



Answers to Hofmann

Luca Gallelli

► To cite this version:

| Luca Gallelli. Answers to Hofmann. European Journal of Clinical Pharmacology, 2010, 66 (8), pp.841-842. 10.1007/s00228-010-0844-z . hal-00598970

HAL Id: hal-00598970

<https://hal.science/hal-00598970>

Submitted on 8 Jun 2011

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

Answers to Hofmann

Luca Gallelli

Received: 10 May 2010 / Accepted: 12 May 2010 / Published online: 8 June 2010
© Springer-Verlag 2010

Sirs,

I welcome the critical comments by Hofmann—despite the fact that, in theory, they may be potentially biased by an evident conflict of interest due to his clear link to pharmaceutical industry. However, they do provide an opportunity to further describe—and clarify—the study under discussion. Below is my response to his comments, point by point.

- 1) This was a spontaneous study that has been on record since 2007 despite not being included in EudraCT. The protocol has been accessible to the local Ethical Committee, and each patient and/or his family was informed of the study and signed an informed consent prior to enrollment.
- 2) This was a simplified double-blind study. This procedure, considered to be appropriate, was selected instead of the classical double blind study in order to exclude any possibility of risk in our elderly patients. A careful reading of the paper demonstrates that the dose of each drug was not changed during the study, in agreement with the protocol.
- 3) The Ethical Committee was well informed of the power of the study and had received documentation to this effect. However, we did not report these data in the paper, as this is often done in many reports of this kind.
- 4) The pricing was not calculated on the basis of five tablets. In fact, we clearly report that pricing was

calculated for a defined daily dose. We also clearly describe in the text that the estimated total price for each tablet of racecadotril and loperamide was 0.575 and 0.33 euros, respectively. Therefore, we calculated a mean of three tablets per day for racecadotril and five tablets per day for loperamide.

- 5) Hofmann writes: “There is no information on how diarrhea was defined, how the end of diarrhea was defined”. A reading of the manuscript reveals that these data are present on page 138 (Methods section).
- 6) I am grateful to Hofmann for his correct observation of two clerical errors: (1) the average age was reported as “ 80 ± 0.2 years” while the correct value is “ 80 ± 2.0 years”; (2) the range was reported as “73–93”, while correct value is “75–83”. However, even taking these two clerical errors into account, the conclusions of our study remain unaltered.
- 7) Again, from just reading the paper it is quite clear that constipation was observed as a side effect among the 50% of the patients for whom the treatment was effective (that is, people who no longer experienced diarrhea)
- 8) I am happy to reply to the questions posed in point 8 because this provides an opportunity to further clarify our study. The observation was performed in two groups of patients enrolled in the study for approximately 1 year (February 2008–March 2009). Therefore, the costs refer to the total costs of treating the episodes of diarrhea in each loperamide or racecadotril treatment group during the study period. Each patient experienced more than one episode of diarrhea in the specified time frame (each episode lasting ≥ 4 days), but we limited the analysis to four episodes. Based on these simple parameters (four episodes,

L. Gallelli (✉)
Faculty of Medicine, Experimental and Clinical Medicine,
University of Catanzaro,
Catanzaro, Italy
e-mail: gallelli@unicz.it

each lasting ≥ 4 days), it was a straightforward calculation to obtain the *average* price of 44.85 euros for racecadotril and 107.5 euros for loperamide. In the Discussion, the prices are higher because they are referring to the total prices, as clearly reported on page 142.

In conclusion, I am grateful for the comments. I believe the role of the pharmaceutical industry should also include

the careful monitoring of all papers that are published in the literature. I hope that this exchange of information represents a starting point in which the role of loperamide or that of other drugs in elderly patients, in particular those with polytherapy, is defined in greater detail.

Best regards,
Luca Gallelli, MD, PhD