



IMDRF

International Medical
Device Regulators Forum

IMDRF Work Item

National Competent Authority Report Exchange Criteria and Report Form

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European Commission



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Principal Objective of the Working Group

To review the current NCAR Exchange System and advise on opportunities for improvement and possible expansion of the system



Action and Progress

- Members of the NCAR program were surveyed for the strengths and weaknesses of the current system
- Review of survey results and a plan for addressing issues was presented to MC
- Proposal to develop the system to include:
 - Stream 1: A two way communication system for serious public health issues, and
 - Stream 2: A one way rapid exchange mechanism for recalls / FSCAs



Stream 1

- **Events leading to or highly likely to lead to an UNANTICIPATED Serious public Health Threat.**
- **Observations from National Trend Analysis** (that are linked to serious public health threat)
- **Requests and /or Share Information** (on issues that have led or are highly likely to lead to serious public health threat; and may affect other jurisdictions).



Stream 2

- **RECALLS / FIELD SAFETY CORRECTIVE ACTIONS (FSCAS)** of international relevance (i.e., multiple jurisdictions) that are a serious public health threat -taking into consideration
 - Population Vulnerable
 - Public Concern / Outrage
 - Written notifications by the NCA to the public (hospitals, physicians, etc.) about a corrective action
 - Implantable device
 - Life sustaining/Life supporting
 - IVD(D) for blood testing and infectious disease
 - Market actions related to over/under radiation exposure
 - Market actions related to new/novel technologies related to medical devices



Action Completed

- ✓ The criteria for the new system has been defined
- ✓ A guidance document outlining the new system has been developed (N14)
- ✓ The format for the information that needs to be exchanged for stream 1 and stream 2 have been defined
- ✓ Participation and Confidentiality have been defined
- ✓ An initial examination of the use of technology to enhance the stream 1 and stream 2 exchanges has commenced



Future Actions

- N14 needs to be finalized
- It is envisaged that the updated proposal will go for a 60 day external consultation early April 2014