IMDRF-MC XII
National Competent Authority Report
Exchange Programme

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Current NCAR and WG members

- Australia
- Brazil
- Canada
- European Union (EU)
- Japan
- USA
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
Thank you for your attention!