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

- Event(s) 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