Adding new perspectives to the *European Respiratory Review*

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The September issue of the *European Respiratory Review* presents two viewpoints on the regulation of medical devices http://ow.ly/mX5E300p3yw

In our previous issue, we introduced two new sections to the *European Respiratory Review*: one entitled "Frontiers in Clinical Practice", with a paper by Jeny *et al.* [1] brilliantly illustrating certain critical aspects of sarcoidosis with some clinical examples, and a second named "Mini-Review: Health and Politics", in which the World Health Organization representative to the European Union, Roberto Bertollini, provided readers with a fascinating snapshot of the measures in place across Europe to combat smoking [2].

The current issue casts light on an on-going debate on the process for approving medical devices, describing experiences in the field of cardiology. Two equally valid viewpoints are put forward: one is presented in a Health and Politics Mini-Review by Rosanna Tarricone [3], an economist and the Director of CERGAS, the healthcare research centre at Milan's famous Bocconi University in Italy, while the other is presented in an accompanying editorial [4] by Maria Frigerio, an extensively experienced clinical cardiologist who is the Director of the Heart Transplant and Heart Failure Programme at the De Gasperis Cardiology Centre, Milan, one of the Europe's leading cardiological and heart surgery facilities.

Some might wonder why a respiratory review journal such as ours should be turning its attention to cardiological medical devices. The answer can be found in the editorial with which I made my debut as the Chief Editor of the *European Respiratory Review* (*ERR*): our intention is to open the review up to specialists from a wide range of fields, strenuously emphasise the interdisciplinary nature of respiratory medicine and modern medicine in general and, just as importantly, tackle topics of common interest to our readers, such as healthcare organisation and policies [5].

The branches of cardiology and cardiac surgery are the closest to pulmonology where medical devices have been most widely used and adopted in recent years. Therefore, we trust that *ERR* readers will appreciate exploring the latest developments in a field that has major crossover with our specific branch of medicine as well.

The mini-review by Tarricone *et al.* [3] offers an interesting perspective on how "real world" data can be used for building reliable evidence (and, consequently, performing health technology assessments) in device-based therapies, when evidence from comparative, randomised studies are unavailable, difficult to obtain or inconclusive. This analysis, based on the example of the MitraClip device (Abbott Vascular, Santa Clara, CA, USA), leaves some significant unanswered questions: is a new technology good just because one regulator allowed it to be used, while another did not? Are Austrian and UK patients deprived of a valuable option due

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only to excessively rigorous methodological, theoretical issues, or are Spanish and Italian patients exposed to the uncertainties of an experimental therapy that has been (perhaps prematurely) included in the healthcare system basket? The accompanying editorial by Frigerio [4] seems to admit that, given the current regulatory environment, no incontrovertible answers are available to clinicians, patients or payers. However, some optimism may derive from several cases pointing to the successful use of "classic" randomised controlled trial methodology in providing sound evidence for supporting or denying the value of device-based therapies. Moreover, the author suggests shifting the "burden of proof" from the post-market to the pre-market setting, possibly with the contribution of public research funding, in order to guarantee a timely and reliable evaluation of innovative therapies, at the same time protecting patients and the community at large from the risks and costs associated with treatments with unproven benefits. I hope that *ERR* readers will take advantage of this cardiological experience, and keep an open-minded but critical attitude when designing, conducting and evaluating research on device-based therapy for respiratory conditions.

References

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4 Frigerio M. Getting approval for new therapeutic medical devices *versus* drugs: are the differences justified? *Eur Respir Rev* 2016; 25; 223–226.
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