HSA Health Sciences Authority

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Regulatory Updates
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Strengthening Post-Market Oversight for Medical Devices

The Evolving Landscape

- Medical device ecosystems are becoming increasingly complex:
  - Devices are interconnected and digitally enabled
  - Deployment often spans multiple healthcare institutions
  - Global supply chains increase system interdependency

- Field Safety Corrective Actions (FSCAs) may have implications beyond individual device performance, including potential impact on healthcare service continuity and system reliance.

Post-market safety signal interpretation

- Interpreting post-market safety signals increasingly requires consideration of both:

- From January 2026, HSA implemented a structured internal review to guide the interpretation and escalation of Field Safety Corrective Actions (FSCAs).
  - **No change to existing regulatory obligations for MD dealers**
  - Internal calibration currently ongoing
  - Approach will continue to evolve with operational experience

Structured Risk Interpretation

- To support consistent interpretation of safety signals, FSCAs are assessed across five key lenses:
  - ⚕️ Clinical outcome — potential patient harm
  - 📈 Risk signal — scope and trajectory of evidence
  - 🛠️ Mitigation — reliability of corrective actions
  - 📣 Communication transparency — clarity and timeliness
  - 🏥 Health-system exposure — degree of system dependency
- This helps ensure escalation decisions consider both patient impact and potential system consequences, rather than device type alone.

Structured Risk Interpretation and Calibrated Escalation

Structured Risk Interpretation matrix

- Each lens assessed using traffic-light scoring (Green / Amber / Red)
- Scores combined to indicate overall FSCA risk profile
- Supports decisions on:
  - Escalation pathway
  - Response timeline
  - Level of management oversight

Tiered Escalation

- Operational review
- Supervisory oversight
- Management review
- Senior management review

Supports proportionate and timely oversight while maintaining established supervisory processes for routine corrective actions.

Malaysia MDA – Singapore HSA Regulatory Reliance

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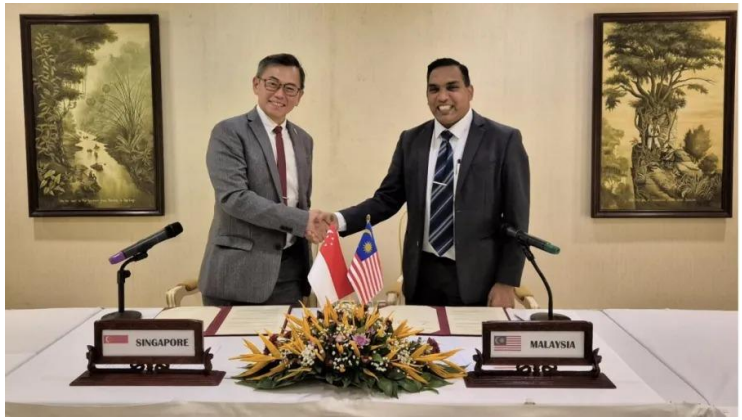

- Regulatory reliance pathway between HSA and Malaysia MDA for Class B, C and D medical devices.
- Allows devices approved in one jurisdiction to leverage aspects of the regulatory assessment in the partner jurisdiction.
- Supports:
  - More efficient regulatory review
  - Reduced duplication of regulatory effort
  - Strengthened regional regulatory collaboration
- Singapore's SHARE system enables companies to opt-in to the reliance pathway during submission.

Update on Implementation

MALAYSIA

Verification Route for MDs registered on Singapore Medical Devices Register (SMDR)

Reciprocal Regulatory Reliance

SINGAPORE

Abridged Route for MDs registered on Malaysia Medical Device Authority Register (MDAR)

- Initial experience supports streamlined review while maintaining regulatory oversight.
- Both agencies have agreed to continue this regulatory reliance arrangement

Thank You!