



## Market Access Compass 2012

Evaluation of the Early Benefit Assessment

(§ 35a SGB V)

Base Study 2012 – Entire Report

# Demo Version



KNORR Health Strategy

# **Imprint**

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## **Foreword**

This report is based on the results of a written survey of pharmaceutical companies and representatives of assessment institutions. The information and conclusions presented are directly derived from the empirical data. However, results are not representative due to the structure and size of the sample.

This study would not have been possible without experts' willingness to share their opinion of benefit assessment process. My special thanks therefore go to the participants in the study.

Carolin Knorr

Rheinstetten, Germany, July 2012

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AkdÄ	Arzneimittelkommission der deutschen Ärzteschaft (Drug Commission of the German Medical Association)
AMI	Arzneimittel-Innovation (Pharmaceutical innovation)
AMNOG	Gesetz zur Neuordnung des Arzneimittelmarktes in der gesetzlichen Krankenversicherung - Arzneimittelmarktneuordnungsgesetz (Law for Reforming the Market for Pharmaceuticals)
AM-NutzenV	Verordnung über die Nutzenbewertung von Arzneimitteln nach § 35a Absatz 1 SGB V für Erstattungsvereinbarungen nach § 130b SGB V – Arzneimittel-Nutzenbewertungsverordnung (Regulation for the Early Benefit Assessment of New Pharmaceuticals)
APA	American Psychological Association
ApU	Abgabepreis des pharmazeutischen Unternehmers (Pharmaceuticals company's actual sales price)
BAnz	Bundesanzeiger (German Federal Bulletin)
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (German Federal Institute for Drugs and Medical Devices)
BGBl	Bundesgesetzblatt (German Federal Law Gazette)
BMG	Bundesministerium für Gesundheit (German Federal Ministry of Health)
EbM	Evidenzbasierte Medizin (Evidence-based medicine)
EMA	European Medicines Agency
EU	Europäische Union (European Union)
FDA	U.S. Food and Drug Administration
FNB	Frühe Nutzenbewertung (Early Benefit Assessment)
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
GKV	Gesetzliche Krankenversicherung (Statutory Health Insurance)
GKV-SV	GKV-Spitzenverband (The National Association of Statutory Health Insurance Funds)
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
KV(en)	Kassenärztliche Vereinigung(en) (Association(s) of Statutory Health Insurance Physicians)
KBV	Kassenärztliche Bundesvereinigung (German National Association of Statutory Health Insurance Physicians)
PEI	Paul-Ehrlich-Institut, Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel (Paul Ehrlich Institute, Federal Institute for Vaccines and Biomedical Pharmaceuticals)

pU	pharmazeutischer Unternehmer (Pharmaceutical company)
RCT	Randomisierte kontrollierte Studie (Randomised Controlled Trial)
SGB V	Sozialgesetzbuch Fünftes Buch (Book V of the Social Code)
VerfO	Verfahrensordnung des Gemeinsamen Bundesausschusses (Code of Procedure of the Federal Joint Committee)
ZVT	Zweckmäßige Vergleichstherapie (appropriate comparator)

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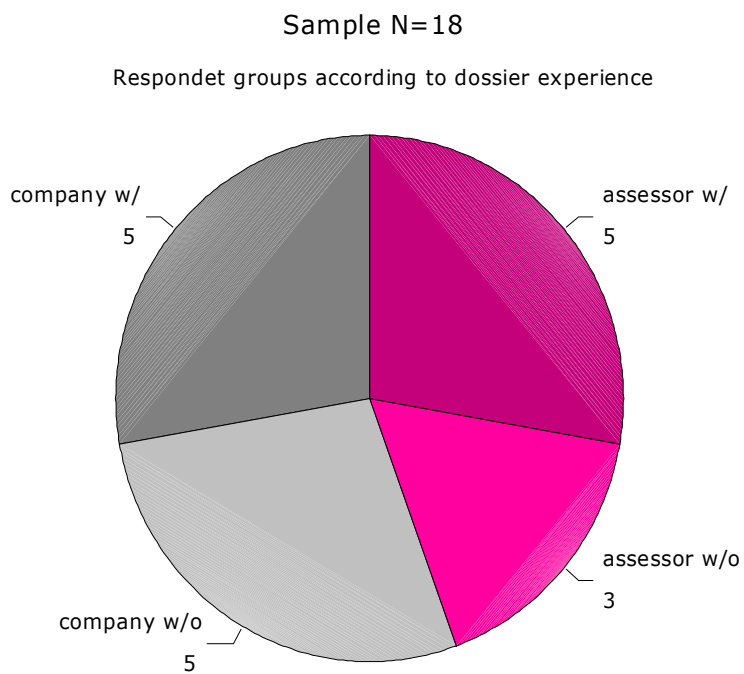
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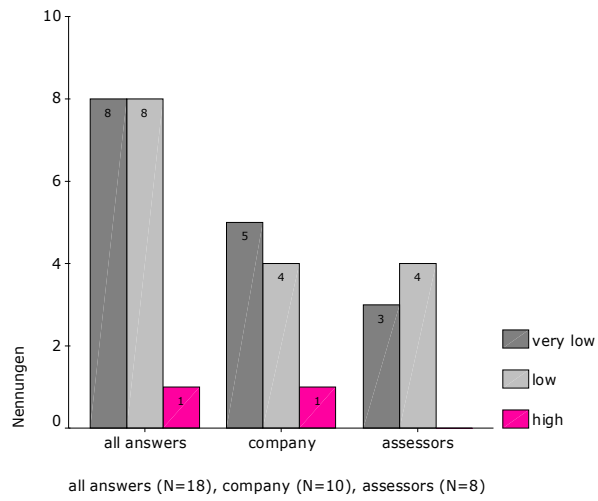
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Extract

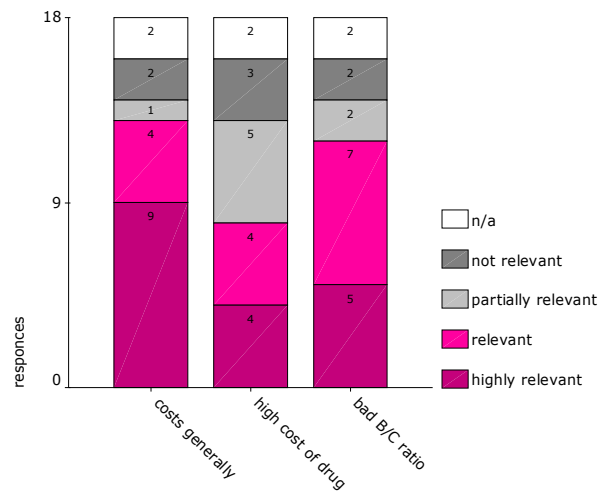
**Diagram 1:** Sample - Respondent groups according to dossier experience



**Diagram 11:** Prospects of success using a divergent comparator



**Diagram 12.1:** Relevance of costs/price for new drugs for the outcome of the assessment proceedings. All answers (N=18)



## **Expert voices**

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Citations

Extract

- 1** „The planned scoping process to determine the appropriate comparative therapy involving the approval authorities was vehemently prevented by the health insurances. However, it could be helpful if there’s a fair exchange.  
(G-BA)
- 2** “ [The problems connected to the determination of the ZVT] „can be resolved at best by involving the advice of a medical expert committee by means of clearly defined criteria, to what a appropriate comparator really is“.  
(Company)
- 3** „ [The problem, that the studies don't contain the required data] „could only be settled if the reimbursement decisions were temporary until the adequate data is available. At present the scheme of VerfO of Federal Joint Committee doesn’t provide this.“ (Scientific advisor / service provider)
- 4** „Suddenly, now the method of slicing the study data into non-predefined subgroups (clearly prohibited by the Method Paper of IQWiG in the past and carried out by IQWiG in the CAPRIE study in clean break with the own directive) is supposed to be 'standard'. In many cases this will produce questionable results with no sufficient statistical power that will influence the decisions.“ (G-BA)
- 5** „From my point of view, it’s justifiable by a major effect with a large result certainty to use the fundament of a single RCT for the assessment, especially since it’s at the issue of the price negotiations.“ (Scientific advisor / University)
- 6** „In diabetes treatment no unmet need is seen by G-BA. However, when a drug achieves a first line indication it then has to demonstrate clinical superiority. This was shown, at most, for the criteria of hypoglycemia in comparison to SU [sulfonylurea].“ (G-BA)
- 7** „Although the IQWiG assessment does not constitute a decision, it can be interpreted as a final decision in the medical community and thus affect the prescription behavior.“ (Company)

- 8** „With new scientific findings [because of these the company could request for a new benefit assessment] nobody really believes in the realistic possibilities to achieve a price increase in year 2 or 3 with the GKV-Spitzenverband after market entry.“ (*Company*)
- 9** „Health economic data is important in arbitration proceedings.“ (*Arbitration board*)
- 10** „Through the extraordinary labour and costs intensive dossier preparation and evaluation proceedings a difference has so far only been made between additional benefit yes (= price negotiations) and no (= price fixing by GKV-SV). If the objective of the AMNOG was to reduce the high German prices to the European level, this would have been possible even without this proceeding. That is why there are already parliamentary initiatives to stop this proceeding.“ (*G-BA*)



## About the author

Carolin Knorr, M.A., a political scientist and market access manager (EBS), founded KNORR Health Strategy in 2006 as a consulting health care research institute and has been its owner and managing director since then.



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