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LETTER TO THE EDITOR

Assessment of medical devices: the Emperor's new clothes

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(The Editors do not hold themselves responsible for opinions expressed by correspondents)

To the Editor,

Sharma et al¹ must be commended for speaking out about the scandalous lack of appropriate regulation for medical devices which are marketed without evaluation of benefit-harm ratio, a state of affairs flies in the face of patient's needs: "a high-level clinical evidence for treatments".

In European countries neither assessments of benefit-harm ratio nor comparative effectiveness (CE) are required for marketing medical devices. Only the "CE marking", meaning Conformité Européenne (European Conformity, as in 1985 France was a leader in the Union), is required. It is about safety standards (e.g. no explosion, no electrocution etc.). The E does not stand for effectiveness! The mark consists of the CE logo (both letters) plus a four-digit identification number from a Notified Body involved in the conformity procedure. Responsibility for "CE marking" lies with whoever puts the product on the market in the European Economic Area.

The Journal rightly offered a tribune for raising the bar,¹ in line with a recent call for CE assessment.² Sadly, in France, the highest court just choose to almost nullify the already weak regulation. On March 2017 the French regulatory agency in charge of medical devices (Agence nationale de sécurité du médicament et des produits de santé) suspended the use and required the withdrawal of several YSY Medical's medical devices within a 6 months delay as the devices have been marketed without CE marking.³ Indeed, several warning letters, the first one issued in 2016, have been useless. YSY Medical challenged the Agency's decision before a regional administrative court which: (a) considered the issue was in its jurisdiction; (b) issued an interim ruling in emergency to suspend the Agency's decision. The Conseil d'État, the highest court in France, confirmed the devastating ruling in February 2018.

In France, EBM does not mean Evidence Based Medicine any longer, but Economy Based Medicine.

REFERENCES

1. Sharma RA, Fumi L, Audisio RA, Denys A, Wood BJ, Pignatti F. Commentary: how will interventional oncology navigate the "valleys of death" for new medical devices? *Br J Radiol* 2018; **91**: 20170643. doi: <https://doi.org/10.1259/bjr.20170643>

2. Schnell-Inderst P, Hunger T, Conrads-Frank A, Arvandi M, Siebert U. Ten recommendations for assessing the comparative effectiveness of therapeutic medical devices: a targeted review and adaptation. *J Clin Epidemiol* 2018; **94**: 97–113. doi: <https://doi.org/10.1016/j.jclinepi.2017.09.022>

3. ANSM. <http://ansm.sante.fr/content/download/102851/1303999/version/1/file/DPS-YSY-MEDICAL-170314.pdf>