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## CORRESPONDENCE

## Response to Letter to the Editor by Dr. Garattini



In response to Dr. Garattini's comments, we would like to say that although the article from 2011 [1] could be considered in support of our view about the mismanagement problems of the application of performance-based risk-sharing agreements (PBRsAs), we based our observations on the direct evaluation of how PBRsAs work in a prescribing center. Moreover, we considered the possibility to include Garattini et al.'s [2] recent interesting contribution to the topic of our article, but we chose not to cite their work because it was lacking reliable data about the actual expenditure by the National Health System for the drugs considered in our evaluation (data that we obtained, instead, from IMS Health).

"Success fee" represents an alternative way to improve existing PBRsAs, and it is arguable that to produce a more efficient outcome it still requires implementation and good management practices from the prescribing centers. We offer a pro et contra comparison of the existing schemes in Italy, however, and it is a fact that "Success fee" introduces the concept of an incentive to the prescribing center in order to apply the reimbursement scheme, providing a purpose to pursue.

We would like to stress the differences that exist between a risk-sharing agreement and the AIFA registries. In fact, PBRsAs aim at containing and rationalizing resources, while the registries have been developed as an instrument for prescription appropriateness (with all the limitations that this could lead to) and may be used as a source of real-life efficacy and safety data.

Finally, we conclude our analysis underlining how critical it is to define a set of criteria to give effectiveness a primary role in the evaluation of the impact of a therapy on the target population and the National Health System: "having a clinically meaningful end point in a clinical trial would make it easier to define the value and the consequential price of a drug, thus reducing uncertainty about treatment efficacy."

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## REFERENCES

- [1] Garattini L, Casadei G. Risk sharing agreements: what lessons from Italy? *Int J Technol Assess Health Care* 2011;27:169–72.
- [2] Garattini L, Curto A, van de Vooren K. Italian risk-sharing agreements on drugs: are they worthwhile? *Eur J Health Econ* 2015;16:1–3.