AHWP – IMDRF ARTICULATION TOWARDS REGULATORY CONVERGENCE

IMDRF-3 Stakeholder Forum

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IMDRF- A HWP win-win partnership

- IMDRF and AHWP should work together to enhance medical devices regulatory harmonization, accelerate regulatory convergence, and achieve alignments of IMDRF and AHWP harmonization efforts
- Have identical working groups and technical committees in both organizations
- Representation of members of each organization in each other work groups.

IMDRF- A HWP win-win partnership(cont.)

- Joint training and capacity building programs to enhance understanding of the benefit of medical devices harmonization and regulatory convergences
- Put in place global post market and adverse events center, where collection of post market notifications (FSCAs/AEs /CAPAs etc) could be sent to and reviewed commonly.

Future Plans and Challenges

- It is easier to establish regulation in countries without any regulatory framework than to build on existing regulation or change them.
- Most of AHWP member economies have regulations for pharmaceuticals and regulators tend to control MDs through ‘drug laws’. A new laws should be established for MDs instead of treating MDs as a drug.

Future Plans and Challenges(cont.)

- The AHWP future efforts will focus on training and capacity building by collaborating and partnering with other regulatory bodies, regulatory-focused organizations, and non-profits organizations such as:
  - The World Health Organization,
  - The Asia-Pacific Economic Cooperation (APEC); and
  - The Regulatory Affairs Professionals Society (RAPS)

Future Plans and Challenges(cont.)

- Even having the (political) will to setup MD Controls, countries may face some challenges such as:
  - Capacity building, both for the regulators and industry members
  - Resistance from Industry members who will find regulations cost a financial and operational burden, business casualties can be expected as a result of introduction of regulations
  - Can the Country administrators and health ministry withstand such resistance?

Conclusion

- Everybody deserves to have an access to a good health service
- Knowing the role of medical devices in revolutionizing medicine with state of the art advances in treatment and detection of many diseases
- Based on this, and in order to have positive contribution to health services provided to people all over the world. IMDRF and AHWP should collaborate with every organization working to ensure safety, quality, effectiveness of medical devices, and their performance according to their intended purpose.

Conclusion(cont.)

- Knowing that there variations in the resources available to countries for setting their regulatory system. AHWP and IMDRF have great responsibility to work together through a well defined strategic direction to establish a platform to help other countries setup their regulatory system and build their capacity

Thank You

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