

HERCA Multi-Stakeholder Workshop on "Generic Justification", Paris, 24-26 October 2016

Plenary Session 2:

**How can CE marking contribute to the
justification process of new types of
practices ?**

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Interrelation between Council Directive 2013/59/Euratom and Medical Device Regulation

Is there any possible conflict between these 2 legal systems ?

1. "A medical device bearing the CE marking, that is to say complying to the general safety and performance requirements (MRD, annex 1), can be placed on the European Market or put into service",

Vs

2. "The use of medical device (bearing the CE marking) is submitted to the regulatory control defined by national regulation (BSS)"

Interrelation between Council Directive 2013/59/Euratom and Medical Device Regulation

From a legal point of view, on the basis of the justification principle :

MS **may not allow** the use of a MD (bearing the CE marking), considering for instance that the risk for patient :

- Is too high in comparison with the expected benefit,
- Or taking into account about other techniques and technologies (BSS, art. 19.2).

Practically, no example of real conflict but ...

Interrelation between Council Directive 2013/59/Euratom and Medical Device Regulation

How to manage the possible conflicts between the 2 legal systems ?

- The justification process depends of national regulations, different possible approaches
- France (example) : PS 5

Whatever the approach, the access to the “risk assessment” and “ clinical evaluation” data produced by the manufacturer (if any), to obtain the CE marking, seems to be very useful for the justification process (BSS, Art.78.2), particularly in the case of practice using a new technology.

Clinical evaluation and risk assessment ? What about this terminology and definitions ?

"Clinical evaluation" :

- used under BSS (Art. 78.2) but no definition
- used under MDD, annex X and further guidance (MEDDEV 2.7/1 rev 4.)
- the clinical evaluation report : part of the documentation submitted to Notified Body for EC certification and, where necessary, to the MDD competent authority

"Risk assessment"

- used in BSS (Art. 78.2) but no definition
- not directly used under MDD
- but "acceptable risk" in Annex 1, and "the acceptability of the benefit/risk ratio in Annex X ...are used

Clinical evaluation and risk assessment ? What about this terminology and definitions ?

Conclusion on terminology (letter from EC, 22-07-2016) :

- "It might be concluded that the national implementation of BSS, Art.78.2, **should** refer to the clinical evaluation ... in the sense of MDD ..."
- "It might be concluded that the national implementation of BSS, Art.78.2, with regard of risk assessment for patients **should** make use of the appropriate MDD provisions concerning evaluation/analysis of radiological risks"

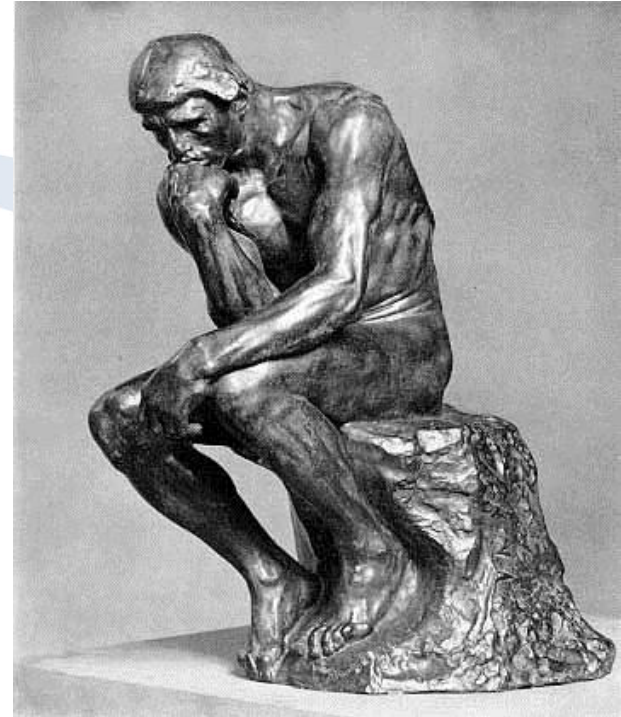
Furthermore, it is added :

- "taking into account that the BSS does not specify the "available elements" of the clinical evaluation "... and "does not define the "adequate information" on the risk assessment",
- The decision on the relevant information to be made to equipment users rests with the MS

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Questions to manufacturers :

- Could the information held by the manufacturer about the risk assessment and the clinical evaluation (CE marking) be made available for the application of Art. 78.2 ?
- Could this information be available in the frame of the justification process related to a new class of medical practice?



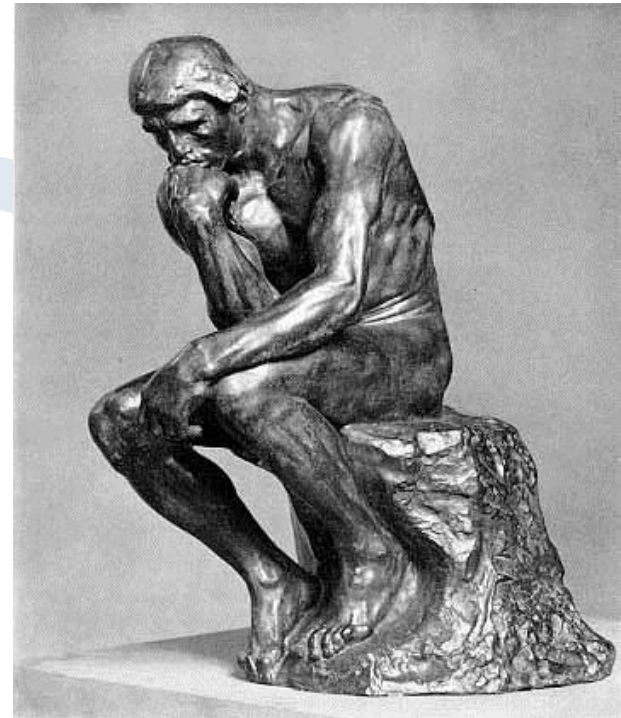
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Practical solution proposed to manufacturer (to correctly apply both legal systems, avoiding administrative burden):

- Do the manufacturers agree, on a voluntary basis, to develop an "harmonised information documentation", and to make this documentation easily available by electronic means ?

A new collaboration between HERCA and manufacturers :

- Do the manufacturers see a role for HERCA to support this effort ?



Thank You for Your Attention!

Interrelation between the BSS and the MDR :

« *Lex specialis derogat legi
generali* »

EC 22-07-2016



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