Retrospective Analysis of Hungarian HTA Submissions Under the Former National Health Economics Guideline

Introduction

In 2024 the renewal of the health economics guideline was necessary as the last one (adopted in 2021) officially expired. As part of this renewal process the HTA department of the National Institute for Public Health and Pharmacy decided to analyze the submissions presented during its tenure.

We reviewed the main health benefit indicators (added health benefit ratio and incremental QALY) and the number of cost-effective submissions. As this guideline's main innovation was the introduction of a differentiated cost-effectiveness threshold based on added health benefit, we sampled the following three main data: incremental QALY, added health benefit ratio and cost-effectiveness conclusion.

Methods

Sampled the 602 reimbursement requests that were submitted to the National Center Public Health and Pharmacy during the period in which the previous Health Economics Guideline was in effect, between November 2021 and June 2025. We excluded those which fit any of the five criteria:

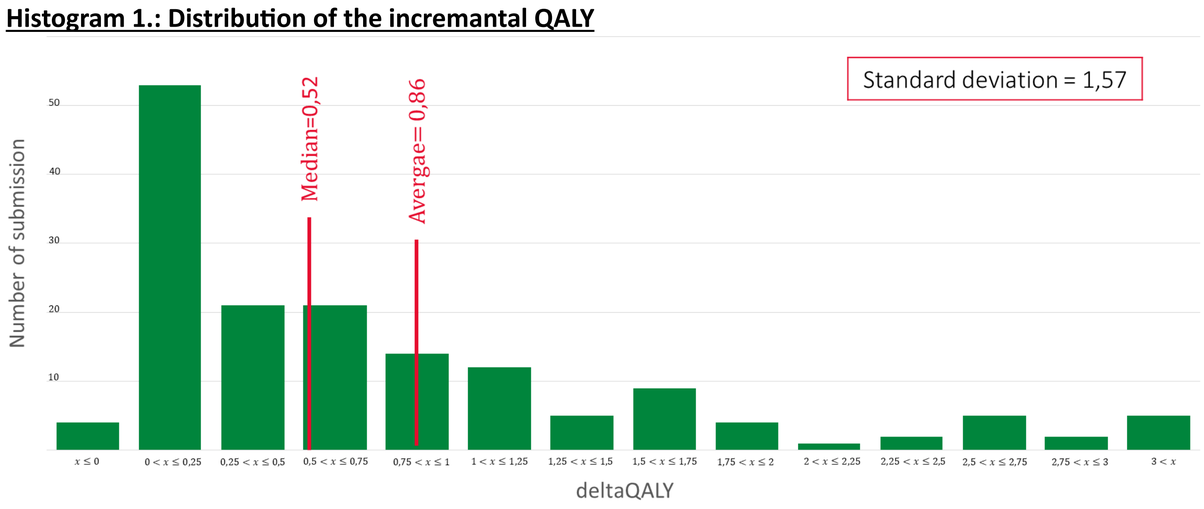
1. It wasn't a cost-utility analysis
2. It was a re-submission in a PICO already appraised
3. It was a request for price increase
4. It did wasn't a duplicate submission for another packaging size, but the same drug
5. It wasn't an orphan drug

The remaining 158 dossiers were aggregated in the three already mentioned dimensions, incremental QALY, added health benefit ratio and cost-effectiveness conclusion calculated by time correct GDP data. It must be mentioned that these are all publicly available on our webpage about all submissions, our main contribution here is to present the data in an aggregated form.

Results

As can be seen from the following histogram, most of the submissions had a low incremental QALY value, with the median 0.52 QALY gained. We can also see a large standard deviation around 1.57 QALY gained, which was caused by the relatively few high QALY gain submissions.

Histogram 1.: Distribution of the incremantal QALY

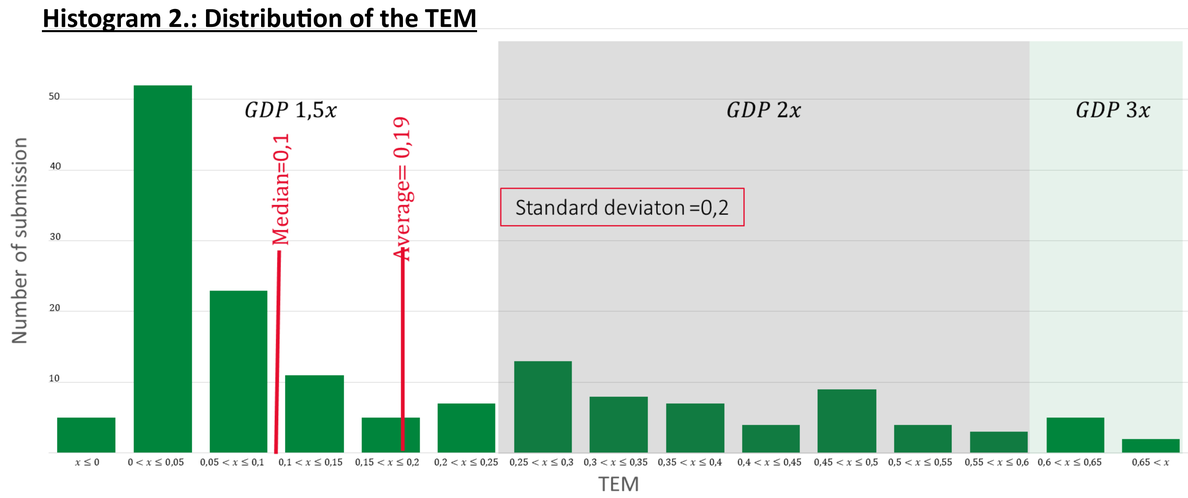


In the second histogram we see the added health benefit ration as defined by the 2021 Hungarian Health Economics Guideline*. Which follows the following formula:

$$added\ health\ benefit\ ratio\ (TEM) = \frac{QALY_{intervention} - QALY_{comparator}}{QALY_{intervention}}$$

As seen these values also concentrate on the left side of the histogram, with a median of 0.1 TEM. This means that the first three columns contain half of the submissions, with less than 10% added benefit for the patients. We can also see clear increase in the histogram after the change of the cost-effectiveness threshold, at 0.25 and 0.6 TEM.

Histogram 2.: Distribution of the TEM



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The table shows that out of all 158 submissions considered by us in this study only 73 (46%) was cost-effective in the base case submitted by the distributor company. Considering that the lowest threshold was changed by the new guidelines** we calculated that only 62 cases would be cost effective under it. Two of the 62 are only because of the newly introduced increased threshold for medicine aimed at children.

Table 1.: Cost-effectiveness conclusion

	Old guideline	New guideline
Sample	158	
Num. of Cost-effective (%)	73 (46.2%)	62 (39.24%)

Conclusions

Although it is hard to see the causes, as it can be seen most submissions have a comparatively low added benefit, with the vast majority falling under the lowest threshold. Although added benefit ratio and cost-effectiveness largely doesn't correlate with the cost effectiveness conclusion (correlation of 0.15), but the low results still means that most submissions failed to present a price in line with the required ICER.

*Ministry of Human Resources. (2021). Az Emberi Erőforrások Minisztériuma egészségügyi szakmai irányelve az egészség-gazdaságtani elemzések készítéséhez és értékeléséhez. Egészségügyi Közlöny LXXI. évf., 21. szám, p2178.

**Ministry of Interior. (2025): A Belügyminisztérium egészségügyi szakmai irányelve az egészség-gazdaságtani elemzések készítéséhez és értékeléséhez. Egészségügyi Közlöny LXXV. Évfolyam 9. szám, p1250.

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