AZ/ OXFORD VACCINE: DISCUSSION WITH SAHPRA

Attendees

Barbara Nel	
Quinton Meyer	
Wayne Muller	(Way forward →AZ to submit request data)
Priti Shan	(In a pandemic need to work with speed, EU)
Deon Poovan	
Portia Nkambule (SAHPRA)	(1.5 million doses, SII some stock for HCW, Section 21 request)
Anban Pillay	
Silverrani Padayachee (SAHPRA)	(Questions re SAHPRA)
Boitumele Semere (SAHPRA)	
Ruth Field	(what would we need to approve Section 21, comparability & quality)
Dr James Southern	
Shyamli (SAHPRA)	(full clinical study report need flux, EUL)
Tohlang (SAHPRA)	
Henry Leng (SAHPRA)	

AZ partner with 15-20 different third party manufacturers to↗ rather clinical overview equitable access

Not full tech transfer comparability master plan & validation master plan

SII holds marketing authorization

R Pharm

SII doing entire manufacture value chain

Comparability strategy = compared to product used in phase 3

Clinical trails, every site compares to product used in phase 3

Share MHRA report for emergency use approval

↘ to publish assessment report in next 7 days

↘EMA report as well

1-2 months thermal degradation – part of comparability process

Approved 2 dose regiment →4.12 weeks dosing interval

PV roll out plan, priorisation of events

There is a full risk Mx plan, need to get Serum's risk Mx plan