In this issue of Value in Health, we launch a new dedicated forum for scientific debate of unresolved questions in pharmaceconomics and outcomes research. By inviting short contributions reflecting different standpoints, the Point/Counter-Point space will provide a platform for clear and concise discussion of themes of general interest to the journal readership. We welcome suggestion for topics. We are planning to work with experts to develop a stimulating set of debates on important topics.

The first Point/Counter-Point of the series is titled “Economic evaluation of medical devices and drugs—same or different?” We have the pleasure to host contributions from Drummond et al. and from Taylor and Iglesias [1,2].

Both papers agree on a number of points. First is the principle that the general methods that govern the application of economic evaluation methods can be equally applied to drugs and medical devices. Second, there are a number of inherent characteristics specific to the technology, which makes the assessment of the (effectiveness and cost-effectiveness) evidence of medical devices somewhat more challenging to assess. Third, they agree that there is currently an asymmetry in the way in which drugs and medical devices are regulated.

Nevertheless, because “the devil is in the detail,” the articles also offer different elements for consideration. First is the need to reconsider the regulatory regimens of medical devices. In their current status, at least in Europe and North America, these regimens provide unclear incentives to R&D, licensing, price competition, and generation of robust clinical evidence. Second is the need to further develop cost-effectiveness methods to account for the issues posed by the evidence base relating to medical devices. Heterogeneous study designs, center and learning effects, bias in nonrandomized evidence, rapidly evolving technologies, absence of a “class effect,” interaction between drugs and devices, and highly dynamic price variation are only few examples.

Perhaps the reader may want to think of whether she wishes to address the “normative” or the “positive” nature of the question (normative statements are concerned with describing how things should or ought to be, how to value them, which things are good or bad, which actions are right or wrong. Positive statements on the other hand are descriptive or explanatory, and in that sense are falsifiable statements that attempt to describe reality). That is, one could attempt to describe the status quo relating to the economic evaluation of drugs and medical devices. Alternatively, one could ask whether economic evaluation of drugs and devices should be different.

Inevitably, these questions will lead to others—such as: Should the decision-making requirements for coverage and reimbursement be different for drugs and medical devices? Should the regulatory framework be the same?

These are important issues that researchers, policymakers, and the pharmaceutical and medical devices industry may need to address in the future.

We hope this debate will stimulate readers to express their views on the question at hand with their colleagues, sharing their experiences in the field.

References

1 Drummond MF, Griffin A, Tarricone R. Economic evaluation for devices and drugs—same or different? Value Health 2009;4 (In press).