



## Market Access Compass 2013

### AMNOG and the consequences

Evaluation of the early benefit assessment (§ 35a SGB V)

Monitor 2013 - report



KNORR Health Strategy

# **Imprint**

## **Publisher**

KNORR Health Strategy

Storchenstraße 13

D-76287 Rheinstetten

Germany

## **Authors**

Carolin Knorr

## **Composition**

In-house

## **Rights**

© KNORR Health Strategy. All rights reserved.

## **Date of publication**

31 October 2013

## **Foreword**

This report from the *Market Access Compass* series analyzes the consequences of the Act on the Reform of the Market for Medicinal Products (Gesetz zur Neuordnung des Arzneimittelmarktes in der gesetzlichen Krankenversicherung – Arzneimittelmarktneuordnungsgesetz [AMNOG]) with reference to the benefit assessment of medicinal products according to section 35a SGB V. The report provides an investigation of the consequences at the national and international level. It is a continuation of the 2012 baseline study that emphasized the legal and formal regulations for a benefit assessment. Nevertheless, the present report is an autonomous unit of investigation.

The results that are presented in this report are based on a qualitative telephone survey among representatives of pharmaceutical companies, experts in the field of self-government and additional participants. All conclusions in this report are based on empirical data. This study would not have been possible without the willingness of the experts to contribute and share their opinions and appraisals. We would therefore like to thank all participants of this study for their effort and support.

Rheinstetten, Germany, October 2013

## Content

Table of figures.....	i
Index of abbreviations .....	ii
Executive Summary .....	1
1 Initial situation, objective and format .....	16
1.1 Assessment of additional benefits and price negotiations .....	16
1.2 Study objective and content.....	17
1.3 Format of the examination report.....	18
2 Method evaluation .....	20
2.1 Evaluation as a means of assessment for measures and processes ...	20
2.2 Methodical aspects of the expert survey .....	20
2.2.1 Choice of approach .....	20
2.2.2 Sample selection .....	21
2.2.3 Design of the interview guideline .....	22
2.3 Evaluation and structure of the presentation.....	24
3 Empirical analysis – Results of the expert survey .....	25
3.1 General assessment.....	25
3.1.1 The essential elements of an early benefit assessment.....	25
3.1.2 Experience from previous procedures .....	26
3.1.3 Changes in the companies and organizations of self-government .....	28
3.1.4 The roles of the individual protagonists.....	29
3.2 Strategies for the assessment of benefits .....	31
3.2.1 Realization of the alignment.....	31
3.2.2 What could be improved?.....	32
3.2.3 Opportunities to influence pivotal procedural steps .....	33
3.2.4 Success factors in comments and hearing procedures .....	35
3.3 Price negotiations and arbitration procedures.....	39

3.3.1	Personal experience of the respondents with price negotiations .....	39
3.3.2	Leaders und key decision makers.....	39
3.3.3	Assessment of the price negotiations and agreed discounts .....	39
3.3.4	Assessment of the list of reference countries "Länderkorb" .....	43
3.3.5	Arbitration procedures.....	43
3.3.6	Criteria for the agreement on the reimbursement price .....	44
3.3.7	Special practice conditions .....	46
3.3.8	Price increase after the price negotiation.....	46
3.4	Europe-wide consequences of the benefit assessment.....	47
3.4.1	Harmonization of the benefit assessments within Europe .....	47
3.4.2	Drivers and restraints of the harmonization .....	49
3.4.3	Is it desirable to achieve a harmonization of the benefit assessments within Europe? .....	50
3.5	Evaluation of opt-out solutions: chances and risks.....	51
3.5.1	Assessment of the opt-out strategy.....	51
3.5.2	Relevance of opt-out medicinal products .....	53
3.6	Selective contracts.....	55
3.6.1	Contracts according to sections 130a para. 8, 130c & 140a SGB V....	55
3.6.2	Criteria for the opening of negotiations and contract conclusion.....	56
3.6.3	Main benefit of the contracts .....	57
3.6.4	Exceptions and needs that are not met by the contract options .....	57
3.6.5	Development of innovative contract options in relation to mere discount contracts .....	58
3.7	Existing market .....	58
3.7.1	Available products on the existing market versus new medicinal products: Similarities and differences in the assessment procedure...	59
3.7.2	Background of the product assessments on the existing market .....	60
3.7.3	Significance of the assessments on the existing market for companies .....	60

3.7.4	Strategic recommendations to the affected companies .....	61
3.7.5	Consequences of the assessment of the existing market for the German healthcare market .....	62
3.7.6	Consequences of the assessment of the existing market for the European benefit assessment .....	63
4	Pragmatic conclusions – requirements for the companies .....	65
	Bibliography .....	73
	Appendix .....	75

## **Table of figures**

Figure 1: Sample according to experience with benefit assessment .....	22
Figure 2: Personal experience with comments and hearing procedures .....	35
Figure 3: Personal experience with price negotiations.....	39
Figure 4: Relevance of the criteria for the agreement on the reimbursement price .....	45
Figure 5: Are we on the way to a standardized benefit assessment? .....	47
Figure 6: Drivers of the harmonization .....	49
Figure 7: Relevance of opt-out medicinal products .....	53