AdvaMed
Advanced Medical Technology Association

Combination Products Regulatory Convergence

Janet Trunzo

BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

November 4, 2012

Outline

AdvaMed
Advanced Medical Technology Association

- Background
- "Guiding Principles" for regulation of combination products
- GHTF Combination Products working definition
- GHTF regulatory principles
- Areas for convergence

Background

AdvaMed
Advanced Medical Technology Association

- Evolution of medical technology
- Lengthy review process when combination products involved
- Difficulty in making jurisdictional decisions
- Need for flexible regulatory scheme applicable to combination products
- Need for appropriate regulatory principles

Guiding Principles

AdvaMed
Advanced Medical Technology Association

- Concise combination products definition
- Prompt assignment to appropriate review team
- Understanding primary mode of action
- Use and application of historical jurisdictional decisions
- Timely and effective premarket review process
- Consistent and appropriate postmarket system
- Timely and effective resolution of scientific disputes

GHTF Combination Products Working Definition

AdvaMed
Advanced Medical Technology Association

"Products that meet the GHTF harmonized definition of a medical device and that are assisted in achieving their intended function by an incorporated medicinal substance or material of biological origin"

GHTF Combination Products Regulatory Principles

AdvaMed
Advanced Medical Technology Association

- Predictable, transparent, efficient, and least burdensome harmonized regulatory framework
- Flexible guidance documents easily adaptable to existing regulatory systems
- Consideration of appropriate elements of medical device, medicines and biologics regulatory models
- Appropriate essential principles, conformity assessment procedures, and classification rules

GHTF Combination Products Regulatory Principles

AdvaMed
Advanced Medical Technology Association

- Determination of regulatory requirements
  - Based on principal intended mode of action of product
  - Consider any secondary modes of action
  - Based on one of traditional regulatory frameworks—not adding 2 together
  - Consider entire product life cycle
  - Include documented risk assessment
  - Application of appropriate international standards

Areas for Convergence

AdvaMed
Advanced Medical Technology Association

- Definition of a combination product
  - Harmonized and concise
- Factors to consider when determining primary mode of action
  - How product achieves its overall intended use
  - Informed by jurisdictional precedents
- Mechanism for designation of primary lead in premarket review process
  - Timely decisions
  - Utilize previous designations

Areas for Convergence

AdvaMed
Advanced Medical Technology Association

- Consistent application of GMP/QS requirements
  - Requirements applicable to constituent part
- Adverse event/vigilance reporting
  - Avoid duplicative reporting
  - Based on type of marketing application
  - Reasonable time frames for reporting
- Registration and listing
  - Avoid redundant registration and listing
  - Based on type of marketing application

Moving Forward

AdvaMed
Advanced Medical Technology Association

Working toward regulatory convergence

- Ensure appropriate experts are involved
- Build on the initial work of GHTF on regulation of combination products
- Identify primary areas of convergence
- Consider guiding principles
- Maintain appropriate level of flexibility in any regulatory scheme

AdvaMed

Advanced Medical Technology Association

BRINGING INNOVATION TO PATIENT CARE WORLDWIDE