Global Medical Technology Alliance
Innovating for a Healthier World

Regulatory Reliance

IMDRF Stakeholders Session

13th September 2022 – Sydney, Australia

"The future of medical products regulation is in convergence/harmonization, collaboration, and networking based on reliance and trust."

Presentation Outline

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- Greater Reliance
- Observations and Recommendations
  - Medical Device Single Review Program
  - Medical Device Single Audit Program
  - Electronic Labelling

Greater Reliance

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The global pandemic emphasized the value of regulatory cooperation and highlighted the opportunities to		
Modernize regulatory systems to create efficiencies, avoid redundancies, and reduce unnecessary complexity	Enhance regulatory capacity.	Promote expedited patient access to important innovative technologies in order to ensure global health equity.

Greater Reliance

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Convergence

A voluntary process whereby regulation and standards across countries and regions are aligned to internationally recognized best practices to include standards. Convergence is not required to practice reliance but it is a strong enabler to facilitate reliance adoption

Reliance

The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to decisions made by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision.[2]

1. IMDRF (2018), IMDRF Terms of Reference
2. WHO (2016), Good Regulatory Practices Guidance

Medical Device Single Review Program (MDSRP)

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Following the governance model of MDSAP,
Develop a work item that includes a pilot for MDSRP

- Allow submissions to be used by other regulators for decisions on marketing applications
- Strengthen the confidence and consistency in the regulatory decision-making process
- Strengthen standards development by promoting the use and development of international consensus standards
- Support patient access to innovative medical technologies

MDSRP – Universal dossier

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Universal Dossier	• Results of the single review can be leveraged for improved patient access to medical devices and IVDs in multiple jurisdictions, without the need for multiple reviews
Non-participating agencies	• Potential to also allow non-participating agencies to rely on the output of the participating agencies; specifically, their pre-market review decision

MDSRP – Pilot

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- Time to move from building blocks to a pilot program
- Solicit two or more IMDRF members willing to participate in a Single Review Pilot
- After determining medical devices/IVDs in scope, solicit industry participation and involvement in both the design and execution phases

Medical Device Single Audit Program (MDSAP)

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- Hugely successful and significant accomplishment of IMDRF
- Significant opportunity for greater reliance on MDSAP by IMDRF jurisdictions
- Reliance will reduce inspection complexities for current and additional jurisdictions.

Electronic Labelling

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- Rapid access to timely labelling, including instructions for use and safety information, even during a pandemic (e.g., stay at home orders).
- Rapid access to the most up to date patient use and safety information
- Electronic format enables the ability to easily search and find specific information
- Supports global environmental sustainability goals

Recommendations

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- Develop a work item that includes a pilot for MDSRP and ensures industry involvement in the design and execution
- Encourage greater reliance by more IMDRF members on MDSAP
- Develop a work item to create an IMDRF guidance encouraging acceptance of electronic labeling under a common format