IMDRF International Medical Device Regulators Forum | 26th Session

Stepwise approach to regulating medical devices: Basic level Controls & Enforcement, Post-Market

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Basic level controls and enforcement; post market

- **Actions by the NRA**
- **Actions by the Manufacturer**

Systems for vigilance Reporting

- NRA Develops a system for users, patients, and manufacturers of Medical device for reporting
- NRA has established system for Complaint reporting device Malfunction at device level and adverse event to the patient (resulting in serious death or serious injury)
- Submission of reports by the NRA to the Manufacturers, notification
- Enforcement actions by NRA~vigilance reports after investigation, trend analysis

Require mandatory notification by the manufacturer of FSCA

- Legal provision requiring manufacturer to report to the NRA-FSCA
- Issuance of alerts or advisories on FSCA's by an NRA through established systems
- A system supporting targeted communication to specific parties (i.e HC Professionals)
- Use communications Technologies accessible and appropriate to the intended recipients~ urgency of the action
- Information exchange with other NRAs

Establish a procedure to withdraw unsafe medical devices from the market

- NRA's are mandated to enforce laws and regulation to protect the public against unsafe medical devices
- Actions the NRA can take to protect public health-Suspension or withdrawal of local manufacturers, authorized representatives, importers or distributors
- Withdrawal from the list of marketed medical devices; recall, quarantine and disposal of medical devices
- Public alert issuance, warning letters, prosecution and financial penalties.
- Information sharing with other NRAs; auditing firms for the manufacturer
- NRAs collaboration with customs, users, patients and manufacturers for enforcement of decision

Establish procedure to issue safety alerts to users

- The NRA to have established procedure to directly notify health-care facilities that use the affected medical devices
- The NRA to inform health care facilities of serious adverse incidents and FSCA by issuing safety alerts, advisories
- The NRA to inform specific users

Undertake market surveillance

- NRA to undertake targeted activities based on oversight of medical devices on the domestic market;

  -Risk assessment of the distribution chain

  -Evaluation of complaints and adverse event reporting

  -Information from the post market surveillance systems of medical device manufacturers

FDA U.S. FOOD & DRUG ADMINISTRATION

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THANK YOU