



October 3-4, 2007
Washington, D.C.



**11th Conference
of the
Global Harmonization Task Force**

WORKSHOP
Regulatory Model for Development of
Device Regulatory Systems

Global Harmonization: The Need

Maria E. Donawa, M.D.

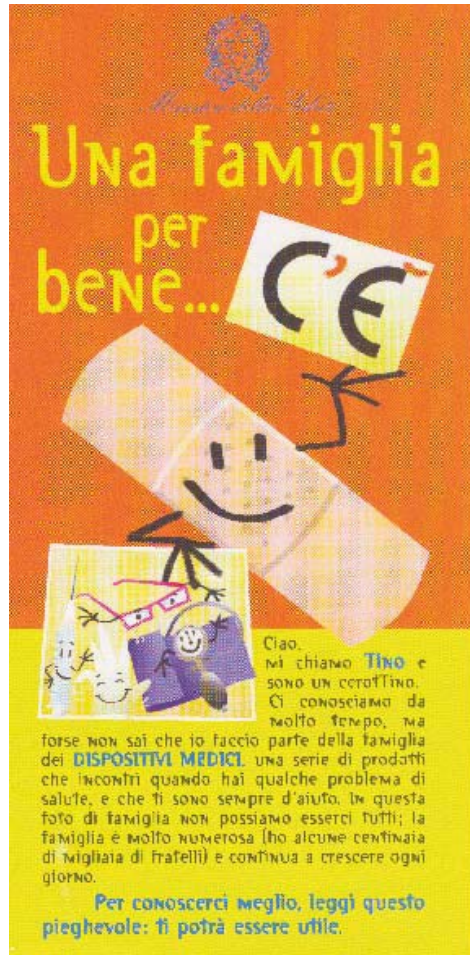
Why some believe harmonization is not needed

- Would increase regulatory barriers worldwide
- Would reduce market introduction flexibility
- Would increase costs for funding regulators and official bodies
- Would lead to undue pressure on governments with insufficient resources
- Would reduce availability of beneficial medical devices

Patient needs for harmonization

- Increased availability of beneficial medical devices
- More consistent and uniform protection against unsafe devices from unscrupulous, uninformed, or misguided manufacturers
- Uniform human subject protection (clinical study participation)
- Improved access to practical information on device regulatory systems

Patient needs



- Guide on medical devices issued by Italian Ministry of Health
- Education of general public
- Means of gathering information on the use and safety of medical devices

User and purchaser regulatory education needs

- Information on device development and production processes
- Basic understanding of regulatory controls and protection measures
- Adverse event education – what to report and to whom, what not to report, and importance of complete event information

Industry needs

- Regulatory requirements based upon a least burdensome approach
- Reduction in number of different regulatory models
- Reduction of variability in degree of regulatory oversight (e.g., differences in level of general and product-specific guidance documents, regulatory involvement in the design of clinical studies, etc.)
- Globally uniform standards, where appropriate
- Less intra-regional variability, e.g., European Union

Globalization and import controls

- Dramatic increase in global development and production of medical devices
- Country of origin may have vastly different regulatory requirements and enforcement systems
- Imports do not always comply with local requirements
- Customs checks cannot always prevent noncomplying products from entering the market

Regulatory efficiencies and best practices

- Improved validity of regulatory actions and decisions
- Uniform interpretation of regulatory requirements
- Ability to share information on best practices
- Reduced costs due to least burdensome requirements

Snapshot of the future



- Minor worldwide differences associated primarily with local language needs
- Globally uniform system of premarket and postmarket requirements and technical and quality standards and expectations
- Increased availability of valuable medical devices due to increased development efficiencies and healthy competition
- More effective regulatory enforcement
- Reduction of healthcare costs

Thank you

Maria E. Donawa, M.D.

President

Donawa Consulting

Piazza Albania, 10 • 00153 Rome, ITALY

Tel: +39 06 578 2665 • Fax: +39 06 574 3786

medonawa@donawa.com

www.donawa.com