

Vaccine Stockpiling

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DCVMN Focus:

Challenges where manufacturers can impact positively the vaccine supply chain in countries to make it more responsive and resilient for improved supply security

Challenges where manufacturers can effectively work together to promote and enhance innovations in strengthening the vaccine supply chain



Main focus in on the secondary stage of the vaccine supply chain





25 June 2019 Meeting to review DCVMN vaccine supply chain priorities

Conclusions:

The three areas selected for a more prominent role of DCVMN in the assessment and development of ideas and concepts in the vaccine supply chain:

1. <u>Traceability</u> – directly linked to data quality

2. <u>Stockpiling</u> - for current and epidemic prevention vaccines

3. <u>New packaging technologies</u> – relevance to developing countries

Supply: Stockpiles address vaccine shortages In multiple scenarios



The need for stockpiles relates to low quantities of released vaccines on spot markets (i.e. availability off the shelf), the need for very fast vaccine deployment, difficulties in foreseeing when an outbreak might occur and under-estimating how much vaccine is needed.

Many countries do not hold sufficient buffer stock in the event of shortages or sudden increased demand.



Demand: Vaccine stockpiling includes both static and rotating buffer stocks

Stockpile investments are an integral part of comprehensive disease strategies. Stockpiling can address disease outbreaks, mitigate uncertain demand forecasts and stock-outs and respond to humanitarian emergencies.

The shift in the global health landscape, with increased pressure from climate change, population increases and mass urbanization, increases the risk of large-scale outbreaks and urban epidemics which would overstretch vaccine supplies and continuously re-define the role and size of vaccine stockpiles (Gavi statement).



"The CEPI strategy (pre-COVID) was to develop phase 1/2 data for proof of concept, then to prepare clinical reserves (stockpiles of non-approved products) so we could respond rapidly to an outbreak. Once vaccines are licensed, we assume stockpiles might follow a model like Ebola. There are opportunities for central stockpiles vs multiple regional stockpiles and they likely change by disease. We model the impact of these clinical reserves including how large they should be to cover 50% probability, 75% probability, and 95% probable outcomes based on our current epidemiology assessments." Personal communication, Vice-Chair, Scientific Advisory Committee



CEPI Portfolio epidemic prevention vaccines

Virus	Potential population affected (millions)	CEPI investment (million US\$)	Stockpile (doses)
Ebola	165	n/a	500,000
Lassa	295	178	
MERS	190	100	
Nipah	1,583	100	
Rift Valley Fever	534	22	
Chikungunya	5,950	59	
Marburg	297	8	
COVID-19	7,854	1,218	COVAX buffer (100m)

Common Stock-outs are a significant problem – reported Developing Countries Vaccine Manufacturers Network on average in 30% of countries (n=194)





Countries already have access to internationally-managed stockpiles

Cholera, Yellow fever, Meningitis, Measles/MR, OPV, Ebola: Global vaccine stockpiles have provided countries with the capacity for rapid response to outbreaks



A snapshot view of the performance of the ICG Manufacturers Network A snapshot view of the performance of the ICG

In 2017, the ICG oversaw and approved the distribution of over 16.5 million doses from the cholera, meningitis and yellow fever stockpiles. All vaccine requests were circulated for decision-making within one working day. Decisions were reached within two working days for 95%, 94% of 88% of meningitis yellow fever and cholera requests. Gaps in laboratory, surveillance, logistics and outbreak response capacity contributed to delays between decision and reception of vaccines by affected countries. Nguyen T. and Richardson S., Vaccine stockpile governance through partnership: The

Nguyen T. and Richardson S., Vaccine stockpile governance through partnership: The International Coordination Group on emergency vaccine provision and its impacts, Abstracts / International Journal of Infectious Diseases 79(S1) (2019) 1–150



Stockpiling feedback from 2019 Hanoi vaccine supply chain workshop

- Bulk stockpiles exist but when to start filling needs to be determined
- Regulatory releases of filled product (takes ~3 months) so cannot address stock-outs or outbreaks
- Problems with released product stockpiles storage, cost
- Capital and operating costs loss of financial interest by holding stock
- Remaining shelf life challenges especially with 24 month shelf life – need for flexibility from countries
- Manufacturer risk needs to be addressed
- Possible quality loss in transport and storage (if off-site)
- Quantification of stockpile
- Short-life vaccines (e.g. flu) limit stockpiling
- Pre-payment for finance stockpiles or financial incentives
- Need to also stockpile labels etc.

Purpose of the current stockpiling workshop

Stockpiles have the risk of causing losses to manufacturers. There is a need for a common view on stockpiling, including the remaining shelf life requirements of countries as this limits the flexibility for both static and rotating stocks.

- Sharing experiences among DCVMN members for both static and rotating buffer stockpiles
- Identifying successes in manufacturers' management of stockpiles
- Determining challenges faced by manufacturers in the management of stockpiles



Way Forward

- Agreement on Next Steps
- Developing case studies of members' experiences
- Articulating best practices in the management of stockpiles
- Sharing among members and donors best practices for the management of stockpiles