			
	Global (Lead (L) or Support (S))	Regional (Lead (L) or Support (S))	National (Lead (L) or Support (S))
PHASE: prior to licencing			
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) **Health Canada (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)** **Health Canada (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)	**EMA** Provision of AESI list (continuously updated), background rates provided by EMA funded project ACCESS (EU) (L) **HPRA** (S)	**Butantan** On-going (BRA) (L) **CDC** (USA) **TGA** (AUS) (L) **HPRA** (S) **WHO/CO** (S) to adopt

	PATH (S)	**WHO** (S) thru RO to adopt/background rates	**Health Canada (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 **Health Canada (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)** **Health Canada (L)**
Contributions to Strategies on injury- compensation policies	**Brighton Collab** (S) **WHO** (S) through COVAX Task Force on liability,	**WHO** (S) through RO, with AEFI regional data	**WHO/WCO** (S) with AEFI national data

	indemnification and compensation **PATH** (S)		
PHASE: licencing			
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)** **Health Canada (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)** **Health Canada (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)** **Health Canada (L)**
PHASE: Early post-licensing/general use			
1. Active Vaccine Safety Surveillance (AVSS)			
Establishment of preferred design and standard study protocol	**Brighton Collab** (S) **CDC**	**CDC** **EMA** For studies included in the RMP as	**Butantan** On-going (BRA) (L)

	CIOMS (L) **WHO (S) (**work with CIOMS, to develop guidance**)** **PATH** (L)	category 1 and 2 in vaccines centrally authorized in the EU (L) **WHO/RO** (S), to train	**CDC** (USA) **TGA** (AUS) (S) **WHO/CO (S)**, to train, implement AVSS **Health Canada (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)
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** **Health Canada (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)** **Health Canada (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) **Health Canada (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)** **Health Canada (L/S)**
2. System for spontaneous reporting of individual case safety reports.			
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 **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 **Health Canada (S)**
AEFI Reporting tools developed / made available (paper based, phone, e-mail, web, reporting-apps)	**Brighton Collab** (L) **UMC** (L) **HPRA** (S)	**HPRA (S)** **WHO/RO** (S) by advocating, training	**UMC** (S) **TGA** (AUS) (L) **HPRA** (L)

	WHO (S) by coordinating **PATH** (S)		**WHO/CO (S)** in implementing, feedback on tools **Swissmedic (L)** **Health Canada (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) **Health Canada (L/S)**
Pooling of data through the different reporting routes	**UMC** (L) **HPRA** (S) **WHO (S)** by coordinating	**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)** **Health Canada (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) **Health Canada (L/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 **Health Canada (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) **Health Canada (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) **Swissmedic (S)** **Health Canada (L/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) **PATH** (S) – Support to manufacturers **WHO** (GACVS) (L)	**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)** **Health Canada (L/S)**
Additional Verification/signal characterization studies	**Brighton Collab** (S) **HPRA** (S) **WHO** GACVS (L) **PATH** (S) – Support 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)** **Health Canada (L/S)**

Publication of results (scientific journal, general media)	**Brighton Collab** (S) **UMC** (L) **HPRA** (S) **WHO** GACVS (L) **PATH** (S) – Support 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) **Health Canada (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)** **Health Canada (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)** **Health Canada (L)**