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Readiness of a Sample of LMICs to Expedite Authorization of COVID-19 Vaccines, and Case Study of Burkina Faso

Neimatu D. Adjabui
Principal Program Manager, PQM+

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African Medicines Regulatory Harmonisation Programme

Promoting the Quality of Medicines Plus (PQM+)

About PQM+

The Promoting the Quality of Medicines Plus (PQM+) program, funded by the U.S. Agency for International Development (USAID) and implemented by the U.S. Pharmacopeial Convention, works to improve systems that assure the quality of essential medical products in low- and middle-income countries (LMICs) to help prevent maternal and child deaths, control the HIV epidemic, and combat infectious diseases through high-performing health systems.

Introduction

- Vaccines are an effective intervention to prevent infectious disease; however, it can take up to 15 years to develop and make them available for the public.
- In public health emergencies, governments must balance between making life-saving vaccines available quickly and the need for protecting public safety.
- Given the pandemic, COVID-19 vaccines were developed and made available in a shorter period and granted approvals under emergency use authorization/listing.

Role of Medicines Regulatory Authorities (MRAs) in Medicines Approval

- MRAs are responsible for ensuring public access to quality-assured and effective medical products, including vaccines.
- For approval for use in a country, a manufacturer's vaccine must meet requirements for quality, safety, and efficacy outlined by the MRA, including rigorous clinical trials.
- The standard approval process involves review of scientific data from the clinical trials of the vaccine and the manufacturing history of the vaccine to weigh the benefit of the vaccine against the risks before granting market authorization or import licenses for the vaccine.

Application of EUA during Product Approval

In public health emergencies, MRAs must decide whether to approve new products based on limited information and greater contextual risk

Governments can use expedited authorization mechanisms such as Emergency Use Authorization (EUA) or Emergency Use Listing (EUL) to approve use of products.

- **EUA** is a mechanism used by the U.S. Food and Drug Administration (US FDA) to expedite the availability and use of medical products, including vaccines, during public health emergencies such as the COVID-19 pandemic.
- **EUL** is a procedure used by WHO to assess unlicensed vaccines and other products to ascertain whether they offer a favorable benefit-risk ratio in the context of a public health emergency. EUL denotes a recommendation that the medical product can be used in an emergency while the product is still under development.

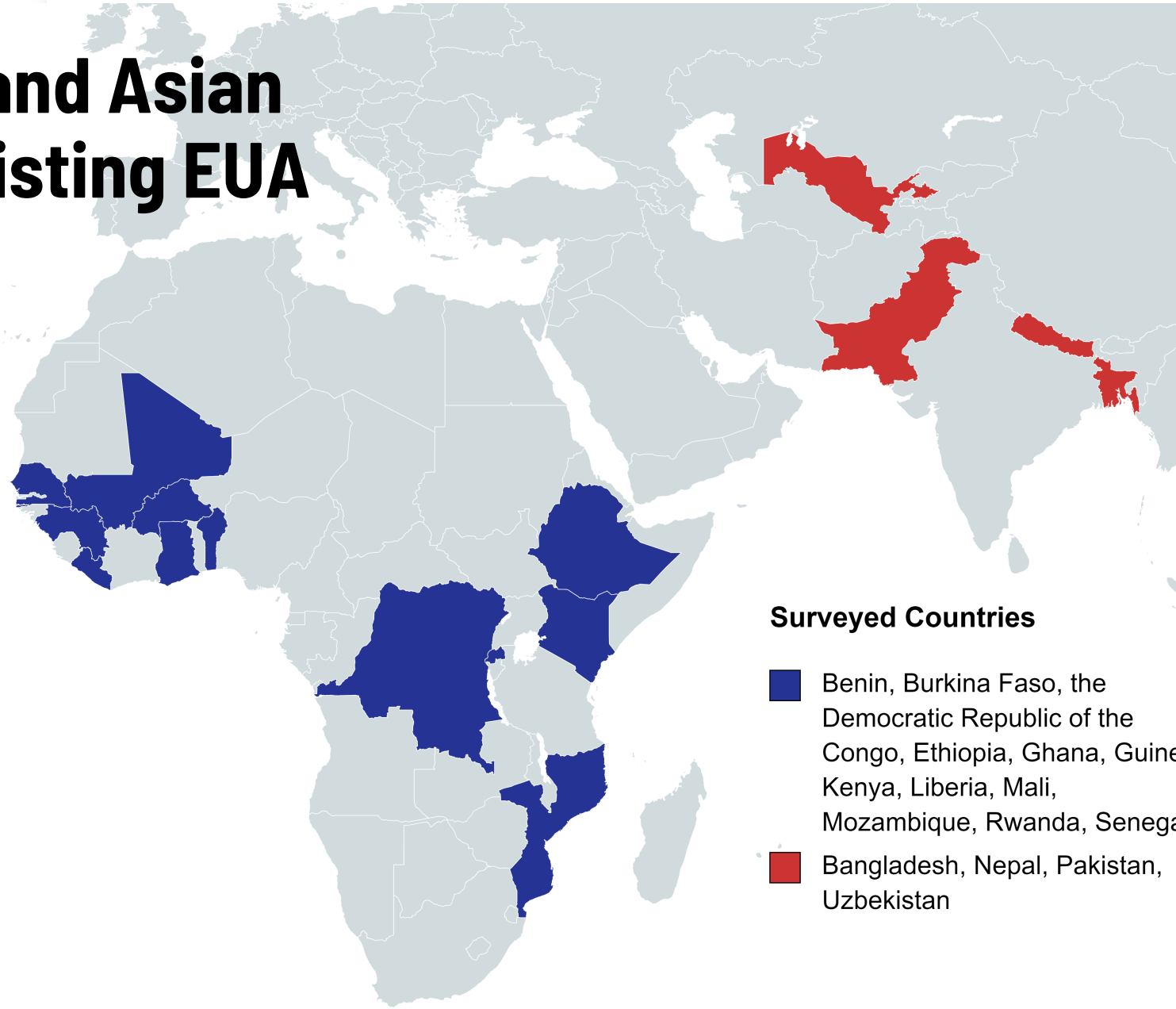
With EUA and EUL, the MRA and the product manufacturer must closely monitor and report any adverse events that follow use of the product with well-established post-marketing surveillance.

LMICs should adopt reliance regulatory mechanisms that allow them to rely on EUA decisions taken by stringent regulatory authorities such as the US FDA or the WHO EUL procedure.

MRAs should implement processes to facilitate transitioning EUAs into full approvals.

PQM+ Survey on African and Asian LMIC Countries on the existing EUA process

- University of Washington, USAID's PQM+'s partner, conducted a survey of existing EUA regulatory processes and procedures for COVID-19 vaccines in 16 countries
- PQM+ developed an interview guide and questionnaire in English and translated it into French
- This guide contained 16 questions to capture information on vaccine approval procedures and requirements
- 12 African and 4 Asian countries responded to the survey



Survey Methodology

The survey questionnaire covered the following topics.

- Traditional vaccine approval pathway
- **Expedited approval pathway**
- Import requirements
- Manufacturer requirements
- Plans for safety surveillance of COVID-19 vaccines
- Names and manufacturers of COVID-19 vaccines approved to date by the country

Outcome of the Survey

Expedited approval pathways

13 countries had some form of expedited pathway

10 countries introduced special expedited pathways for approving COVID-19 vaccines after the start of the pandemic.

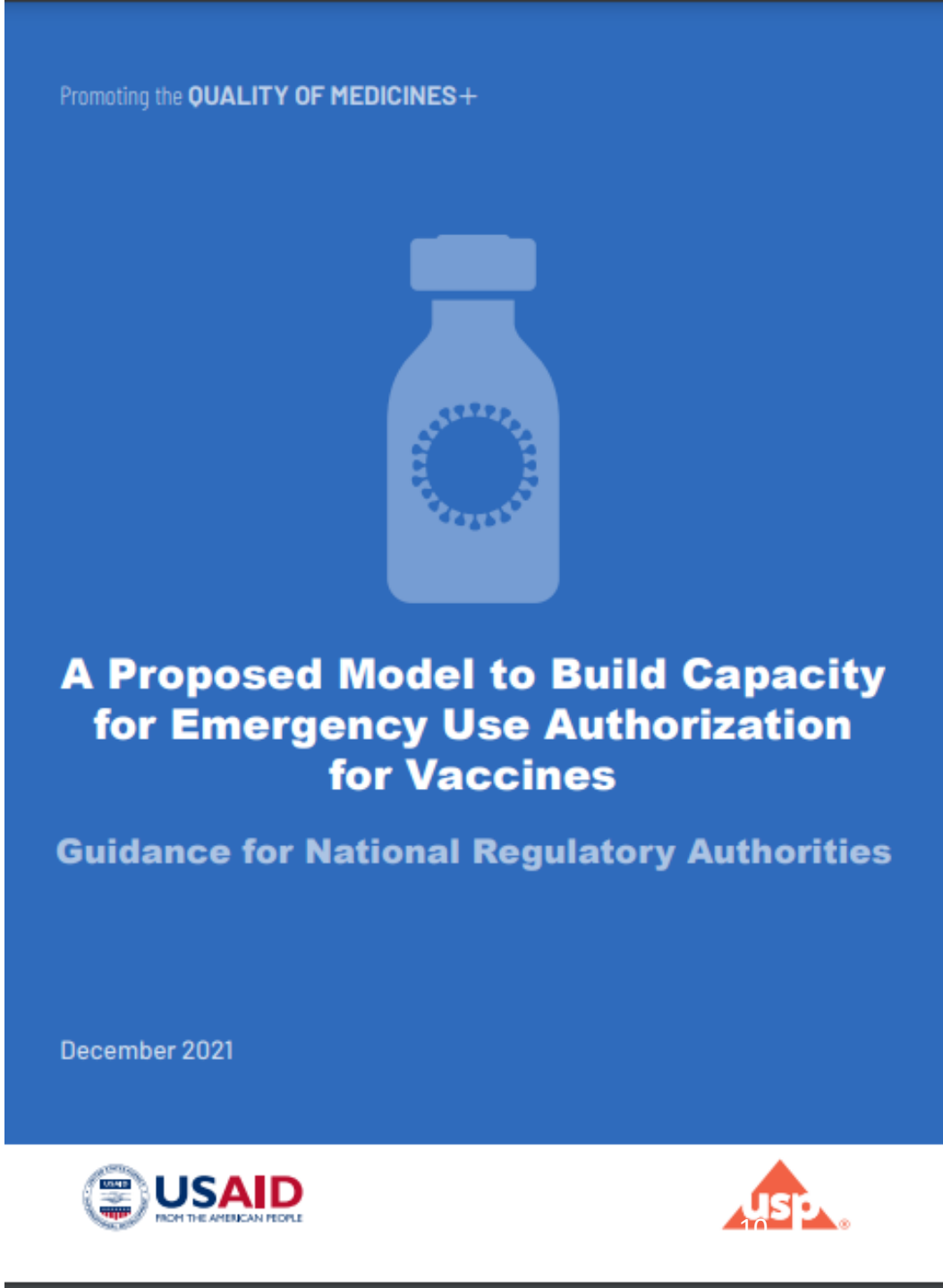
- 5 countries had measures prior to the pandemic but added measures targeting COVID-19 vaccines
- In 5 countries, the special expedited pathways for approving COVID-19 vaccines were the first such measures in that country.

Reliance

- 11 countries' expedited approval pathways included the recommended practice of reliance on authorization and decisions taken by other qualified regulatory authorities.

PQM+ Support in Building MRA Capacity to Implement EUA

- The survey results led to development of a guidance document by PQM+ program titled " *A Proposed Model to Build Capacity for Emergency Use Authorization for Vaccines: Guidance for National Regulatory Authorities"*.
- This guidance document provides practical instruction to MRAs on adopting, implementing, and managing expedited approval pathways for vaccines, focusing on COVID-19 vaccines.



Case Study – Burkina Faso

Context

- Burkina Faso had a national legal text that provided for exemptions in public health emergencies.
- The law provided abbreviated approval covering all health products, including vaccines based on recognition under certain conditions

Case Study – Burkina Faso

PQM+ Support in Building Capacity of L'Agence Nationale de Régulation Pharmaceutique (ANRP) for granting EUA

- Conducted a training needs assessment and developed a custom EUA training for ANRP staff
- 23 participants from ANRP, the national quality control lab (ANSSEAT) and other departments in the Ministry of Health were trained
- Training outcome – A 21% knowledge gain recorded

Case Study – Burkina Faso

Developing and operationalizing regulatory pathways

- Drafting and validating **regulatory guidelines** for granting EUA in Burkina Faso
- Reviewing and revising, where needed, and validating their **ministerial decree**
- Develop 4 **regulatory documents** to operationalize issuing EUAs in Burkina Faso:

  (1) Standard operating procedure (SOP) for granting EUAs,

  (2) Work instruction for reliance,

  (3) Work instruction for accelerated approval and

  (4) Work instruction for recognition

Case Study - Burkina Faso

PQM+ Supported ANRP to convene a session to review dossier for Moderna vaccines to facilitate granting of EUA

- Convened a workshop for ANRP's committee technical experts to establish its safety, efficacy, and quality for the Burkina Faso population.
- Issued an EUA for the Moderna vaccine by ANRP:
  - Supported evaluation of the Moderna vaccine's safety, efficacy, and quality for the Burkina Faso population.
  - Evaluation report was reviewed by the Technical Commission for the Approval of Health Products which recommended the issuance of an EUA for the Moderna Vaccine by ANRP.
  - Provided ANRP's technical committee additional training on EUL and new EUA guidance.

Conclusion

- MRAs quickly added regulatory measures specific to COVID-19 in response to the pandemic.
- Additional support may be needed for formal adoption of EUAs/EULs, expansion to other medical products, and for the operationalization of these regulatory measures in preparation for the next public health emergency.

Future Implications

- NMRAs should establish the necessary regulations, guidelines and SOPs to ensure the efficient regulatory mechanisms are in place.
- Regulatory actions may incorporate decisions of WHO-Listed Authorities, stringent regulatory authorities, ML4, ML3 to review, assess and approve vaccines, diagnostics, therapeutics for any future pandemics, epidemics, or national emergencies.
- Clear regulations and guidelines with timelines will facilitate access to the urgently needed quality assured, safe, and efficacious vaccines and therapeutics to be used during pandemics

Thank you!