2012 APEC Advanced Workshop of Good Review Practice relating to Medical Devices

Session D:
CRITICAL THINKING AND DECISION MAKING

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Insight on some European ideas

Laurent SELLES
Health Technology and Cosmetics
European Commission

Health and Consumers

CRITICAL THINKING MEANS…

Dealing with several conflicting objectives

- High level of protection of human health and safety
- Better functioning of EU single market
- Support of innovation
- Support of competitiveness of industry
- International convergence

CRITICAL THINKING MEANS…

To have clear ideas on a number concepts:

- Scope
- Role of economic operators
- Traceability
- Transparency
- Classification
- Conformity assessment
- General safety and performance requirements
- Clinical data
- Vigilance and market surveillance
- Role of standards
- Governance

CRITICAL THINKING MEANS…

Role of economic operators: clear set of obligations and responsibilities

Manufacturers

- Quality management system
- Post-market surveillance plan
- Technical documentation/STED
- Qualified person

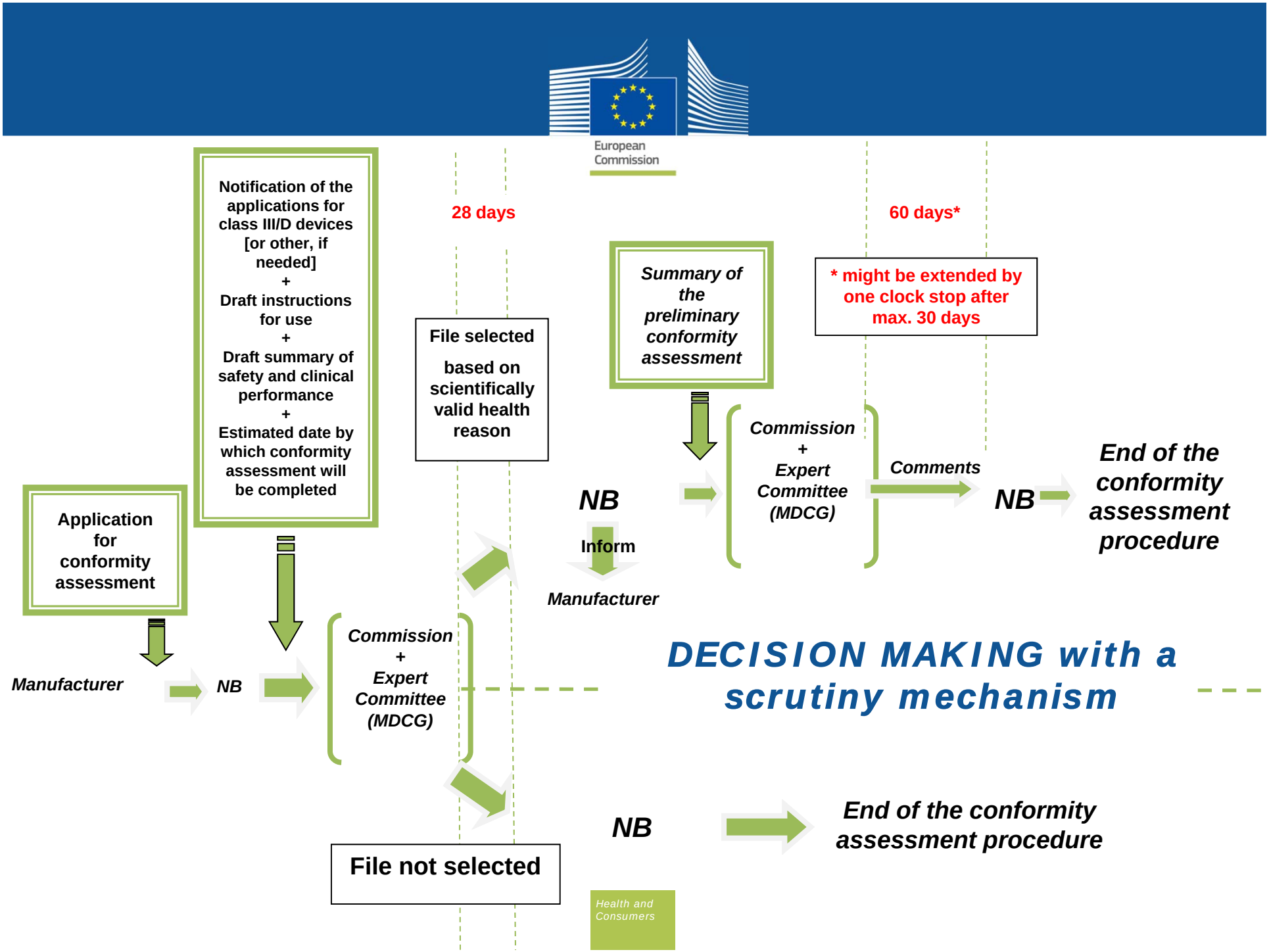
Authorised representatives

- Written mandate
- Minimum tasks
- Qualified person

CRITICAL DECISION MAKING MEANS…

Tightened supervision of Notified bodies:

- Reinforced minimum requirements (independence, impartiality, competence, resources and processes)
- New process for designation and monitoring ('joint assessments')
- Scrutiny mechanism applicable to high-risk devices
  - Early information
  - Possibility to check in individual cases the preliminary conformity assessment


European Commission
Notification of the applications for class III/D devices [or other, if needed]
+
Draft instructions for use
+
Draft summary of safety and clinical performance
+
Estimated date by which conformity assessment will be completed
28 days
60 days*
* might be extended by one clock stop after max. 30 days
File selected
based on scientifically valid health reason
Summary of the preliminary conformity assessment
Application for conformity assessment
Manufacturer
NB
Commission + Expert Committee (MDCG)
NB
Inform
Manufacturer
Commission + Expert Committee (MDCG)
Comments
NB
End of the conformity assessment procedure
DECISION MAKING with a scrutiny mechanism
File not selected
NB
End of the conformity assessment procedure
Health and Consumers

European Commission

CRITICAL DECISION MAKING MEANS…

For the conformity assessment

- **Annual surveillance audits**
- **Unannounced factory inspections and sample testing**
- **Rotation of auditors**

CRITICAL THINKING MEANS…

Special procedures for Conformity assessment

- For MD with ancillary medicinal substance: streamlined consultation of pharmaceutical authority
- For human tissue engineered MD: consultation of authority responsible for human tissues & cells
- For companion diagnostics: consultation of pharmaceutical authority (personalized medicine)

European Commission

CRITICAL THINKING MEANS…

Regarding Clinical data

Clinical investigations

- Streamlined procedures, aligned with proposed rules on clinical trials on medicinal products
- Option for single application by sponsor in case of multi-Member State studies
- Always required for class III and implantable MD

Clinical evaluation

- Continuous process, incl. post-market clinical follow-up

CRITICAL THINKING MEANS…

Regarding Vigilance and Market Surveillance

Vigilance

- EU vigilance portal
- Central reporting of serious incidents and field safety corrective actions
- Reporting of FSCA outside EU regarding devices placed also on the EU market
- Trend reporting (for classes IIb/C and III/D)
- Enhanced coordination between authorities
- Extended role of notified bodies

CRITICAL THINKING MEANS…

Better Vigilance and Market Surveillance

Market surveillance

- Clearer rights and obligations of market surveillance authorities (e.g. in-market controls)
- Clearer procedures for national provisional measures (e.g. safeguard clause, corrective actions against non-compliant products)
- Mutual information and control

CRITICAL THINKING MEANS…

Regarding “Governance”:

Reinforced coordination

- **Medical Device Coordination Group**
  - **Experts representing national authorities (MD and IVD)**
  - **European Commission: chair**

Technical, scientific and logistic support

- **European Commission: DG SANCO & Joint Research Centre**

European Commission

CRITICAL THINKING MEANS…

RECOGNIZING that implementation of existing legislation needs improvement:

Notified bodies

- Harmonized designation and monitoring by Member States (Commission Regulation under preparation)
- Review of existing designations
- Best practices for conformity assessment by notified bodies (Commission Recommendation under preparation)

European Commission

CRITICAL DECISION MAKING MEANS…

Looking for *Scientific expertise*

- **Mandates to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on**
  - **PIP silicone breast implants**
  - **Metal-on-metal hip joint replacements**

- **Support from European Commission's in-house science service**

Further information

- **Website of the European Commission:**

http://ec.europa.eu/health/medical-devices/index_en.htm

- **Functional mailbox of the medical devices' unit:**

sanco-cosmetics-and-medical-devices[at]ec.europa.eu