

Contents

1	INTRODUCTION: BACKGROUND, CONTENT AND LIMITS OF THE OPINION	7
2	TERMINOLOGY, FACTS AND ISSUES	11
2.1	Individual responsibility and solidarity	11
2.2	Scarcity	13
2.3	Rationalization	17
2.4	Rationing	20
2.5	Prioritization	22
2.6	Limitation of treatments and services: an international comparison	23
2.7	Fitness for purpose, medical benefit and economic efficiency	27
2.8	Accepted medical standard	28
2.9	Medical practitioners as “rationers”?	30
3	EVALUATION OF THE COSTS AND BENEFITS OF MEDICINAL PRODUCTS	31
3.1	Assessment of medical benefit	31
3.1.1	Health-related quality of life	32
3.1.2	The definition of medical benefit used by the IQWiG	34
3.1.3	Use of QALYs as a measure of medical benefit	36
3.2	Cost assessment	38
3.3	Cost-effectiveness analysis	40
3.3.1	Introduction	40
3.3.2	Cost-effectiveness analyses within a specific indication	40
3.3.3	Cost-effectiveness analyses for multiple indications	44
4	HOW BENEFIT ANALYSES AND COST-EFFECTIVENESS ANALYSES FOR MEDICINAL PRODUCTS FEATURE IN THE LAW GOVERNING STATUTORY HEALTH INSURANCE IN GERMANY	47
4.1	Introduction	47
4.2	Limitation of treatments by exclusion and restriction of prescribing of medicinal products	49
4.3	Limitation of treatments by the setting of maximum amounts for a medicinal product	51

4.4	Pricing through negotiation and setting of reimbursement amounts	52
4.4.1	Early evaluation of medical benefits	52
4.4.2	Cost-effectiveness analysis	54
4.5	Interim conclusion	57
5	ETHICAL PROBLEMS RAISED BY THE EVALUATION OF MEDICAL BENEFITS AND COSTS	59
5.1	Quality assurance and patient protection	59
5.2	Maximization of medical benefits and fairness	60
5.2.1	Introduction	60
5.2.2	QALYs and fairness	61
5.2.3	Inter-individual valuation of life	66
5.3	Values and rights	68
6	CONSTITUTIONAL FRAMEWORK	74
6.1	Individual constitutional rights	74
6.1.1	Fundamental considerations	74
6.1.2	The “minimum subsistence level” in relation to medical care	76
6.1.3	The Federal Constitutional Court’s decision of 6 December 2005	79
6.2	Cost-effectiveness analysis and the requirements of the principle of equality	82
6.3	Cost-effectiveness analysis in the light of the principles of democracy and the rule of law (Article 20(2) and (3) of the Basic Law)	86
6.3.1	Fundamental considerations	86
6.3.2	The G-BA	87
6.3.3	The IQWiG	90
7	SUMMARY AND RECOMMENDATIONS	92
	DISSENTING OPINION	96
	ABBREVIATIONS	123
	GLOSSARY	125