World Health Organization

Covid-19 Vaccine Safety Ecosystem workshop

Synergies and unmet needs for Covid-19 vaccine safety

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

Task

Design of a master plan for the establishment of a coordinated global safety surveillance system, preparing for the introduction of Covid-19 vaccines

Synergies and unmet needs for Covid-19 vaccine safety – Results of the Survey

- **The following pages present the consolidation of the results of a survey** sent to key organizations of the Covid-19 vaccine safety ecosystem
- **11 organizations replied to this survey:** Brighton, Butantan (Brazil), CIOMS, CDC, EMA, HPRA (Ireland), Path, Swissmedic, TGA (Australia), UMC, WHO
- Therefore, **the analysis** presented in the following pages **is not exhaustive**

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 (1/4)

>2 organizations involved | 1-2 organizations involved | No organization involved (=potential gap)

PHASE: prior to licensing	Global	Regional	National
Clinical trials protocol, critical safety endpoints, registry			
Risk Management Plans			
Identify AESI, priority criteria and background rate			
Templates for Benefit – risk evaluation per vaccine product (e.g. using BRAVATO)			
Data sources and networks to study background AESI rates			
PV Requirements for pandemic preparedness (e.g., checklists, guidance)			
Contributions to Strategies on injury- compensation policies			
PHASE: licensing			
Safety specification per vaccine product			
Pharmacovigilance plan per vaccine product			
Risk minimization plan per product with annex by country			

Planning for the pharmacovigilance of Covid-19 vaccines (2/4)

>2 organizations involved | 1-2 organizations involved | No organization involved (=potential gap)

PHASE: Early post-licensing/general use:

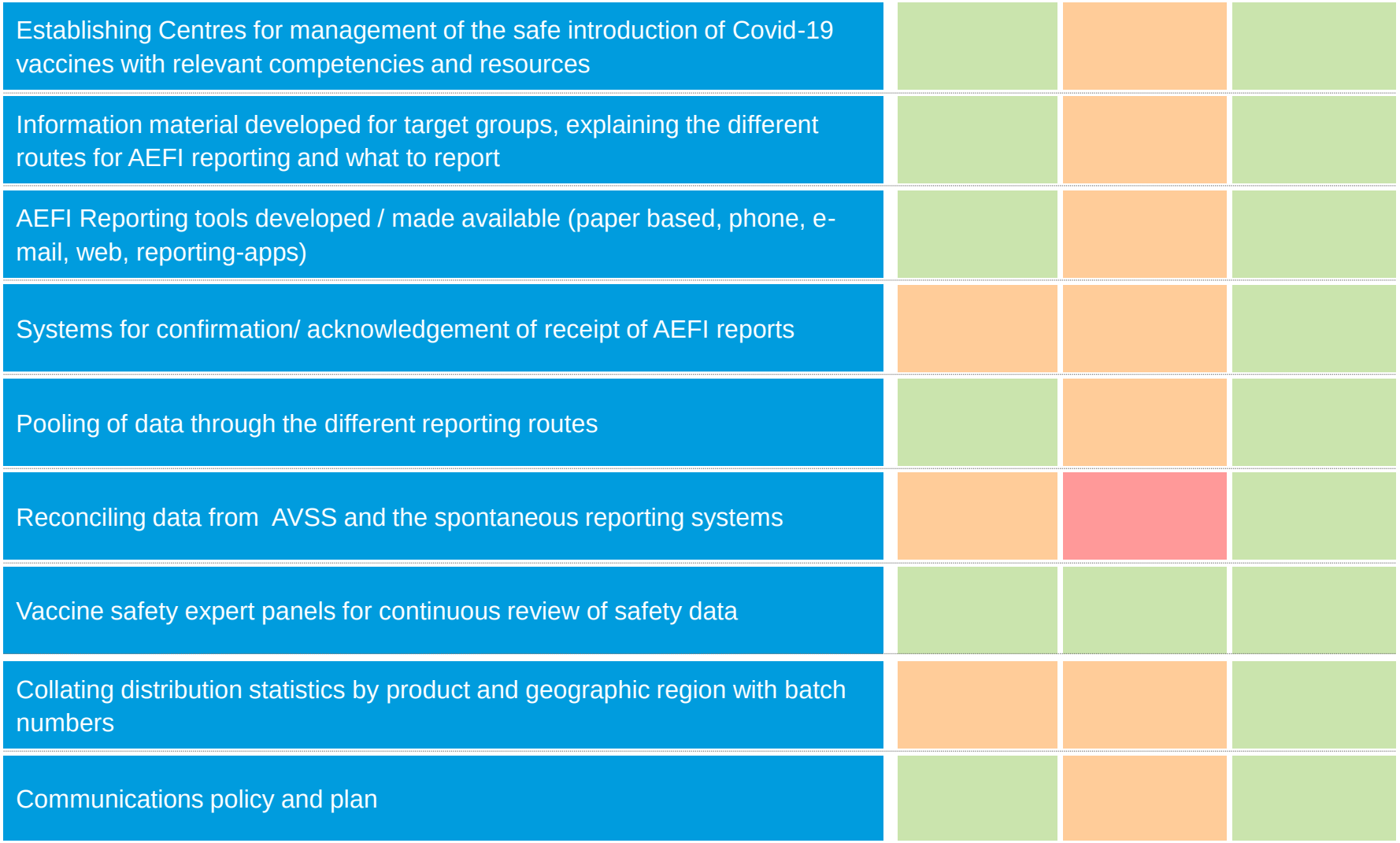
1. Active Vaccine Safety Surveillance (AVSS)	Global	Regional	National
Establishment of preferred design and standard study protocol			
Decision on number, size, location and responsible investigator of AVSS			
Establishment of a global office to coordinate operations of local safety follow-up studies and data streams			
Ethical clearance for collecting personal and clinical information in countries			
Develop information material for vaccine recipients taking part in AVSS			
Software for recording of vaccine details and contact details of recipient			
Training of staff to carry out follow-up interviews			
Software (E2b) for recording of AEFIs by investigator			
Communication facilities for transmission of collected data to national, regional and global data analysis center			
Statistical package for near real-time screening for AESI reports			
Establishment of safety data review committees with Standard Operating Procedures for their activities			
Establishment of communications policy and plan for interaction with regulatory authorities, the scientific community, media and the public			

Planning for the pharmacovigilance of Covid-19 vaccines (3/4)

>2 organizations involved | 1-2 organizations involved | No organization involved (=potential gap)

PHASE: Early post-licensing/general use:

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



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

>2 organizations involved | 1-2 organizations involved | No organization involved (=potential gap)

PHASE: Later stage activities following general use	Global	Regional	National
Verification and characterization of identified new safety signals/clusters			
Additional Verification/signal characterization studies			
Publication of results (scientific journal, general media)			
Updating of Summary of Product Characteristics (product labelling) based on outcome of study.			
PHASE: Periodic reporting by MAH			
Periodic Benefit Risk Evaluation Report (PBRER) Legislations, Guidelines, Records etc			

Most critical phases

Early phase of market introduction

- Rapid increase in number of recipients
- Establishing safety profile from CT in real-world settings
- Spontaneous reporting inadequate
- Active Vaccine Safety Surveillance
  - Incidence rate calculations
  - Needs implementation in many diverse populations
  - Same methodology ➡ pooling of data ➡ better sensitivity
  - Requires coordinated implementation

Most critical phases

Country implementation requires close collaboration between **National Immunization Programme** and **National Medicines Regulatory Agency** with their PV-centre

- History of close collaboration often lacking
- Combination of critical data from both parties needed
- Combined expertise required for analysis and response

Most critical phases

Common platform for information sharing

All key stakeholders need access to the same data from the global safety surveillance

- inconsistent information causes confusion/rumours
- reconciliation of global/regional/national databases
- reconciliation of data from active surveillance and spontaneous reporting systems

Most critical phases

A comprehensive/coordinated communication strategy

- Inform media and the public of who is responsible for what
  - Early and repeatedly
- Explain carefully concept of coincidental effect
  - Temporal association ≠ causality
- Stakeholder coordination of public statements to avoid confusion

Thank you for your attention