ANNOUNCEMENT: IMPLEMENTATION OF MDA-CAB WORKSHOP 2024 OUTCOMES

Dear **Medical Device Industry Stakeholders**,

Greetings from the Authority!

We are pleased to announce the outcomes and implementation plan following the MDA-CAB 2023 Workshop (December 6 to 7, 2023) and recent MDA-CAB 2024 Workshop Series I (March 1, 2024). Your active participation and invaluable input have significantly contributed to the enhancement of our processes.

Key Outcomes

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

Implementation Phases

1. Amendment Phase
- Purpose: Align CAB procedures with new templates and processes, make necessary amendments, and conduct internal training.
- Duration: April 1, 2024 - April 30, 2024

2. Pilot Phase
- Purpose: Test and familiarize with the new GDPMD and Verification Report Templates and TAT, identify potential issues, and provide feedback.
- Duration: May 1, 2024 - October 23, 2024

3. Full Implementation Phase
- Purpose: Adopt the GDPMD and Verification Report Templates and TAT into standard operating procedures after thorough testing and refinement.
- Refinement Dates: October 24, 2024 - October 31, 2024
- Start Date: November 1, 2024 (Subject to the decision in MDA-CAB Workshop 2024 (Series II) on October 24, 2024)

Call for Feedback

To ensure the effectiveness of these updates, we invite you to provide your feedback through the following online feedback form: Feedback Form. Feedback can be submitted multiple times during the Pilot Phase until September 30, 2024. All feedback will be discussed in the upcoming MDA-CAB Workshop 2024 (Series II).

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 Control Division (BKPP)
Medical Device Authority (MDA)
Ministry of Health (MoH)
Level 5, Prima 9 (Block 3547)
Prima Avenue II, Persiaran APEC
63000 Cyberjaya, Selangor Darul Ehsan
Date: **July 1, 2024**

CAB Registration Unit (CABRU) | Tel: +603-82300356/0372 | E-mail: cab.registration@mda.gov.my