IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

IQWiG Reports - Commission No. A11-28

Retigabine - Benefit assessment according to § 35a Social Code Book V[1]

Extract

[1] Translation of Sections 2.1 to 2.6 of the dossier assessment ("Retigabine – Nutzenbewertung gemäß § 35a SGB V" (Version 1.0; Status: 10.02.2012). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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2 Executive summary

2.1 Executive summary of the benefit assessment

Background

On 14.11.2011, in accordance with § 35a Social Code Book (SGB) V, the Federal Joint Committee (G-BA) wrote to IQWiG to commission the benefit assessment of the drug retigabine. The assessment was based on a dossier compiled by the pharmaceutical company, which was sent to IQWiG on 14.11.2011.

Research question

The benefit assessment of the drug retigabine was carried out for the indication "adjunctive treatment of partial onset seizures with or without secondary generalization in adults aged 18 years and above with epilepsy" [1].

As specified by the G-BA, add-on lamotrigine is the appropriate comparator therapy for the benefit assessment. In cases where lamotrigine is used as monotherapy, add-on topiramate is regarded as the appropriate comparator therapy.

However, in its dossier the pharmaceutical company compared retigabine with lacosamide and thus deviated from the G-BA's specifications. Moreover it provided no adequate justification for this deviation.

Results

By choosing a different comparator therapy, the dossier of the pharmaceutical company did not address the question described above. Accordingly, the studies submitted by the company were not relevant for the benefit assessment – neither for a direct nor an indirect comparison. Therefore no proof of an added benefit of retigabine in comparison with the appropriate comparator therapy specified by the G-BA can be inferred from the evaluation presented in the company's dossier.

Probability and extent of the added benefit, patient groups with therapeutically important added benefit

Based on the results presented, the extent and probability of an added benefit of the drug retigabine is assessed as follows:

- There is no proof of added benefit.

In respect of patient groups with a therapeutically important added benefit, the result is as follows:

- There are no groups of patients for whom a therapeutically important added benefit is proven.

The decision regarding added benefit is made by the G-BA.

2.2 Research question

The benefit assessment of retigabine was carried out in relation to its approved indication of "adjunctive treatment of partial onset seizures with or without secondary generalization in adults aged 18 years and above with epilepsy" [1].

The pharmaceutical company designated the following treatment as appropriate comparator:

- Lacosamide 50 mg, 100 mg, 150 mg and 200 mg

By doing so, the company deviated from the appropriate comparator therapy specified by the G-BA, which is:

- Lamotrigine
- In cases where lamotrigine is used as monotherapy, topiramate as adjunctive therapy is regarded as the appropriate comparator.

The pharmaceutical company did not make use of the option of seeking advice from the G-BA regarding the appropriate comparator therapy. In the Institute's view – which is presented in detail in Section 2.7.1 of the full dossier assessment – the pharmaceutical company does not provide adequate justification for this deviation.

In this dossier assessment, IQWiG used the appropriate comparator therapy specified by the G-BA for the benefit assessment of retigabine.

The assessment was carried out in relation to patient-relevant outcomes.

Further information about the research question can be found in Module 3, Section 3.1 and Module 4 Section 4.2.1 of the dossier and in Sections 2.7.1 and 2.7.2.1 of the full dossier assessment.

2.3 Information retrieval and study pool

The only available study pool was the list of studies provided by the pharmaceutical company. This contained no relevant studies. The company undertook other methods of information retrieval (search in trial registries, bibliographical searches for the indirect comparison of retigabine and lacosamide) with a view to what it regarded as the relevant research question. However these searches did not address the actual question (comparison of retigabine with the comparator therapy specified as appropriate by the G-BA).

Overall, none of the studies were relevant to the benefit assessment.

Further information about information retrieval and the study pool for the present benefit assessment can be found in Module 4 Sections 4.2.2, 4.2.3 and 4.3.2.1.1 of the dossier and in Section 2.7.2.3 of the full dossier assessment.

2.4 Results concerning added benefit

Since no study of relevance for the benefit assessment was submitted neither for a direct nor for an indirect comparison, there is no proof of added benefit of retigabine compared with the appropriate comparator therapy specified by the G-BA.

This differs from the approach of the pharmaceutical company, who present an indirect comparison between retigabine and its chosen appropriate comparator; this process leads the company to derive an overall added benefit of retigabine.

Further information about the results on added benefit can be found in Module 4 Sections 4.3.1.3 and 4.3.2.1.3 of the dossier and in Section 2.7.2.4 of the full dossier assessment.

2.5 Extent and probability of the added benefit, patient groups with therapeutically important added benefit

The data submitted provide no proof of added benefit of retigabine compared with the appropriate comparator therapy specified by the G-BA. Hence there are also no patient groups for whom a therapeutically important added benefit can be derived.

This differs from the pharmaceutical company's evaluation, which showed a non-quantifiable added benefit of retigabine compared with its chosen appropriate comparator therapy (lacosamide).

Further information on the extent and probability of added benefit and on patient groups with therapeutically important added benefit can be found in Module 4 Section 4.4 of the dossier and in Section 2.7.2.5 of the full dossier assessment.

2.6 List of included studies

In its evaluation the pharmaceutical company did not include any relevant study comparing retigabine with the appropriate comparator therapy specified by the G-BA.

Keywords: retigabine; epilepsy; benefit assessment

References

1) Trobalt -EMEA/H/C/001245 -IB/0008/G. Annex I - Summary of Product Characteristics (accessed 01.03.2012). http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001245/WC500104835.pdf

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