IMDRF International Medical Device Regulators Forum

IMDRF VII
National Competent Authority Report Exchange Programme

Jean-François ROCHE

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 & Guillerme Buss **(** Health Surveillance Specialists, ANVISA)
- □ Canada:
  Barbara Harrison (Senior Corporate Regulatory Compliance Advisor , Health Canada)
- □ European Union:
  Jean-François Roche [Chair] (Policy Officer, GROW I4, 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)
- □ Invited expert: AHWP/ Saudi Arabia:
  Essam M. Al Mohandis (Executive Director of Surveillance and Biometrics, SFDA)

State of play

● IMDRF N14 REV 4 DOCUMENT WAS ENDORSED FOR PUBLIC CONSULTATION BY IMDRF MC IN WASHINGTON.

● PUBLIC CONSULTATION TOOK PLACE UNTIL END DECEMBER.

●COMMENTS RECEIVED FROM 1 JURIDICTION, 4 PROFESSIONAL ORGANISATIONS AND 1 COMPANY

● 2 TELECONFERENCES HOLD WITH THE NCAR WORKING GROUP ON 14 AND 21 JANUARY

● SOME LIMITED CHANGES INTRODUCED IN FINAL DOCUMENT

Main changes in N14 Final

- More accurate definition of the role of NCAR Secretariat
- Clarification of wording of chapter 6.1 on report exchange for confidential and non confidential NCARs
- No changes on substance
- Editorial changes throughout the document

Work Plan

1. March–mid April 2015

• Drafting of implementation materials on reporting criteria, participation, confidentiality and reporting forms

2. Mid April – October 2015 (Pilot phase)

•Participation limited to IMDRF MC members who already participated to the GHTF exchange program

•Use of implementation materials for new members

•Twinnings between a new and a former participant

3. November 2015- April 2016 (full implementation)

•Progress report to the MC (IMDRF IX)

•Possible proposal for an extension (2nd phase)

Thank you

for your attention!