



SAHPRA: Enabling access to vaccine during public health emergencies

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Agility was critical in enabling accelerated access to health products during the COVID-19 pandemic



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Review

Regulatory Agilities in the Time of COVID-19: Overview, Trends, and Opportunities

Winona Rei Bolislis MA, Maria Lucia de Lucia, Felipe Dolz DVM, PhD, Runyi Mo MSc, Makoto Nagaoka PhD, Heraclio Rodriguez MBA, May Li Woon MPharm, Wei Yu MSc, Thomas C. Kühler PhD  

1. Regular communication with the public
2. Process improvements and regulatory frameworks for Public Health Emergencies
 - Expedited evaluations
 - Emergency Use Authorization for
 - Clinical trial requirements
 - Enhanced collaborative review pathways

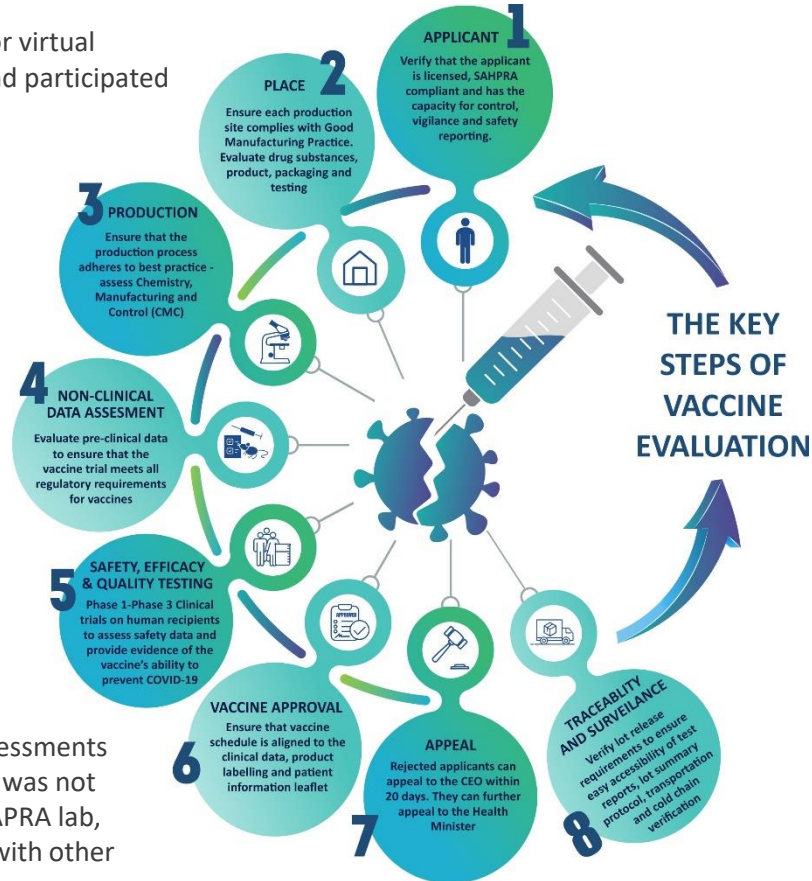
Key steps of vaccine assessment that required agility

- 2 Implemented remote inspections using tools for virtual platforms, joint inspections with other NRAs and participated in WHO inspections.

- 3 Increased capacity in the areas of Clinical and Quality assessment

- 4 Reliance on the WHO PQ assessment reports and those of other NRAs like USFDA and EMA

- 6 For the lot release assessments where the technology was not transferred to the SHAPRA lab, Reliance was applied with other WHO Accredited labs



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SAFETY, EFFICACY & QUALITY TESTING

Phase 1-Phase 3 Clinical trials on human recipients to assess safety data and provide evidence of the vaccine's ability to prevent COVID-19



THE KEY ASPECTS OF VACCINE EVALUATION

ASSESSMENT OF SAFETY DATA (PHASE 1-2)

- Requires an adequate number of vaccine recipients and monitoring for a sufficiently long time
- Safety is monitored across all three phases of clinical trials
- Typical is a **sequential process** with the regulators **receiving data at the end of phase1 then again after phase 2**
- **Submission and decision making as data becomes available**

ASSESSMENT OF EFFICACY DATA (PHASE 3)

- Requires **robust evidence of the vaccine's ability** to prevent infection/reduce disease severity from well-conducted phase 3 clinical trials in humans.
- Made decisions in the absence of confirmed **Correlates of Protection**
- For COVID-19 Clinical end points of **minimizing symptoms, reduction of hospitalization and reduction of hospitalization**
- SAHPRA may require data considering the local disease burden or disease epidemiology i.e **in case of COVID-19 SAHPRA required efficacy against variants of concern**

ASSESSMENT OF RISK MANAGEMENT PLAN (PHASE 4)

- Applicant's ability to record and report side effects
- In the case of COVID-19, assessment of efficacy against emerging variants of concerns is critical

Standard

Phase 1
10-30 volunteers
6-12 months
Phase 2
50-200 volunteers
6-24 months

Standard

Phase 3
1000-5000 volunteers
1 year for EUL
2-4 year for Registration

Standard

Phase 4
In market assessment
3-6years

COVID/ PHE

Phase 1
10-30 volunteers
6-12 months
Phase 2
50-200 volunteers
6-12 months

COVID/ PHE

Phase 3
500-1000 volunteers
1 year for EUL
1.5-3 years for Registration

COVID/ PHE

Phase 4
In market assessment
3-6years

SAHPRA Learnings from COVID-19 response will enable building efficiencies

OPEN TO LEARN from other regulators and apply what is relevant for the local context

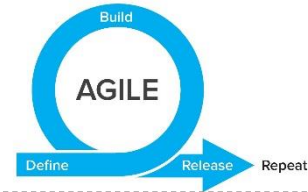


COLLABORATIVELY engage stakeholders that support the availability of data to enable making science based decisions



Efficient
regulator

AGILITY and URGENCY in regulatory processes to accommodate rapid pace of change



STRIDENT, science based regulatory decisions to ensure the safety of the public





Thank you