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Article — Published Version

Authors' Reply to Gandjour: "10 Years of AMNOG: What is the Willingness-to-Pay for Pharmaceuticals in Germany?"

Applied Health Economics and Health Policy

Provided in Cooperation with:

Springer Nature

Suggested Citation: Büssgen, Melanie; Stargardt, Tom (2023) : Authors' Reply to Gandjour: "10 Years of AMNOG: What is the Willingness-to-Pay for Pharmaceuticals in Germany?", Applied Health Economics and Health Policy, ISSN 1179-1896, Springer International Publishing, Cham, Vol. 22, Iss. 1, pp. 127-128,
<https://doi.org/10.1007/s40258-023-00851-3>

This Version is available at:

<https://hdl.handle.net/10419/309464>

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Authors' Reply to Gandjour: "10 Years of AMNOG: What is the Willingness-to-Pay for Pharmaceuticals in Germany?"

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Accepted: 26 October 2023 / Published online: 2 December 2023
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We feel honoured that our publication "10 Years of AMNOG: What is the Willingness-to-Pay for Pharmaceuticals in Germany?" [1] is leading to discussions. In the following we would like to respond to a comment made by Gandjour [2], which questions our methodology in three aspects:

- (a) Gandjour notes, that the primary endpoints used in this paper are not patient relevant and thus not relevant to the Germany payer/decision maker. While this might be correct for HbA1c in diabetes, this is not correct for mortality in cardiovascular drugs [3], and for the Psoriasis Area and Severity Index (PASI) 75 score in psoriasis [4].

However, there is no better diabetes-specific (patient-relevant) endpoint that is consistently used across all products that we analysed. We thus used HbA1c in our calculations as this surrogate parameter is a well-known predictor of long-term diabetes complications [5] (e.g. diabetic retinopathy, cardiovascular diseases, nephropathies, neuropathies, etc.) resulting not only in (I) higher long-term costs for the health care system, but also in (II) patient-relevant comorbidities.

- (b) Furthermore, Gandjour questions the conversion of mortality into life-years gained. For cardiovascular drugs, we converted the mortality reduction into life-years gained by multiplying the mortality reduction by the difference between life expectancy and the average age of the study population. This is a common way to make mortality values more tangible and understandable that has even been used by the National Institute

for Health and Care Excellence (NICE) in the past [6]. However, we agree that there are more refined ways to accomplish this. Using life expectancy of those in the underlying randomized controlled trials (RCTs) at the age of their inclusion as suggested by Gandjour is one of them. However, given the data at hand, we decided to stick to our 'more standard' approach.

- (c) Our calculations were based on the PASI 75 score as this has been the most reported in clinical trials and gave us the most evidence. Clinically meaningful differences in terms of minimal clinically important differences (MCIDs) were calculated to put clinical outcome measures into relation to one another. However, all analyses were run on the original dataset with the most evidence from clinical trials (e.g. for psoriasis, the PASI 75 score was used).

Consequently, the key message stays the same: willingness-to-pay values vary between €33,814.08 per one percentage point HbA1c reduction for diabetes; €10,970.83 per life-year gained for cardiovascular disease; and €663.46 per 1% PASI decrease for psoriasis.

Declarations

Availability of Data All data are contained within the manuscript.

Author Contributions Both authors are responsible for conception, drafting, and approving the submitted version.

Funding Open Access funding enabled and organized by Projekt DEAL.

Conflicts of Interest The authors declare no competing interests.

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This reply refers to the comment available online at <https://doi.org/10.1007/s40258-023-00852-2>.

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