



IMDRF

International Medical
Device Regulators Forum

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

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**DG GROWTH - Health Technology and Cosmetics Unit,
European Commission**



WG composition

- Australia:
Pamela Carter (Director, Device Vigilance and Monitoring Section, Office of Product Review, TGA)
- Brazil:
 - Stela Candioto Melchior (Gerência de Análise e Avaliação de Risco, ANVISA)
 - Maria Gloria Vicente & Guilherme Buss (Health Surveillance Specialists, ANVISA)
- Canada:
Barbara Harrison (Senior Corporate Regulatory Compliance Advisor , Health Canada)
- European Union:
 - Jean-François Roche [Chair] (Policy Officer, GROW D4, EU Commission)
 - Andrea Hanson (Product Manager, Health Products Regulatory Authority, Ireland)
 - Carmen Ruiz-Villar (Head of Service , Vigilance Unit , Medical Devices Department, AEMPS)
 - Ekkehard Stoesslein (Deputy Head of Division, BfArM)
- Japan:
 - Koichi Fujiwara & Miho Sato (Office of Safety, PMDA)
 - Masahiro Takahata (MHLW)
- USA:
 - Nancy Pressly (Associate Division Director, FDA)
 - Millin Courtney (MDR Analyst, FDA)



State of play

- At IMDRF-9 MC meeting in Brasilia, the MC took note of the phasing in (Pilot) of the NCAR Exchange from October 2015 to March 2016
- The Pilot phase has now expired and all MC members are entitled to participate to the Exchange programme or to apply for participation provided relevant confidentiality arrangements are in place



Feed-Back – October 2015/September 2016

- Several training sessions were organised within the various jurisdictions
- 26 NCAR were issued, out of which 8 did not comply with N14 requirements
- The 8 invalid NCARs are related to the Pilot phase (all NCARs exchanged in the post-Pilot phase were compliant with the N14 requirements)
- 56% of valid reports were circulated by non EU countries
- 56% of the reports circulated were confidential (80% of reports by non-EU countries were classified as confidential)



Next Steps

- To keep on with the development of new confidentiality arrangements among MC jurisdictions in order to allow for the increase of exchanged NCARs and wider participation to the programme (involvement of IMDRF MC members which are not yet part of the NCAR Exchange)
- An evaluation report on the functioning of the Exchange programme and a possible proposal for follow-up is planned for the MC of March or September 2017 (depending on progress)