# Regulatory Pathways for LA Formulations for HIV
# IAS – ILF Forum June 28, 2022

Ray Corrin
WHO Prequalification of Medicines Program

# CAB LA

Long-acting cabotegravir (INI)

# Regulatory Bodies

- nation or region-specific
- verify safety/efficacy/quality claims of a product
- highly detailed, based *only* on submitted data

vs

# Guidelines Bodies

- WHO, national, specialist societies
- broader mandate describing use
- less detailed, based on publications, expert interpretation

*Rarely talk to each other >> COI*

# WHO Prequalification

Began in 2001

*Not* a regulatory body

but…

has a type of regulatory function

PQ:

advice to generic sponsors on BE study design

CSA (Co-ordinated Scientific Advice):

advice to sponsors on clinical development issues

# Innovator *vs* Generic

*Innovator Sponsor:*

SRA-approved label not altered

*Generic sponsor:*

PQ creates SmPC & PIL
aligned with WHO Guidelines

Re-labelling >> for factors not in view
at time of original trials

# CAB LA

- SRA-approved only by FDA
- No WHO PQ generic application to date
- Must appear in PQ EOI to apply

- FDA label requires NAT for HIV

  *before and with each dose (i.e. q 2 mo)*

# *Why?*

HPTN 083 Study in MSM:

6 pts with “pharmacologic failure”

- Masking of early infection
- Delays in correct dx of HIV
- HIV viral resistance development

Potential large consequences >> transmission of resistant HIV

# Regulator

- Post-approval trial commitment
  for trial during and for 1 yr post-PrEP

- More stringent labelling requirement
  >> NAT

# WHO Guideline Development Group (GDG)
# ??

- New HIV guideline version due July 2022
- *In theory*, PQ'd generic CAB LA
  >> labelled differently from innovator
- Relief? >> rapid/cheap point-of-care NAT


Thank you