ANNOUNCEMENT: INTRODUCTION OF THE SECOND PILOT PHASE FOR MDA-CAB WORKSHOP 2024 OUTCOMES

Dear **Medical Device Industry Stakeholders**,

Greetings from the Authority! We are pleased to announce the introduction of the Second Pilot Phase for the implementation of the outcomes from the MDA-CAB Workshop 2024. This decision follows the comprehensive refinements made during the MDA-CAB Workshop 2024 (Series II) held on October 24-25, 2024. Your active participation and invaluable input have significantly contributed to enhancing our processes, and we are committed to ensuring a smooth and effective transition towards full implementation.

Key Outcomes

1. Mutual GDPMD Report Template Implementation
2. Mutual Certification Processes Turnaround Time (TAT) Implementation
3. Mutual Verification Report (GMD & IVD) Template Implementation

The finalized templates and processes are available for download at: Documents

Second Pilot Phase Implementation

Purpose: Align CAB procedures with new revised templates and processes, make necessary amendments, and continue testing and refinement using the finalized templates and processes from the October 24-25, 2024, workshop. Gather additional feedback to ensure the effectiveness of the updates.
Duration: January 20, 2025 until the issuance of the official guidance document by MDA.

Rationale for the Second Pilot Phase

The Full Implementation Phase, originally planned to commence on November 1, 2024, was deferred to allow for the issuance of an official guidance document by MDA. This document is crucial to providing comprehensive instructions and ensuring consistent application across the medical device industry. To maintain momentum and facilitate further refinement, the Second Pilot Phase has been introduced. Stakeholders are encouraged to utilize this extended phase to familiarize themselves with the finalized templates and provide constructive feedback.

Call for Feedback

To ensure the continued effectiveness of these updates, we invite you to provide feedback during the Second Pilot Phase. Feedback can be submitted multiple times through the following online form: Feedback Form. Your input will be invaluable in finalizing the implementation process.

We appreciate your cooperation and continued support throughout these implementation phases. Should you have any questions or require further information, please do not hesitate to contact us as shown at the Appended Signature below. Thank you for your attention and valuable contributions.

Best regards,
Pre-Market Controls Division (BKPP)
Medical Device Authority (MDA)
Ministry of Health (MoH)
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Date: **January 20, 2025**