Medical devices clinical evaluation in the heart of the MD Directive review

Agence française
de sécurité sanitaire
des produits de santé

afssaps

Jean-Claude Ghislain, director,
MD evaluation directorate,

The european « Clinical Evaluation Task Force »

- **During the MDD review process(Art. 11 Section 4)**
- **Participation of all stakeholders**
- **Chair : Afssaps**

(clinical evaluation = main issue on the agenda of the french presidency CAs meeting in july 2000)

CETF work output

- **Evaluation of clinical data : A guide for manufacturers and notified bodies**
  - **Meddev 2.7.1 (Avril 2003)**
- **Post Market Clinical Follow up (PMCF) of medical devices under MDD directive**
  - **Meddev 2.12/2 (Mai 2004)**
- **Proposal for Annex X modification**

Clinical evaluation in the MDD review (90/385 and 93/42)

ANNEX I : (NEW)

- **Delete the last E.E. n° II 14**

  « where conformity with the essential requirements must be based on clinical data, as in section I(6), such data must be established in accordance with Annex X. »

- **Add a new general E.E. n° I 6b**

  « demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X. »

- **With links in all conformity assessment procedures**

New Annex X

- **Confirmation of conformity and acceptability of the benefit/risk ratio must be based on clinical data :**
  - From a critical evaluation of the relevant scientific literature where there is demonstration of equivalence of the devices
  - Or from a critical evaluation of the results of the clinical investigations made
  - Or from a critical evaluation of the combined data from literature and trials

New Annex X

- **In the case of implantable and class III devices clinical investigations shall be performed unless it is duly justified to rely on existing data**
  - *MEDDEV on implementation of Annex X for clinical evaluation*

New Annex X

- **The clinical evaluation shall be documented in the technical documentation of the device**
- **The clinical evaluation and its documentation must be actively updated with data obtained from the post market surveillance. Where post market clinical follow-up as a part of the post market surveillance plan for the device is not deemed necessary, this must be justified and documented.**
  - *MEDDEV on the PMCF*

Post Market Clinical Follow-up (Meddev 2.12/2)

- **Two main criterias for implementing a PMCF plan :**
  - **Where a risk, identified during the premarket assessment, has to be monitored**
  - **Where the premarket clinical evaluation cannot cover the life duration of the device in the patient**
- **Not always necessary but justification to be documented**
- **A new obligation for manufacturer, and a new role for NBs, Cas ?**

CETF ongoing work plan

- **Drafting guidelines on some categories of devices :**
  - Coronary stents
  - Hip prothesis
  - …
- **A difficult exercise in the medical device sector**
- **For an early regulation of new devices categories**
- **Active participation of industry is needed**

GHTF activities on clinical evaluation

- Europe suggested this work item to the SC, a preliminary group prepared a proposal and the SC decided to create a new SG5
- After a first chair by Australia, Susanne Ludgate is now chairing the group, and two other european regulators are participating
- A first document has already proposed as final document, and CETF will adapt quickly the european MEDDEV in accordance with it.
- First informal contacts on the issue of guidelines

CONCLUSIONS

- The new directive is not a revolution but an important step to clarify the requirements
- But the question for tomorrow will be to develop a market surveillance program
- Guidelines for devices categories are probably an essential tool for regulation
- The main regulatory challenge is innovation