



IMDRF

International Medical
Device Regulators Forum

**IMDRF-MC XII
National Competent Authority Report
Exchange Programme**

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Device Regulators Forum

Current NCAR and WG members

- Australia
- Brazil
- Canada
- European Union (EU)
- Japan
- USA



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Why international exchange of information on safety issues?

- National competent authorities receive reports on safety issues on their territory
- Same problems likely to occur globally – need to exchange PMS information
- Facilitates verification that reporting is made globally
- Cooperation in assessment of safety risks favours a harmonised approach



NCAR (National Competent Authorities Report) Exchange Program (1)

- Created 1999 under GHTF
- Critical review 2012 identified problems:
 - uneven participation
 - timing
 - type and detail of information
 - confidentiality restrictions



NCAR (National Competent Authorities Report) Exchange Program (2)

Relaunch of new NCAR exchange with pilot (Oct 2015- March 2016)

- Better defined reporting criteria
- Stricter confidentiality and participation criteria
- New form
- Including early warnings (trends/analysis)
- Better training
- Limited to previously participating MC members

Full implementation (April 2016-to date)

- Open to additional MC members subject to confidentiality arrangements



NCAR (National Competent Authorities Report) Exchange Program (3)

From relaunch until now

- 38 reports issued – 29 exchanged (only 1 invalid report during the operational phase)
- Relatively even distribution: confidential/non-restricted, sharing information / information requests, EU/non EU



Evaluation Report (1)

Evaluation report to MC on the functioning of NCAR Exchange and with proposals for follow-up and extension of scope/participation

- Functioning is largely satisfying for current participants but participation is limited to MC members
- Need to revise N 14 document to include instructions on how to summarize confidential information received from information requests



Evaluation Report (2)

- To facilitate access for other NCAs and NGOs to information related to corrective actions and recalls when this information has been made public by a MC member
- To create a webpage on IMDRF website which contains the links to the recall notification sections of all IMDRF members' websites and make it publicly available



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Thank you for your attention !