CE marking for implantable medical devices: What's going on behind the doors of the hospital?

OHP-018

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BACKGROUND:

- ✓ A **CE marking**, delivered by a **notified body**, **is required** for most of the implantable medical devices (IMD), except custom-made IMD and those intended for clinical investigations, **before being placed to market**.
- ✓ Thereby, the IMD granted with CE marking is certified to follow the **essential requirements** of the **council directive 93/42/EEC** amended by the directive 2007/47/EC.
- ✓ Nevertheless, the French national agency of drug and healthy products published an alert in May 2013 regarding a **French company** which brought to market a **hip prosthesis without CE marking**.
- ✓ According to us, it seemed important to check for the CE marking of our implantable medical devices.

PURPOSE:

- ✓ Our purpose is **to assess the conformity of the elements** provided to the hospital pharmacy during the request for proposals (RFP) of 2011 by the supplier **to prove the CE marking** and, currently for IMD falling within **Classes IIb and III**.
- ✓ We also want to draw up a method allowing to be sure of the validity of the CE marking.

MATERIALS & METHODS :

- ✓ A **list of wordings for implant medical devices** falling within **Classes IIb and III** of the request for proposals has been established.
- ✓ A **grid** has been developed (based on the council directive 93/42/CEE), summing up:
  - the **evaluation modes of the conformity** according to the medical device class
  - the **evidence testifying of the CE marking** provided by the supplier to the hospital pharmacy
  - the **expiration date** of these evidences.
- ✓ From the grid we developed, **three criterions** have been pointed out for each wording of the request for proposals (WRFP) **to assess the conformity of the CE marking**:
  - the **whole evidence** testifying of the CE marking has been provided by the supplier
  - the **validity** of these elements **for the time of the request for proposals**
  - and their **current validity**.
- ✓ A **rate of conformity during the request for proposals** (RcRFP) and a **current rate of conformity** (RcC) have been defined according to the following formulas:

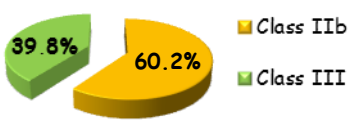
$$RcRFP = \frac{\text{Number of RFP wordings with the whole of the valid evidence testifying of the CE marking during the RFP} \times 100}{\text{Number of RFP wordings}}$$

$$RcC = \frac{\text{Number of RFP wordings with the whole of the valid evidence testifying of the CE marking at the time of the RFP and up to date} \times 100}{\text{Number of RFP wordings}}$$

RESULTS:

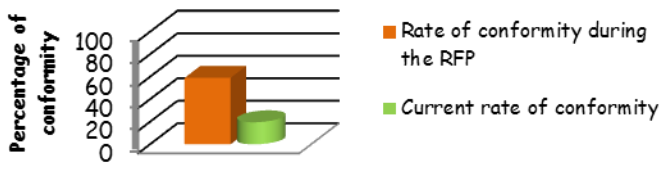
- ✓ 959 request for proposal wordings were counted.

Proportion of class IIb and class III IMD in the 959 RFP wordings



- ✓ The **whole evidence** testifying of the CE marking was provided in **60.1%** of the cases (in 85.4% of the cases for the class IIb IMD and in 22.15% for the class III).
- ✓ In **98.8%** of the cases, these elements were **valid**, leading to a **RcRFP of 59%.**
- ✓ Currently, the **RcC** equals to **19.6%** (33% of the provided evidence remain valid).

Progression of the CE marking conformity from the RFP to now



Considering the poor rate of conformity at the time of the RFP took place and now, it seems important to draw up a method allowing to be sure of the validity of the CE marking.

CONCLUSIONS:

This study proves that it is necessary to bring into sharp focus the conformity of the CE marking to secure the health of the patient.
Therefore, a procedure has been drawn up that enables the conformity and the validity of the CE marking to be checked whenever they are needed.