SUMMARY of PRELIMINARY OUTCOMES
WHO INFORMAL CONSULTATION ON
REGULATORY PREPAREDNESS TO ADDRESS PUBLIC HEALTH EMERGENCIES

During the development of products or procedures to address access to unlicensed products during public health emergencies, it is imperative to involve national regulatory authorities (NRAs), especially those from low- and middle-income countries (LMICs) and those affected by an emergency. Also, when implementing the recommendations below, WHO should ensure that there is appropriate participation and representation of all potentially affected NRAs. Furthermore, effective emergency responsiveness from less well-resourced NRAs will only be possible if current efforts to capacitate and make functional LMIC NRAs are supported and accelerated.

WHO will reflect on these outcomes with a view towards developing an action plan based on priorities and available resources.

1. WHO should clarify aspects of the current EUAL process:
   a. WHO should change the name of the process from “Emergency Use Assessment and Listing” process (“EUAL”) to “Emergency Use Listing” process (“EUL”) as in the EUAL acronym the ‘A’ is not well understood. Many equate “A” with ‘authorization’ as in the U.S. FDA Emergency Use Authorization (“EUA”) process.
   b. The EUAL should only be used in exceptional circumstances; it should be noted that it is not for general use for every outbreak or during initial response to an outbreak.
   c. The EUAL should be primarily used at the declaration of a Public Health Emergency of International Concern (PHEIC), but can be used in other public health emergencies, if appropriate.
   d. The use of the EUAL must have a science-based rationale describing what appropriate benefit(s) may accrue from the use of product – its use must not be based simply on hope or political pressure.
   e. Relationship of EUAL process and listing decision to activities at the NRA level
   f. How the EUAL relies on assessment work products already performed by NRAs
   g. How the EUAL may be used by NRAs and procurers in their decision-making
   h. WHO should ensure timely communication of any potential decision with regulators prior to final decision announcement; this can be done via conference calls and communication tools such as talking points and/or Q&As.
   i. WHO, in collaboration with NRAs, should develop or recommend a common template for EUAL application that can be used for both WHO and NRA applications for emergency use.

2. WHO should institute a pre-EUAL submission process to obtain, maintain, and evaluate in an on-going manner available data to better prepare to make an EUAL listing decision as quickly as possible once a public health emergency occurs and the context in which the product might be used is known:
a. The Pre-EUAL submission should be limited to pathogens or situations outlined in the WHO R&D blueprint.

b. The Pre-EUAL submission should be applied to new products or repurposed products.

c. In addition to data collection on product safety, efficacy, and quality, the following matters should be addressed as part of the process:
   i. The need for any new physical standards / guidelines / companion diagnostics / other normative guidance.
   ii. Plans for (as appropriate) :
      1. Clinical trials (with possible pre-approval of trials by responsible NRAs and ethics committees/boards).
      2. Use in first responders.
      3. Use in Health Care Workers.
      4. Use in wider populations.

iii. Any interactions with potentially affected NRAs.

iv. Plans for collecting, saving, transporting, exporting any biological samples if used under a future EUAL

v. Communication plans if used under a future EUAL

vi. Pharmacovigilance plans if used under a future EUAL

3. WHO should ensure that that relevant pre-EUAL submission information and other relevant information developed during the emergency can be shared with relevant NRAs and ethics committees/boards by:

   a. Establishing mechanisms for sharing such data before the need for a specific EUAL.

   b. Developing (or recommending) a common template for data submission so that data can be easily shared with NRAs and ethics committees/boards.

4. WHO should map/landscape the current emergency provisions (regulatory and legislative) in LMICs and address legal or regulatory deficiencies that might prevent rapid implementation of any measures required to be implemented during an emergency.

5. WHO should develop a clear set of expected minimum competencies that NRAs and ethics committees/boards should have for handling the emergency use of unlicensed medical products during a public health emergency. To support this work WHO should:

   a. Explore how these minimum competencies could be incorporated into the Global Benchmarking Tool (GBT) and supporting processes.

   b. Develop training modules and expertise verification mechanisms for NRAs and ethics committees/boards that wish to implement these competencies (using the Coalition of Interested Partners process).

   c. Define how these competencies interface with International Health Regulations emergency
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version 25 May 2017

6. WHO should develop guidance, in collaboration with experts on ethics, on the procedures and pathways for the use of unlicensed medical products during a public health emergency and give guidance/assistance on when it is appropriate to use these procedures and pathways.
   a. This guidance should include a glossary of various names of procedures and how WHO will use these terms. Such terms could include: Emergency Use Listing (if that is the new name for the current EUAL procedure), Emergency Use Authorization, Conditional Approval, Accelerated Approval, Approval Under Special/Exceptional Circumstances, Expanded Access, Compassionate Use etc.
   b. This guidance should include procedures for best communications practices (to the public, to practitioners, to government officials), for best pharmacovigilance practices, for best supply chain security practices, and for best continuity of business practices, in addition to unlicensed medical product assessment for access during an emergency.

7. WHO should finalize the AVAREF guidelines and associated templates for expedited review of Clinical trials (both by regulatory and ethics committees/boards) in the context of a public health emergency.
   a. Include provisions for including experts/NRAs from outside Africa as deemed appropriate in specific outbreaks.
   b. Conduct table top exercise to further inform the process and amend as necessary.

8. WHO should explore the use of other regional platforms and the feasibility of adapting models like AVAREF to other geographic areas to facilitate expedited regional assessment of clinical trials in the context of a public health emergency.

9. WHO should explore the feasibility of a “diagnostics preparedness consortium” and measures to facilitate sample availability to support product development/product validation.

10. WHO should explore ‘mock-up’ practices for expedited review of candidate products on an annual basis with interested NRAs and ethics committees/boards.

11. WHO should continue developing measurement (physical) and written standards (Guidelines) that serve as a basis for regulatory evaluation, PQ and EUAL, taking into consideration: 1) priority pathogens defined by the Blueprint and 2) a more flexible and dynamic approach to developing and establishing standards for quality, safety and efficacy of products for use in PHE. Collaboration with CEPI and other partners is critical for a coordinated and timely outcome at the global level.

It should be noted that progress on this important area will be pending resources provided to WHO.