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International Medical
Device Regulators Forum

IMDRF-MC XI
National Competent Authority Report
Exchange Programme

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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 with pilot (Oct 2015-March 2016)

- Stricter confidentiality and participation criteria
- New form
- Includes early warnings (trends/analysis)
- Better training
- Stronger role of the Secretariat
- Limited to previously participating MC members

Full implementation (April 2016-)

- Open to additional MC members subject to confidentiality arrangements



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

From relaunch until now

- 32 reports issued – 23 exchanged (only 1 invalid report during the operational phase)
- Even distribution: confidential/non-restricted, sharing/requests, EU/non EU

Evaluation

- Report to MC with possible proposals for follow-up and extension of scope/participation (Sept 2017)



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Thank you for your attention !