



Reimbursement of Innovative Medical Technology in Germany



General Survey of
Problems in Reimbursement and successful
Strategies for entering the German Market

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Agenda

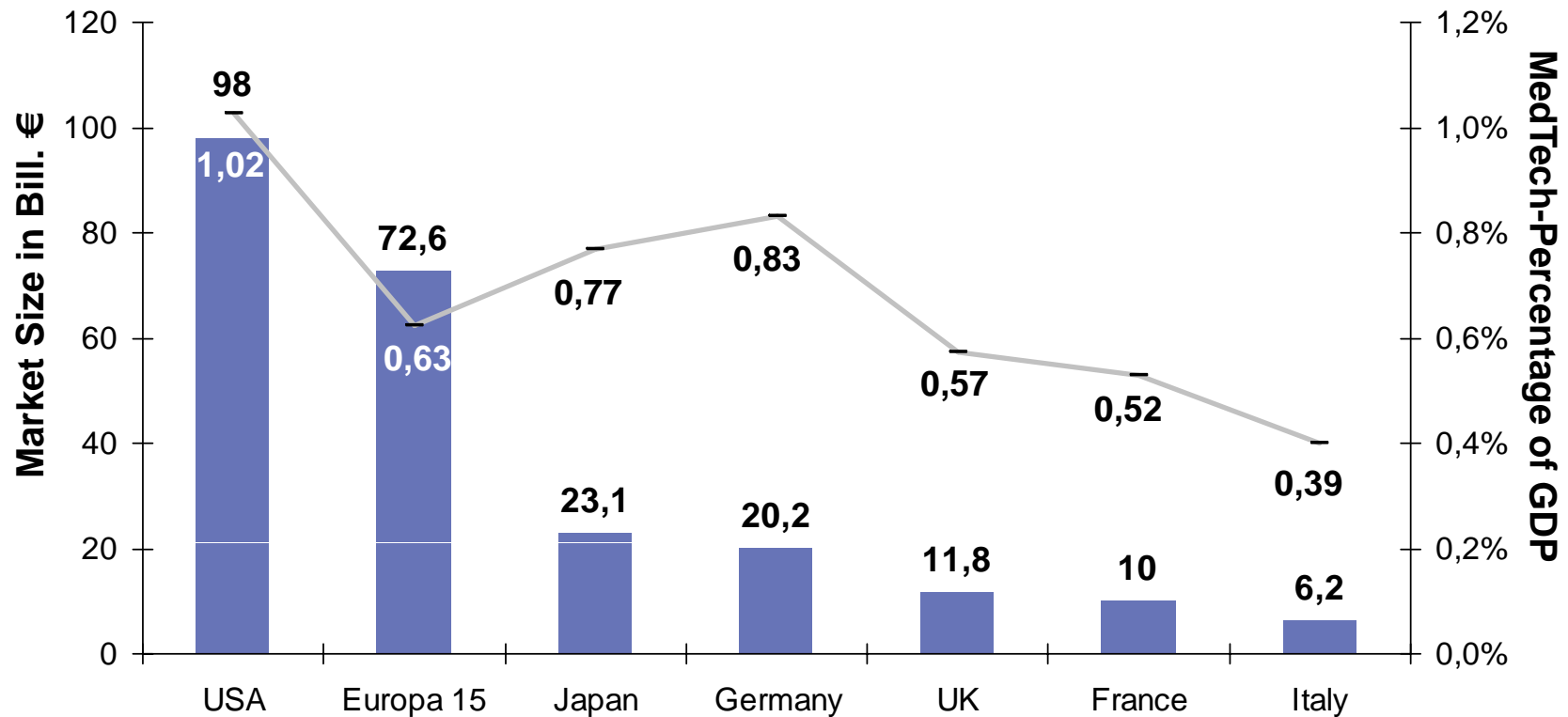
- I. **German market for healthcare technology**
 - II. **Health care in Germany – Basic information**
 - III. **Problems in Reimbursement of new technologies**
 - IV. **Strategies for Winners**
 - V. **Future Trends**
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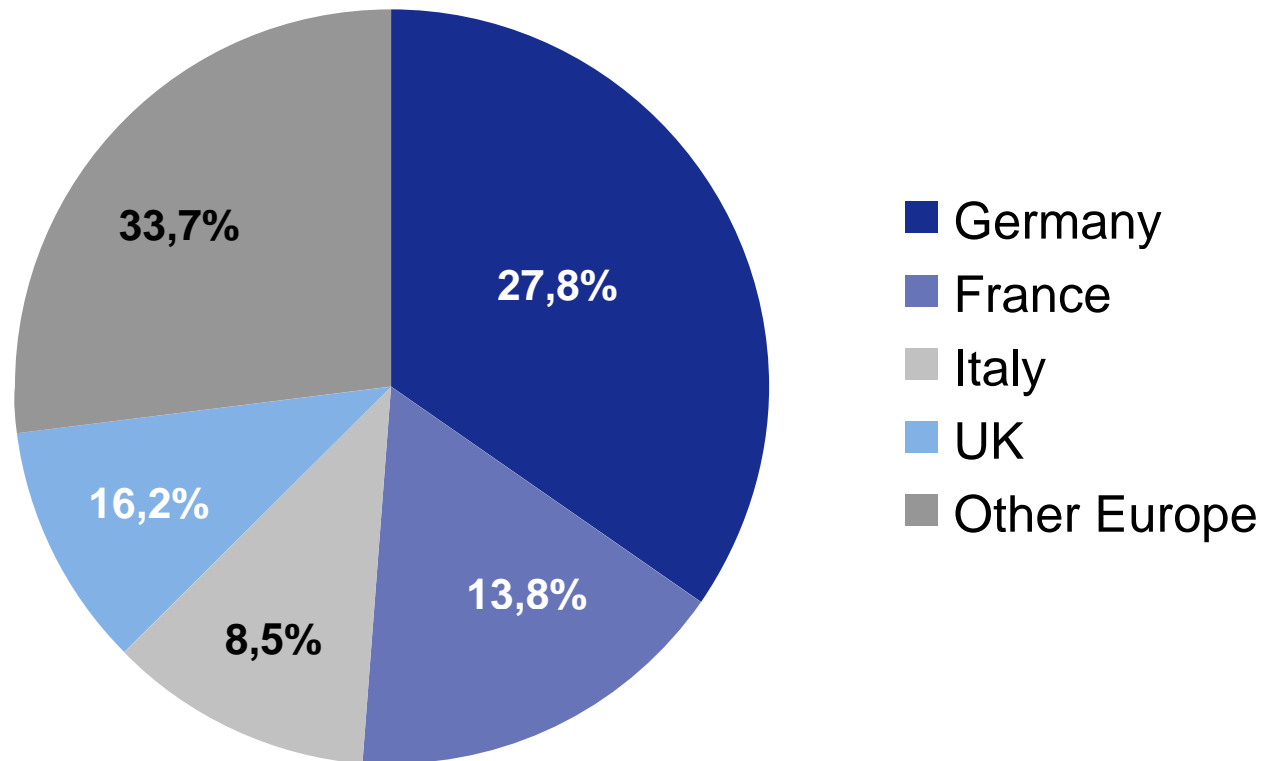
Germany spends more on medical technology than most other developed countries

World Market for Medical Technology 219 Bill. € in 2007



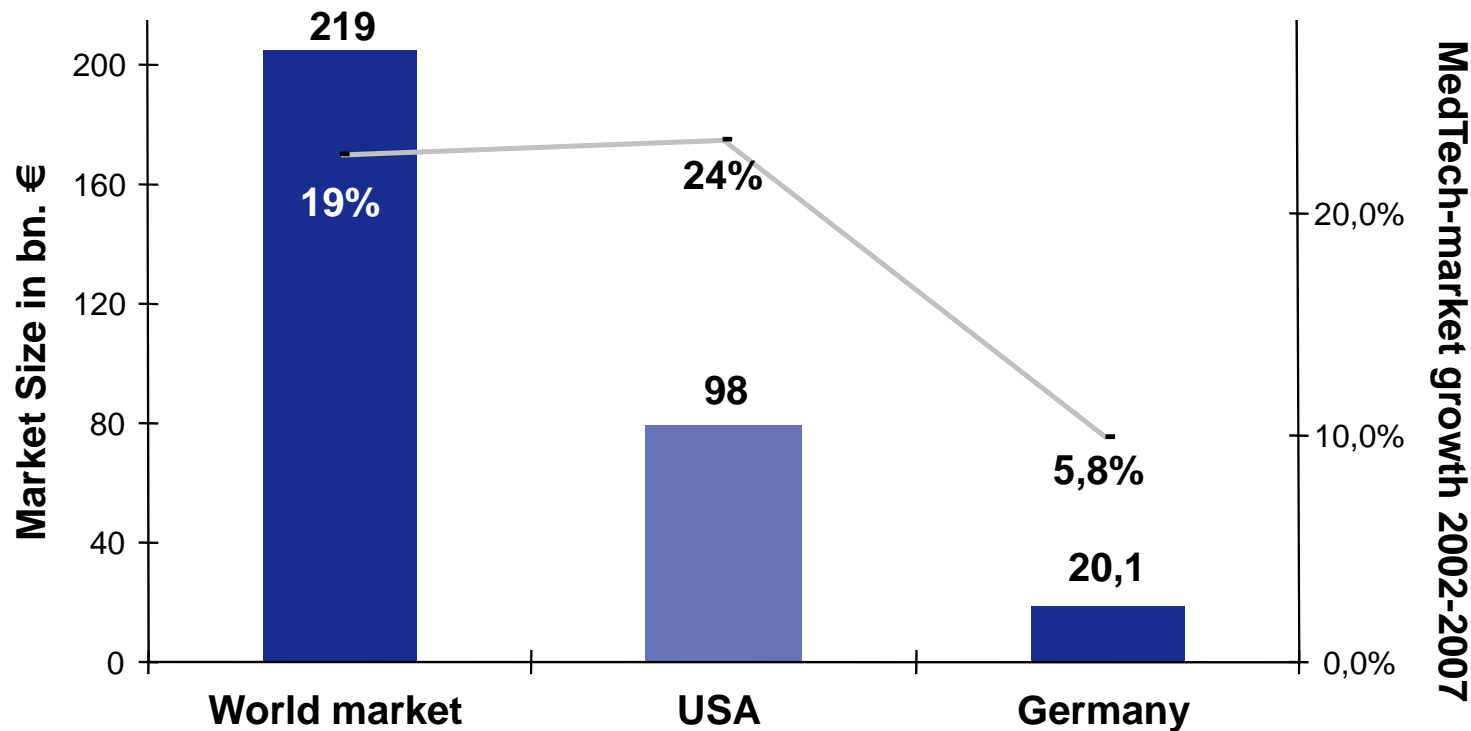
Germany accounts for 27,8% of the European market

European market for Medical Technology in 2007



But: Due to restrictive budget policy and pricing pressure, the German market is far under average worldwide growth

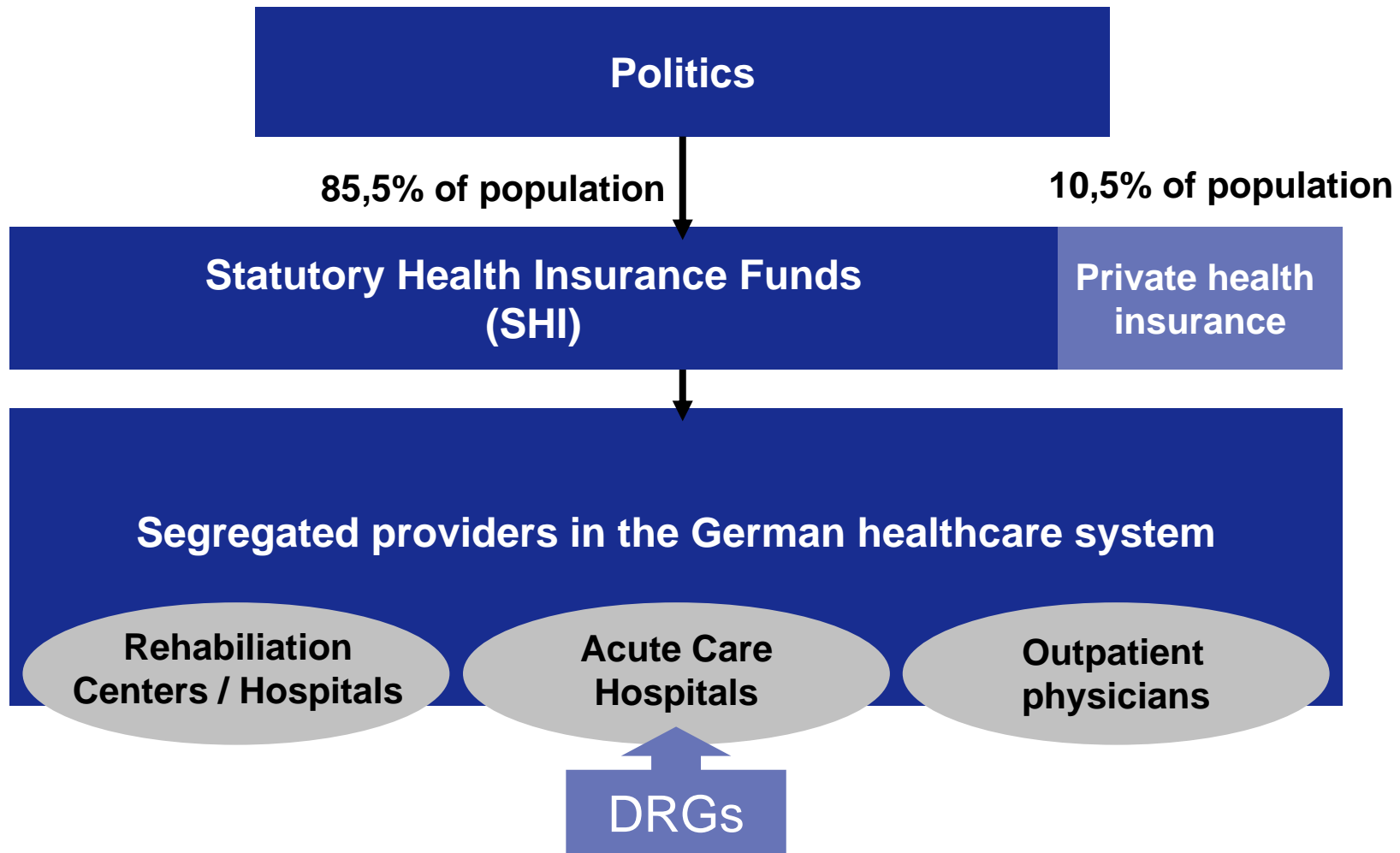
Markets for Medical Technolog in 2007



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-

As one of the few „Bismarck“ – systems, Germany has a non-government owned type of compulsory health insurance

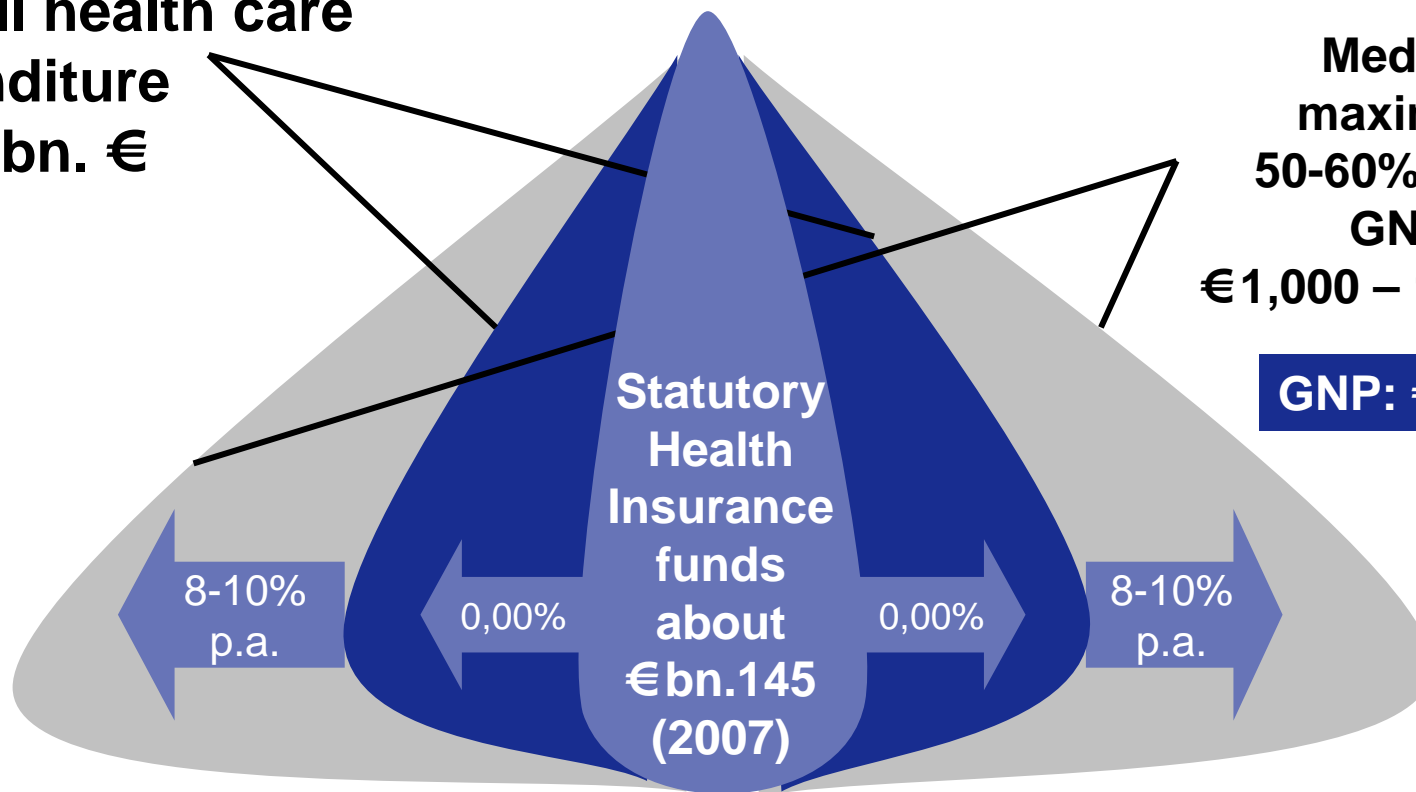


Governmental budgeting in Germany: For political reasons one of the most dynamic growth markets is throttled

overall health care expenditure
252,8 bn. €

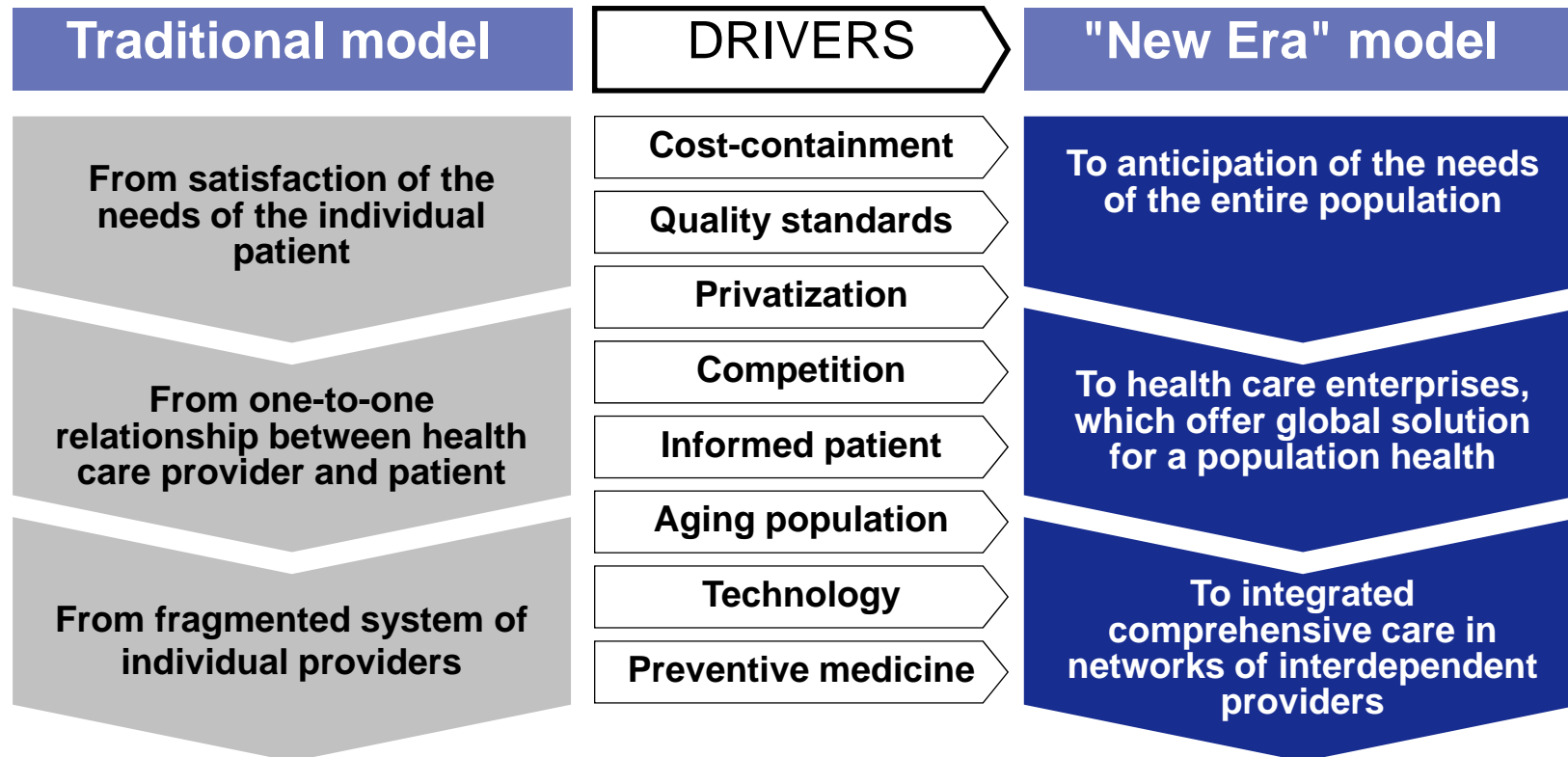
Medical maximum
50-60% of the
GNP:
€1,000 – 1,200 bn.

GNP: €2.423 bn.

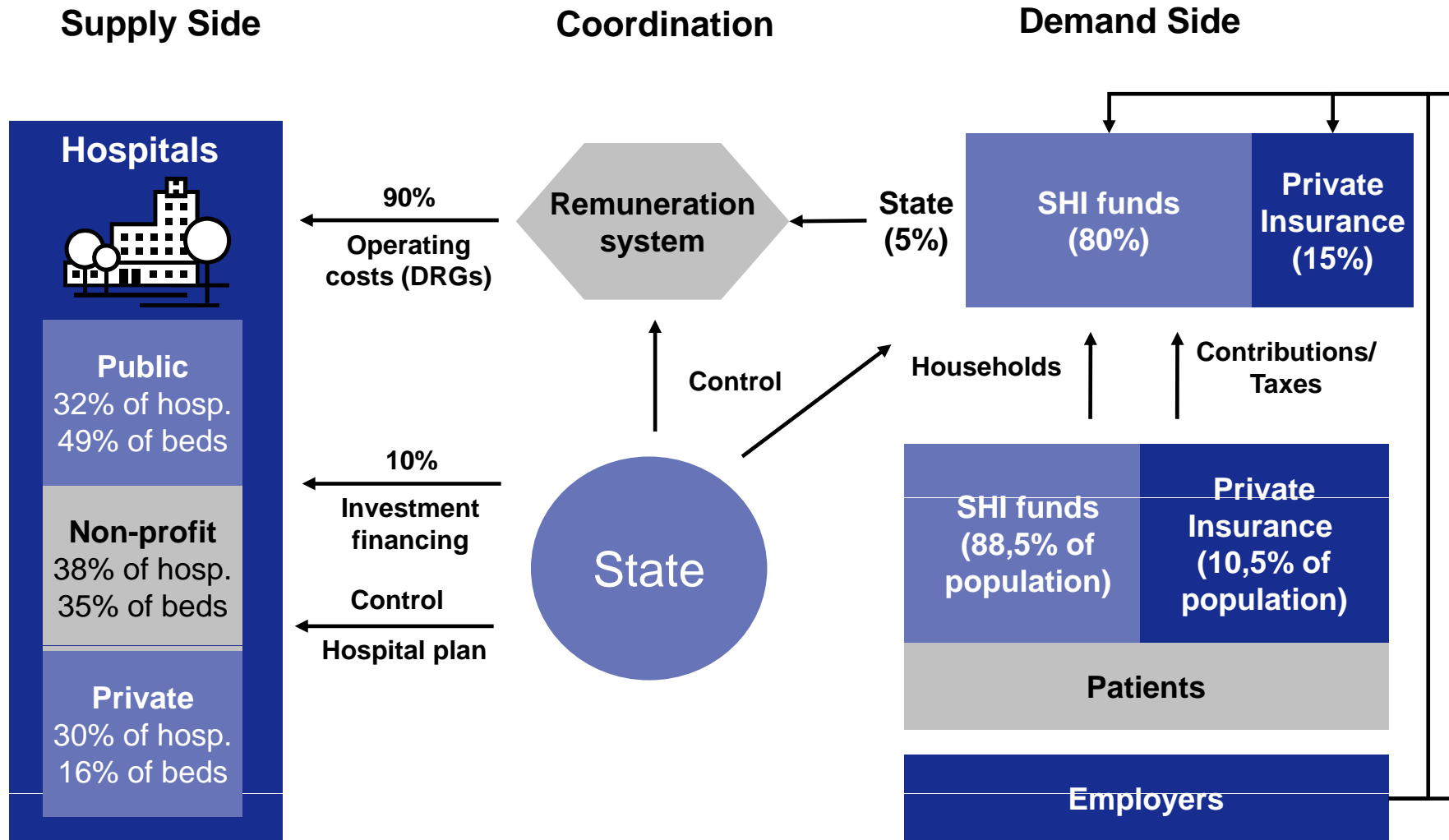


But it is getting better: As everywhere else, the German health care system is undergoing a radical change process

From fragmented system to an integrated industry



The SHI-funds play the dominant role in Germany's Hospital care system: reimbursement by SHI funds has to be achieved



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-

Germany's reimbursement schemes vary between market segments

Reimbursement scheme of the health care sector and market segments

		Market segment		
		1.	2.	3.
		Regular statutory health insurance Funds (SHI)	Private health insurance/complementary insurance	New Care Organizations (individual contracts)
Health care sector	Inpatient	1.1 Regular inpatient care (DRG)	Private complementary insurance (GOÄ)	Out-of-pocket Integrated health care delivery based on §§ 140 a-d Social Law (Individual)
			(DRG, etc.)	
Outpatient	1.2 Regular outpatient and ambulatory care (EBM 2000plus)	Private health insurance (GOÄ)		
		Private complementary insurance (GOÄ)		

Due to enormous cost pressure, it is getting more difficult to achieve reimbursement for innovative technologies

General Information on the German Health Care system

- Total health care expenditures in Germany 2007: 252 bn. Euro*
- Health care dominated by Statutory Health Insurance (SHI)
 - Insured: 70 mio. (85,0% of population) in 2007**
 - SHI expenditures: 145 bn. Euro in 2007**
- Regulation of health care by governance control or central self-administration
- Reimbursement in hospitals driven by DRGs
- Reimbursement in outpatient setting is driven by the EBM

Trends

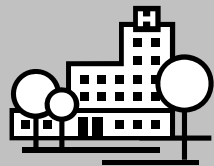
- System and providers under enormous cost pressure
- Shift from inpatient to outpatient services
- Increasing importance of evaluation of efficacy and efficiency of procedures
- Individual contracts on integrated health care delivery

Effects for manufacturers

- More complicated market entry
- To achieve reimbursement by the SHI is important (market share)
- New opportunities through selective contracts
- Health economics become more important for product choice

It is getting increasingly difficult to enter the German market with innovative products

Providers view



Problems:

- DRGs with fixed prices
- Almost fixed hospital budgets
- Increasing costs
- Huge investment needs
- Planning of benefits by state
- No real competition

Reaction:

- Incentive to lower costs
- Shifting of price pressure to industry
- Buying center in hospital
- Buying syndicates

SHI funds' view



Problems:

- Permanently rising expenditure coupled with income deficiencies
- Little influence on health care process and providers

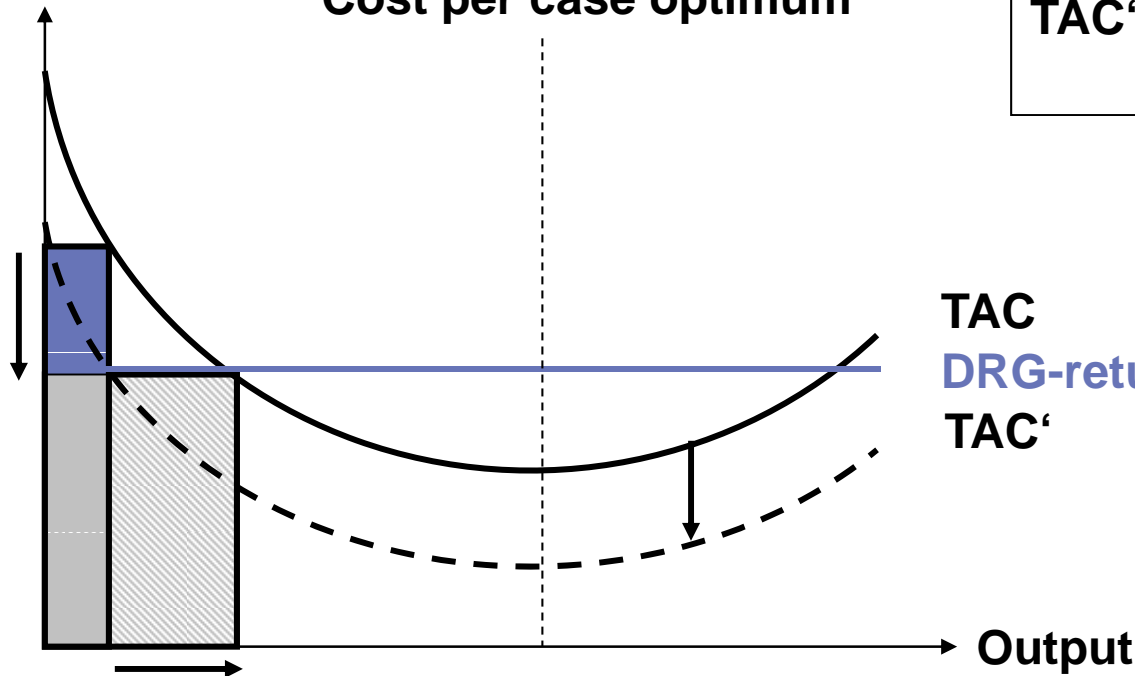
Reaction:

- Caution with reimbursement of innovations
- Evaluation of efficacy and efficiency of new products by self governing bodies

The DRG-System sets incentives to lower hospital costs and increase output

Cost/
Returns
per case

Cost per case optimum

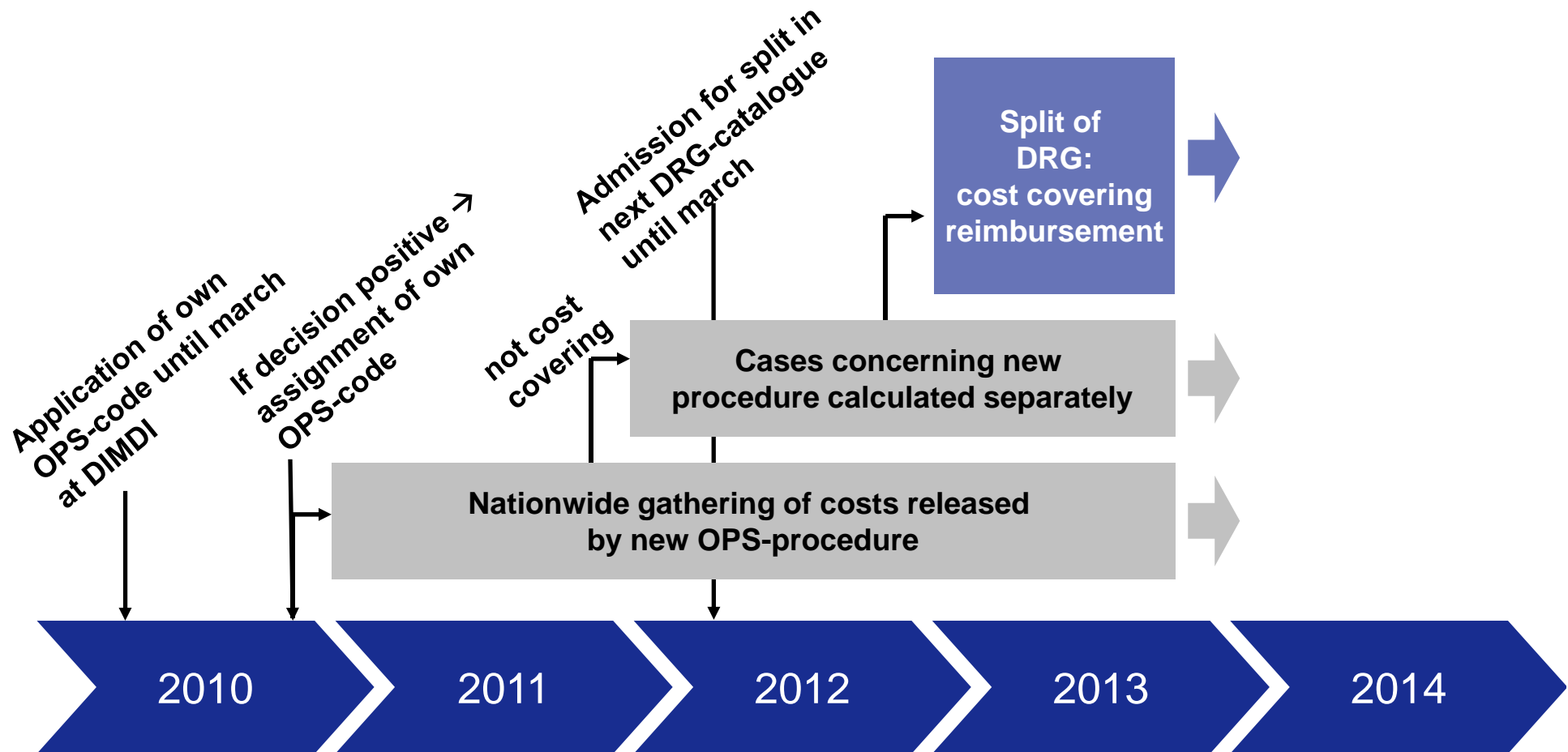


TAC: Total Average Cost

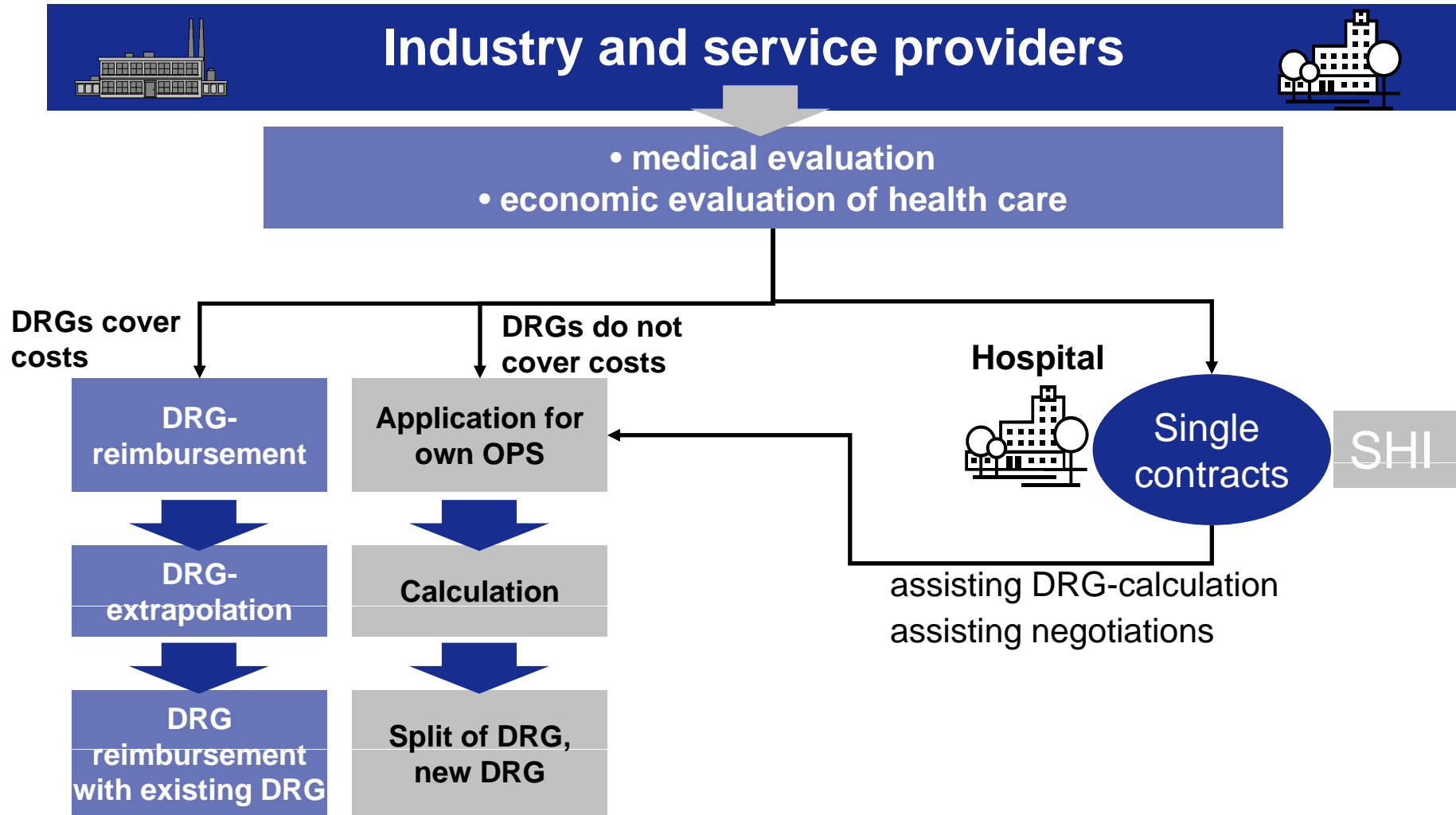
TAC': Total Average Cost
after cost containment

TAC
DRG-return
TAC'

The splitting of an existing DRG to achieve higher reimbursement for innovative medical devices takes a long time

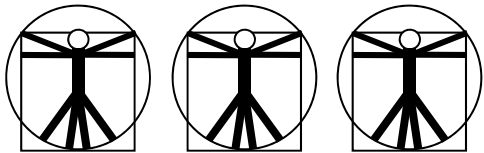


The procedure's appropriate mapping has to be analyzed – innovation clause



As an addition, it is possible to achieve reimbursement based on single contracts

Regular compulsory inpatient health care



All SHI Funds together

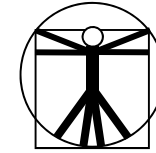


- Uniform services
- Fixed DRG reimbursement



All inpatient care providers together

Integrated health care delivery based on §§ 140 a-d Social Law



Single SHI Fund

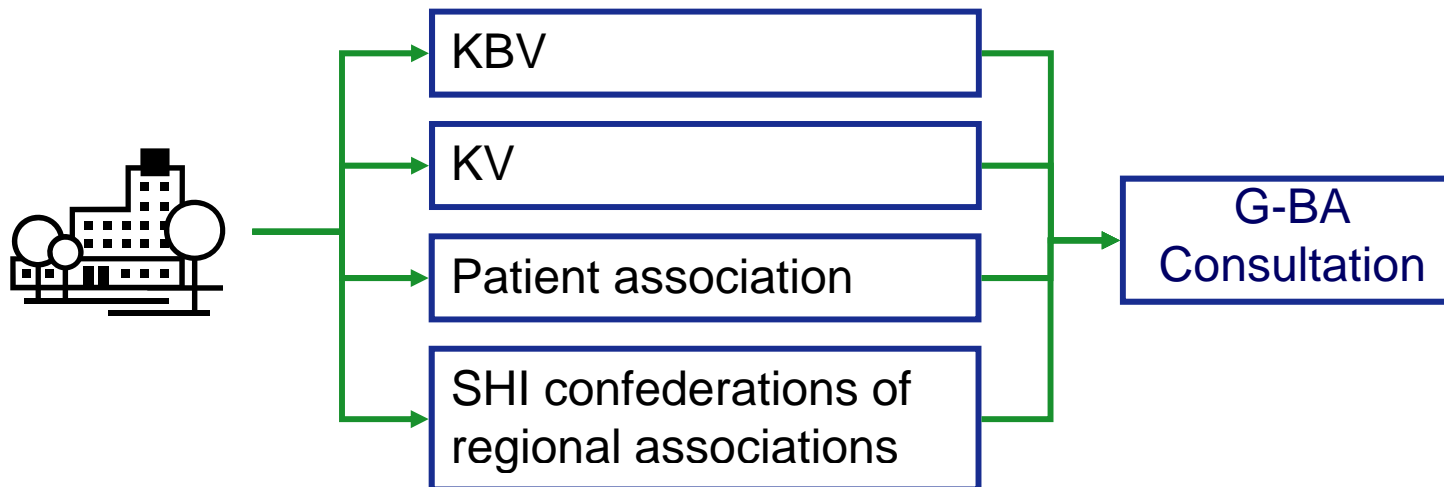


- Contracted services
- Negotiated reimbursement



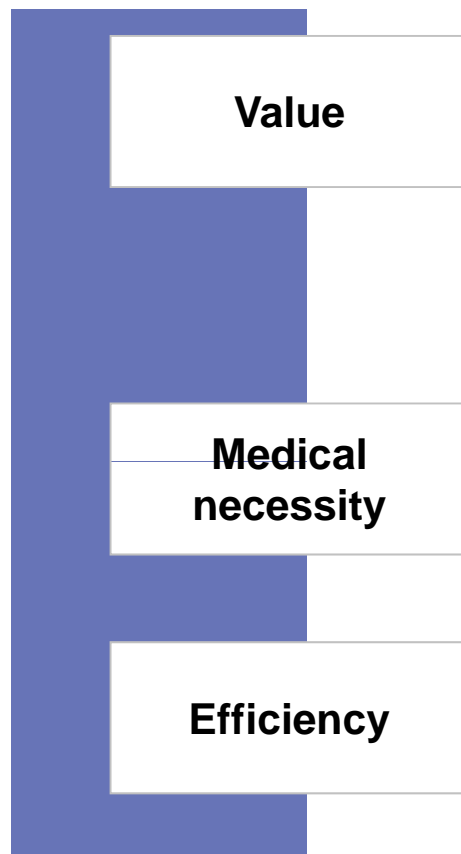
Single inpatient care provider

Before new treatment and diagnosis methods can be implemented into the EBM they have to be checked by G-BA



Applications for consultation can only be filed by KBV, KV, patient organizations with representatives among the G-BA and the SHI confederations of regional associations

The G-BA-check includes value, medical necessity and efficiency



- Proof of effectiveness concerning the indicated indications
 - Therapeutic consequence of a new diagnosis
 - Value risk proportion
 - Quantification of the desired and undesired consequences
 - Benefits in comparison with other methods with the same aims
-
- Relevance of the medical problem
 - Diagnostic and therapeutic alternatives
 - Spontaneous course of disease
-
- Cost estimate based on patients or insured
 - Cost benefit analysis based on patients or insured
 - Cost benefit analysis based on totally insured
 - Cost benefit analysis in comparison to other methods

If a method fails the g-BA-check, it will never be financed within the SHI through the EBM or through any other mechanism

Fail g-BA-check

- Method can not be financed within the SHI-system
- Even if the method is established already in hospital it is not allowed to be used for SHI-insured patients any longer
- Integrated Care contracts which used that method have to be canceled as well

pass g-BA-check

- Valuation Committee integrates the new method into the EBM
- Valuation committee consists of 7 members of the SHI confederations of regional associations and 7 members of the national association of SHI-physicians

Reimbursement issues are spread over several public institutions



GBA
*Joint commission between
providers and sickness funds*



IQWiG
*Evaluation institute
(both medical and economic)*

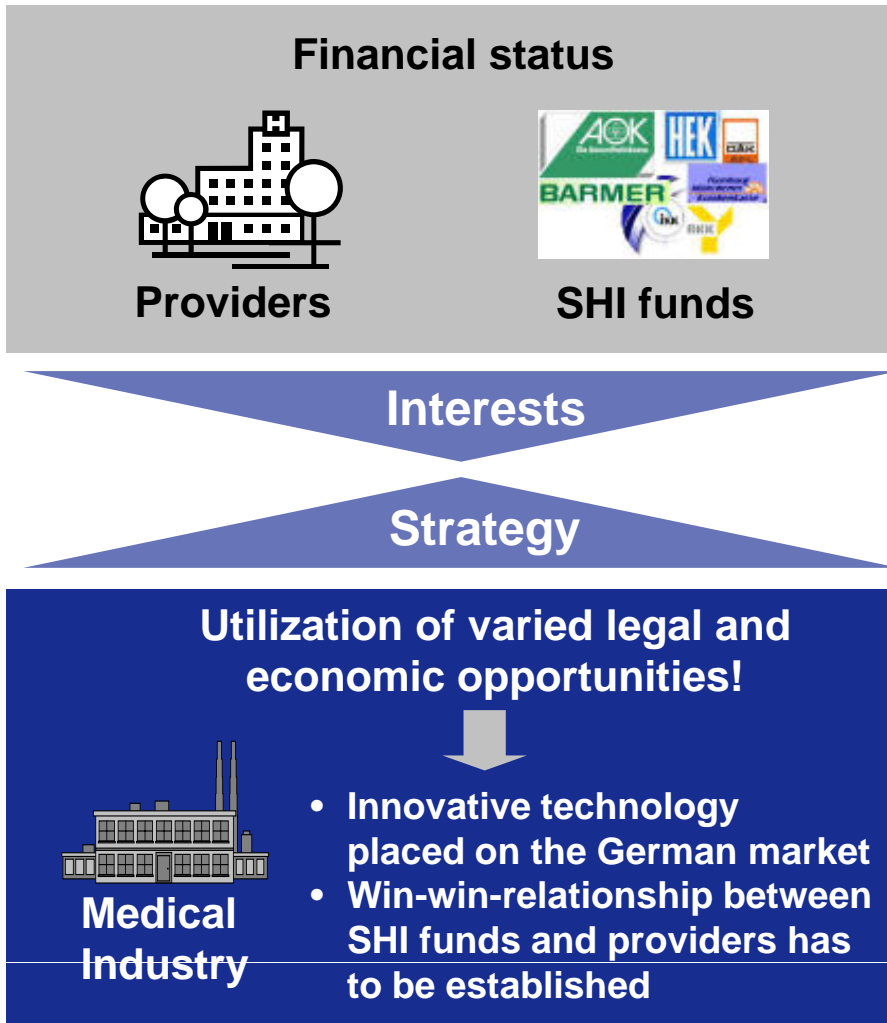


DIMDI
*Cataloguing institute
(e. g. ICD and OPS)*



InEK
*Hospital reimbursement institute
(issues DRG catalogue)*

Although to achieve reimbursement is difficult in Germany, there are opportunities to make good profits



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We help you asking the right questions ...

<p>Step 1: Medical Evaluation</p>	<ul style="list-style-type: none"> • Does the use of the new product make sense out of the medical view? • Is the use associated with good efficacy and effectiveness? • Is the new technology superior in efficacy (utility) compared to former methods and actual market leaders? • Is the products' use indicated in ambulatory health care or in hospital care? • What kind of innovation do we have? (process or product innovation)
<p>Step 2: Placement</p>	<ul style="list-style-type: none"> • Where has the new product to be placed on the market? • Which strategic considerations influence the placement? • What kind of providers are our target group? • What are the interests of customers, SHI funds, politics, self government bodies, patients and the public?
<p>Step 3: Economic Evaluation</p>	<ul style="list-style-type: none"> • Is the use of the new technology efficient and profitable? • Is the use cost-effective out of the providers' view? • Is the use cost-effective out of the SHI fund's view? • Is the new technology superior in efficiency compared to former methods and actual market leaders?

... and map out a successful strategy

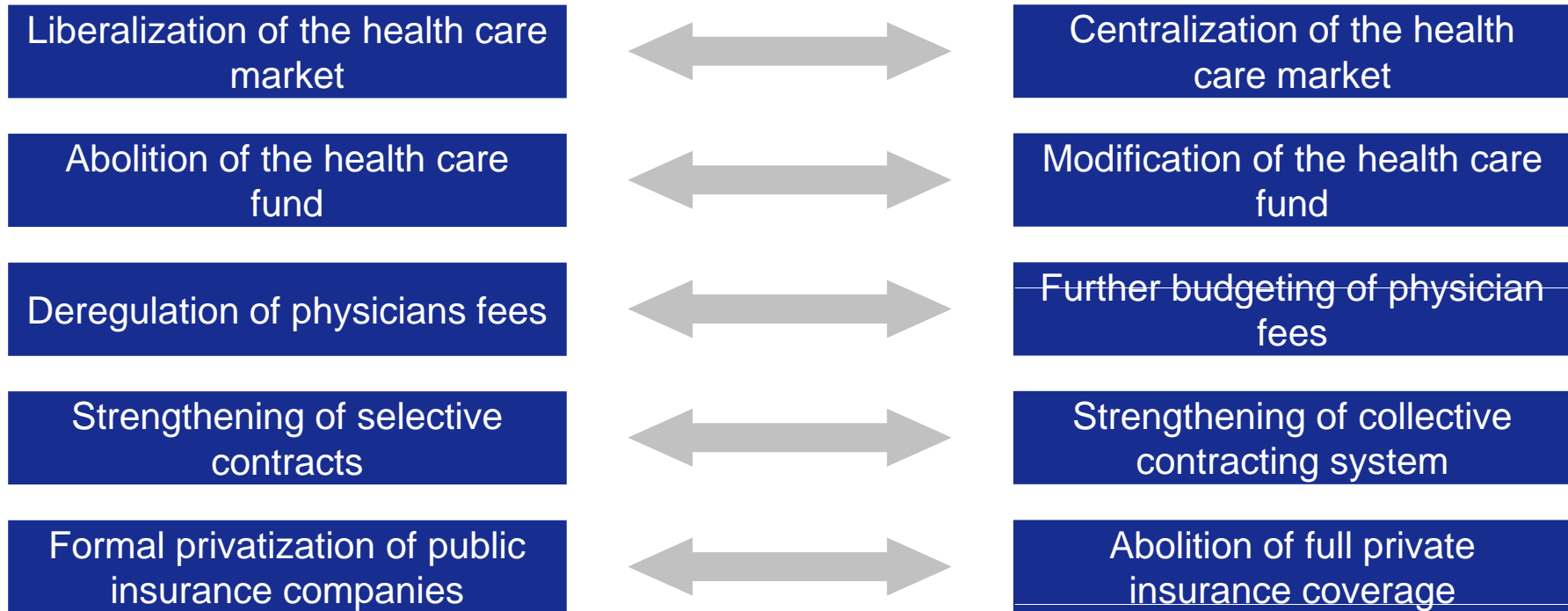
<p>Step 4: Regular reimbursement</p>	<ul style="list-style-type: none"> • What reimbursement is achieved with legal remuneration systems (for example: G-DRG-system or EBM in ambulatory health care)? • Is coding of the innovation possible? • Is correct grouping in DRGs given? • What amounts of reimbursement are achieved? • Does the reimbursement cover the costs of the method? • Should DRG splitting be aimed for?
<p>Step 5: Exceptions to regular reimbursement</p>	<ul style="list-style-type: none"> • Is the new method affected by one of the many legal exceptions? • What circumstances lead to the assumption that the innovation is affected by a legal exception? • What amount of reimbursement is achieved in that case?
<p>Step 6: Alternative forms of reimbursement</p>	<ul style="list-style-type: none"> • Should you rather embark on an alternative strategy? • What alternative reimbursement options are available? • Are there better opportunities in reimbursement with alternative forms? • Are interest groups interested in cooperation? • What reimbursement has to be achieved in other reimbursement forms (e.g. individual contracts) to have a win-win-situation for all involved groups?

Individual reimbursement strategies

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-

As CDU/CSU and FDP are in government since 2009, chances for liberalization are growing



We developed a different model of reimbursement financing to be considered by legislation

- 1 A quick entering of innovations into the remuneration system of the SHI funds is necessary
- 2 Quality requirements for care providers need to be defined
- 3 Legal security and transparency for the application process is important
- 4 Every interested person should be entitled to file an application
- 5 Obsolete procedures have to be excluded from the system of the statutory health Insurance funds
- 6 A structured transition into the system of the SHI funds needs to be guaranteed
- 7 Prices should be negotiated, not administered
- 8 The strongly segregated inpatient and outpatient sector need to be integrated

Please feel free to contact us with your reimbursement questions



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