WHO Informal Consultation on options to improve regulatory preparedness to address public health emergencies

Starling Hotel, room London II
Route François-Peyrot 34, 1218 Le Grand-Saconnex

17 to 19 May 2017

Agenda

Chair of the meeting
Helen Rees

Rapporteurs
Elwyn Griffiths
Mac Lumpkin

Wednesday 17 May

SESSION 1  13:00-15:00

Opening remarks
Marie-Paule Kieny (10 min)

Self-introductions
(15 min)

Rationale for the meeting, ways of working and expected outcomes, including a summary of ICDRA and Blueprint SAG recommendations
Helen Rees, Chair (10 min)

What are the problems we are trying to fix?

i)  A regulator’s perspective: personal experience of being in the hot seat as a regulator in a public health emergency
   Mimi Darko, Ghana FDA (20 min)

ii) An ethicist’s perspective
    Aissatou Toure, Institut Pasteur Dakar (20 min)

iii) Facilitating global access to innovative products for public health emergencies
     Mac Lumpkin, BMGF (20 min)

Coffee Break 15:00-15:30

SESSION 2  15:30-17:30  Parallel Sessions (PS):

Does EUAL procedure need further development?

PS 1:  Emergency authorization processes for diagnostics  (120 min)

Facilitator
Mark Page, NIBSC

Rapporteur
Willy Urassa, WHO

i)  WHO EUAL experience so far
    Irena Prat, WHO (15 min)

ii) Lessons learned from Ebola and Zika on product development for diagnostics
    Arlene Chua, WHO (15 min)

iii) Product developers perspective
     Jesus Rueda, EDMA (15 min)

iv)  A regulator’s experience of emergency authorization processes
     Uwe Scherf, US FDA (15 min)

Discussion - options for going forward
(60 min)
PS 2: Emergency authorization processes for vaccines (120 min)

Facilitator: Helen Rees, Chair
Rapporteur: Ana Maria Henao Restrepo, WHO

i) WHO EUAL experience so far
   Carmen Rodriguez-Hernandez, WHO (10 min)

ii) Product developers perspectives
   (a) IFPMA
      Marie-Chantal Uwamwezi, MERCK (10 min)
   (b) CEPI
      Karianne Johansen, CEPI (10 min)

iii) A regulator's perspective of emergency authorization processes
    Marco Cavaleri, EMA (10 min)

Discussion - options for going forward (80 min)

PS 3: Emergency authorization processes for therapeutics and biotherapeutics, including convalescent plasma (120 min)

Facilitator: Mac Lumpkin, BMGF
Rapporteur: Martin Friede, WHO

i) WHO EUAL experience so far
   Ray Corrin / Regine Lehnert, Consultants to WHO (15 min)

ii) Lessons learned from Ebola and Zika on product development for therapeutics and biotherapeutics, including convalescent plasma
    Michael Kurilla¹, NIH (15 min)

iii) A researcher's perspective
    Peter Horby, ISARIC (15 min)

iv) A regulator's perspective of emergency authorization processes
    (a) US FDA
       Luciana Borio (15 min)
    (b) Health Canada
       Liz Anne Gillham-Eisen (15 min)

Discussion - options for going forward (45 min)

End of day and reception

¹ Chair of Ebola STAC
Thursday 18 May

SESSION 3  09:00-10:30 Future options for the WHO EUAL

Facilitator  

Helen Rees, Chair

Report from parallel sessions  

(10 min / rapporteur)

i) Report from the session on diagnostics  

Willy Urassa (Rapporteur)

ii) Report from the session on vaccines  

Ana Maria Henao Restrepo (Rapporteur)

iii) Report from the session on therapeutics and biotherapeutics  

Martin Friede (Rapporteur)

Discussion – potential ways forward for the EUAL process  

(60 min)

Coffee Break 10:30-11:00

SESSION 4  11:00-12:30 Consensus on options to improve regulatory preparedness

Facilitator  

Wiltshire Johnson, Sierra Leone

i) Regulatory pathways - what pathways are available and what else is needed?  

Emer Cooke, WHO (10 min)

ii) A case study – approval of anthrax therapeutics using the animal rule  

Ed Cox, US FDA (10 min)

iii) Options to improve regulatory preparedness  

(a) AVAREF  

Mimi Darko, Ghana FDA (10 min)

(b) ICMRA  

Ian Hudson, MHRA (10 min)

iv) Tools to assess regulatory preparedness  

Mike Ward, WHO (10 min)

Discussion – regulatory capacity building needs and solutions  

(40 min)

Panellists: Marco Cavaleri, Mimi Darko, Wiltshire Johnson, Mac Lumpkin, Liz Sadove, Mike Ward

Lunch 12:30-13:30

SESSION 5  13:30-15:00 Norms and standards for countermeasures for emerging infectious diseases

Facilitator  

Elwyn Griffiths

i) Access to reference preparations and panels in support of product validation  

Mark Page, NIBSC (10 min)

ii) Implications of the Nagoya protocol  

Daniel Hougenodbler, WHO (10 min)

iii) Quality requirements and non-clinical studies  

Klaus Cichutek, PEI (10 min)

iv) Clinical trial designs for priority pathogens: update on method discussion  

Pierre Gsell, WHO (10 min)

Discussion – norms and standards needs and solutions  

(50 min)
Coffee Break 15:00-15:30

SESSION 6  15:30 – 17:30 Parallel Sessions (PS)

Safety and vigilance for emergency use products

PS 4:  Evaluation product safety for vaccines and therapeutics (120 min)

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<td>Rapporteur</td>
<td>Daisuke Tanaka, WHO</td>
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i) A regulators perspective on therapeutics and biotherapeutics

Marco Cavaleri, EMA (20 min)

ii) A regulators perspective on vaccines

Marion Gruber2, US FDA (20 min)

Discussion - options for going forward (80 min)

PS 5:  Performance assessments for diagnostics (120 min)

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i) Experiences of evaluating investigational product performance, including research use only IVDs, in an emergency setting

Cassandra Kelly, FIND (15 min)

ii) A regulators perspective

Wiltshire Johnson, Sierra Leone (15 min)

iii) Field users perspectives

Sophie Duraffour, BNITM (15 min)

Discussion - options for going forward (75 min)

End of day

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2 Also representing GACVS
**Friday 19 May**

**SESSION 7  09:00 – 10:30 Options to improve regulatory preparedness for public health emergencies**

Facilitator  
*Helen Rees, Chair*

**Report from parallel sessions**  
*(10 min / Rapporteur)*

i) Report from the session on safety evaluations for vaccines and therapeutics  
*Daisuke Tanaka (Rapporteur)*

ii) Report from the session on performance assessments for IVDs  
*Irena Prat (Rapporteur)*

**Plenary discussion**  
*All participants*

i) Potential ways forward to improve regulatory preparedness

ii) How will we know if we have achieved success? Options for monitoring and evaluating progress

**Conclusions**  
*Helen Rees, Chair*

**Coffee Break 10:30-11:00**

**SESSION 8  11:00 – 13:00**

**CLOSED SESSION (by invitation only)**

Recommendations to WHO

End of meeting and lunch