



Agence nationale de sécurité du médicament
et des produits de santé

CAMD TF Shortages update

Agence d'évaluation, d'expertise et de décision dans
le domaine de la régulation sanitaire des produits de
santé

CAMD TF

◆ Main goal :

- Making the Art 10a European Commission proposal work
 - Criteria, templates, process
 - Keep it simple
 - Ensure effective collection, sharing and management of information

◆ 12 participating MS + EU COM

- BE, CZ, DE, DK, ES, FI, FR, IE, IT, NL, PT, SE, **SP**
- Link with EU COM to share and to **address** questions in right fora (MDCG – CAMD)

◆ Start during CAMD in Ghent March 2024

- Presentation and breakout session to share ideas and expectations of NCAs

◆ 12 participating MS + EU COM

- 2 meetings

Key topics 1

◆ Clarification of the scope

- Field of MDCG / EU COM Q&A
- Need to clarify wording to reach a clear and common understanding and share it with stakeholders (mainly manufacturers)
 - “interruption of supply of a device”
 - “reasonably foreseeable”
 - “serious harm or risk of serious harm to patients or public health”
- Preparatory work
 - List of questions/considerations set up by TF
 - Proposal to set a WS between volunteers from MDCG Q&A /EU COM/ TF members

Key topics 2

◆ Criteria

- Clarify which interruption of supply fall in scope of art 10a
- Limit communication to only relevant situation
- Identify clear, understandable criteria
 - Able to characterize risk situation
- Some challenges about information
 - Identification of alternatives
 - Availability of alternatives
 - Market share at national level

Key topics 3

◆ **Templates and process**

- Harmonized approach needed
- Based on FSCA/FSN process and template
 - Similarity between the 2 processes
- Think about two “information” levels (under discussions)
 - Basic level of information only describing situation
 - More complete information for most critical situations
 - On specific request by NCA
 - Including shortage management plan
- IT system for easy input and sharing information

Next steps

◆ ASAP

- Scope clarification
 - Work to be shared with MDCG and EU COM
 - Consolidated list of questions/consideration from CAMD TF

◆ Before end of May

- Suggested list of criteria
 - Limited number, simple, easy to understand
- Template
 - List of information requested (Basic)
 - Suggested template (Based on FSCA template)
- Process
 - Clear pathway from notification to information sharing
- IT prerequisites
 - Essential features



Thanks for your attention !

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