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Further Lessons: Considerations and Best Practices for Addressing Public Health Emergencies

IMDRF Stakeholders Session

14 September 2021

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Presentation Outline

- Background
- Challenge
- Early Lessons Learned
- Recommendations
- Specific Attention

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Background

- Need for rapid review and approval mechanisms to meet specific needs during COVID-19 pandemic
- Access to COVID diagnostic tests, personal protective equipment, ventilators in high demand
- Required close collaboration with regulators, developers and healthcare providers

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Challenge

- Clinical and Regulatory
  - Access to virus samples
  - Accuracy of, and access to, comparator test
  - Changing and moving targets
  - Lack of clarity in regulation
  - Lack of harmonization in regulations to enable marketing authority at pace with urgent need to scale
- Scaling production in a short period of time
- Access to Real World Data

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Early Lessons Learned

- Leverage regulatory decisions from other regulators
- Regulatory agility during pandemic has been critical
  - Remote audits in place of on-site
  - Leverage regulatory reliance
  - Use of alternative sources for clinical evidence

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Recommendations

- Ensure that current IMDRF documents acknowledge the need to ensure rapid review and approval
- Utilize reliance mechanisms to promote rapid review and approval
- Consider the development of specific IMDRF guidance to promote the use of rapid review and approval mechanisms during a global pandemic
- Ensure adequate training and communication for regulators
- Regulatory agility should be leveraged beyond pandemic

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Specific Attention

- IMDRF – Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (N47 - 31 Oct 2018)

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Specific Attention

- WHO - Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices
- WHO - Good regulatory practices in the regulation of medical products
- WHO - Good reliance practices in the regulation of medical products: high level principles and considerations
- WHO - Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics

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Specific Attention

- Most effective mechanism to achieve Global Medical Device Regulatory Convergence is Regulatory Reliance and Recognition
- Fundamental element of Reliance and Recognition is use of international standards
  - By National Regulatory Authorities
  - By Industry
- IMDRF Essential Principles explain how
- WHO Guidance recommends and reinforces

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Specific Attention

NRA designated lead for Reliance and Recognition:

- Implementation of IMDRF Essential Principles (and other IMDRF docs)
- Implementation of WHO Guidance for Medical Technologies
- Awareness of the relevant international standards that underpin the Essential Requirements (ISO, IEC, et al)
- NRA protocols for the use of for use of international standards as a basis for national technical regulations

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Specific Attention

- Question 1: Do the NRA and Manufacturer have a formally designated lead for these functions of Reliance, Recognition and Standards?

- Question 2: If not, will these functions occur and be prioritized?

- Critical in “normal” times and particularly necessary for pandemic response and recovery.

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COVID-19 Implications

- Implementation of these WHO and IMDRF documents within the National Medical Device Regulatory Authorities will codify the prioritized use of international standards as a basis for medical device technical regulations, serving as a policy foundation enabling regulatory reliance and recognition.

- Therefore…

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COVID-19 Implications

- The aligned regulatory requirements, as well as the regulatory reliance and recognition that can be enabled by them, may free NRA resources to address prioritized COVID-19 tasks, relieving the need to start from zero for the following tasks:
  - Creating new medical device technical regulations with country-unique content which may diverge from the international standards
  - Conducting new device reviews with unavailable or limited staff resources

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Contacts

Nicole Taylor Smith
GMTA Regulatory Committee Representative
Medtronic

Janet Trunzo
GMTA Regulatory Committee Chair
AdvaMed
JTrunzo@AdvaMed.org