



# Eudamed

**WG meeting**

Brussels, 14<sup>th</sup> November 2012

Update GMDN PAG



## **PAG Members and Meetings**

- Advisory Group to the GMDN Agency
- Set up by GHTF
- Members: regulators from USA, Canada, Japan, Australia and EU, AHWP representatives, industry from AdvaMed, MITA, Eucomed, JFMDA and EDMA
- Met three times in 2012
- Next meeting foreseen for 20/21 February 2013

# Issues discussed (1)

**1) Transparency and controls around changes to Preferred Terms (PT) – developments of new PT's and obsolete terms**

**MS Input needed**

**2) Regulatory Use Document - MS Input needed**

**3) Version Control - MS Input needed**

**4) Appeals Process**

**5) Possibility to report discrepancies between Regions**

**6) GMDN use in the FDA UDI database**

## Issues discussed (2)

**7) ISO New Work Item Proposal – Review of ISO 15225**

**8) Training/Manuals**

**9) Developments with IHSTDO**

**10) Issues in relation to GMDN Use**

**11) Participation in Agency Structure (PAG, Trustees, Members) - MS Input needed**



# Eudamed2 & GMDN

**Eudamed GMDN update:**  
**every 2 weeks**

**Obsolete GMDN Codes:**  
**to allow entering existing devices with an obsolete GMDN code**

**Solution for informing Eudamed users of new GMDN codes:**  
**Notice at Eudamed home page:**

**Last GMDN code list updated the 14 November 2012**



European  
Commission

Thank you

Health and  
Consumers