Extraordinary Virtual

International Conference of Drug Regulatory Authorities (ICDRA)

20-24 September 2021

# Plenary 3

## Emergency Use Listing Medicines, Vaccines, and IVDs including inspections during the COVID-19 global pandemic

Tuesday, 21 September 2021
1-3 pm Geneva time

Dr Agnes Saint Raymond
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# House Keeping


- Interpretation available in French and Russian
- Presentation slides and recording link will be shared by email for those who registered after the Webinar.
- This Webinar is being recorded and your attendance is consent to be recorded. Thank you!
- **Please ask your questions through the Q & A Chat function**. The panelists will do their best to address them.
- For any technical assistance, please email Angela Lopes (lopesa@who.int)

# Plenary 3: Agenda

- Opening and introduction of panel members (5 min)
  - Co-moderators: Agnes Saint-Raymond (EMA), and Ms Heeyoung Park (MFS)
  - Panelists: Mr Deus Mubangizi (WHO), Dr Gustavo Mendes Lima Santos (ANVISA), Dr Tracy Moore (MHRA), Ms Ntetselele Kago (BoMRA)
  - On behalf of **GMTA**, Ms Nicole Taylor-Smith and on behalf of **IFPMA**, Dr Stephan Ronninger

- Panel discussion-Contextualization of product assessment and inspections using the EUL tool in managing availability during the pandemic Good Regulatory and Good Reliance Practices (15 min)
- WHO setting the scene on EUL procedure (Assessment and inspections) Presentation by Deus Mubangizi (15 min)
- Lessons learned from the pandemic involving Devices Presentation by Nicole Taylor-Smith (8 min)
- Assessment of Vaccines using EUL Presentation by Gustavo Mendes Lima Santos (8 min)
- Remote Assessment (inspections) Presentation by Tracy Moore (8 min)
- Industry experience with remote inspections and going back to normal Presentation by Stephan Ronninger (8 min)
- Country perspective on utilizing EUL process Presentation by Ntsetselele Kago (8 min)
- Panel discussion (Questions to the panel via Chat with response from the panel via live feedback or chat response (10 min)
- Outline recommendations and closing (5 min)

# Plenary 3: Panel Discussion

- Panel discussion (questions & comments/questions from the chat) (10 min)

# Plenary 3: Summary

**Available collaboration mechanisms and facilitated pathways allowed for work sharing in areas related to assessment and inspections with new tools developed**

- Due to Global pressure, Industry and Regulators had to accelerate decisions on products to treat, prevent and diagnose Covid infections
- Existing mechanisms were used and new innovative tools were developed
- Challenges, reliance, mutual recognition and risk benefit resulted in greater work and information sharing between regulators, procurers and decision bodies
- Due to different experiences, solutions were developed allowing greater regulatory flexibility
- Some solutions could be carried forwards

# Plenary 3: Recommendations

- Continue momentum of work and information sharing, reliance, mutual recognition and risk benefit decisions by regulators, procurers and decision bodies
- Continue using new tools such as digitalization to allow for visibility, structure, accountability and greater operational excellence in the area of inspections
- Continue using rolling submissions with greater emphasis on post approval submissions
- Advocate more frequent engagements between Regulators and Industry

# THANK YOU