

Meeting with J&J

22Dec2020

Attendees

Francisco Paco

Anban Pillay

Aluwani

Submitted to SAHPRA – rolling evaluation } submitting to other regulators as well

SAHPRA deadline for first approval “provisional registration”

1st Q Part of

Timelines for submitting application → final part dossier – 2nd Q

Exceptional use

Recruitment completed → 45000k globally 7000 in SA clinical trails

Distribute 1st batches in 2nd quarter = need agreements with countries etc

↗25% = 9 million doses ↘ not all available in Q2

Need forecast → % of adult population

Pricing and budget = informs forecast

Single / two dose? = single dose for pandemic

Price~ not for profit → public

~ not more than \$10.00~ includes distribution to a single distribution point in the country

~ one single price for whole world

final confirmation --signing a bilateral agreement

in the interim → just need a signal

Draft document → minus 20°C

Storage – 2-8 °C, transport & liab

Doses for vial – 5 doses, 10 vials per cartons

Vial per shipper pack 48 cartons ↘

per shipper flying → VVM?

3 months shelf

Injection site