

NEW AND EMERGING TECHNOLOGIES : Regulatory challenges.

*Agence française
de sécurité sanitaire
des produits de santé*



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- **To regulate medical technologies is a general challenge every day**
- **For the french agency AFSSAPS, new and emerging technologies are an issue of scientific surveillance**
- **And our challenge is regarding devices designed on the basis or utilizing components coming from new/emerging technologies**
- **The challenge is scientific before to be a regulatory one**

Three sources of information :

- Scientific literature and congresses
- Authorization of clinical trials on MDs
- Declaration of new class IIb/III MDs (art.14 Direct.)

*and a project in our strategic plan to
« accompany innovation »*

- There is no universal definition of innovation, but the agency has to address issues on innovation of public health interest when :
 - The expected benefit may create a need for a rapid access to the device for patients
 - And/or a new risk, known or suspected, has to be managed
 - And/or a regulatory issue has to be solved

- We are at the beginning of the process, and we hope a good feedback of research teams and manufacturers
- It is a movement of anticipation, general for all health products, and combined devices could be a good experimentation field
- But the national level is not the most appropriate, and we need to find partners to share experience
- However, it may allow the agency to contribute to european and international developments

- The european regulatory framework is not well adapted to regulate new/emerging technologies
- It would be necessary to create a procedure to collect information from notified bodies on the opening of conformity assesment procedures for « new devices »
- We will probably need soon a centralized procedure to discuss the evaluation report of the NB, to appreciate the level of available data and to regulate the requirements for new devices categories

- The Medical Devices Experts Group has already created a working group on new emerging technologies, following preliminary discussions between competent authorities on the initiative of the Dutch presidency
- The european commission has mentioned in the report on the implementation of the MDD, that the procedure of consultation of Member States introduced for MDs of animal origin in the directive 2003/32 could be interesting for other issues
- But at present, there is no measure in the proposal of new MDD

- Emerging regulatory challenges is the goal number one of the GHTF strategic direction
- A review of GHTF strategic direction has been decided during the SC in nov. 2005 with an ad hoc group
- A stage report at the SC last monday indicated that this goal is probably the less well understood or acted upon
- There is a need to identify new technologies with public health concerns presenting a new regulatory challenge

- **Devices related to new emerging technologies with public health concerns remain to be identified**
- **GHTF could be the best place to discuss this issue for a global approach rather than a late harmonization**
- **The most important challenge will be to allow a fast development of innovation associated to a high level of security for worldly patients**

THANK YOU FOR YOUR ATTENTION