



Consulting for the pharmaceutical industry,
medical devices and diagnostics companies

Hamburg, 2019

Reimbursement of Innovative Pharmaceuticals and Medical Devices in Germany



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Agenda

The German pharmaceutical market

Basic information on German health care system

Reimbursement of innovative drugs

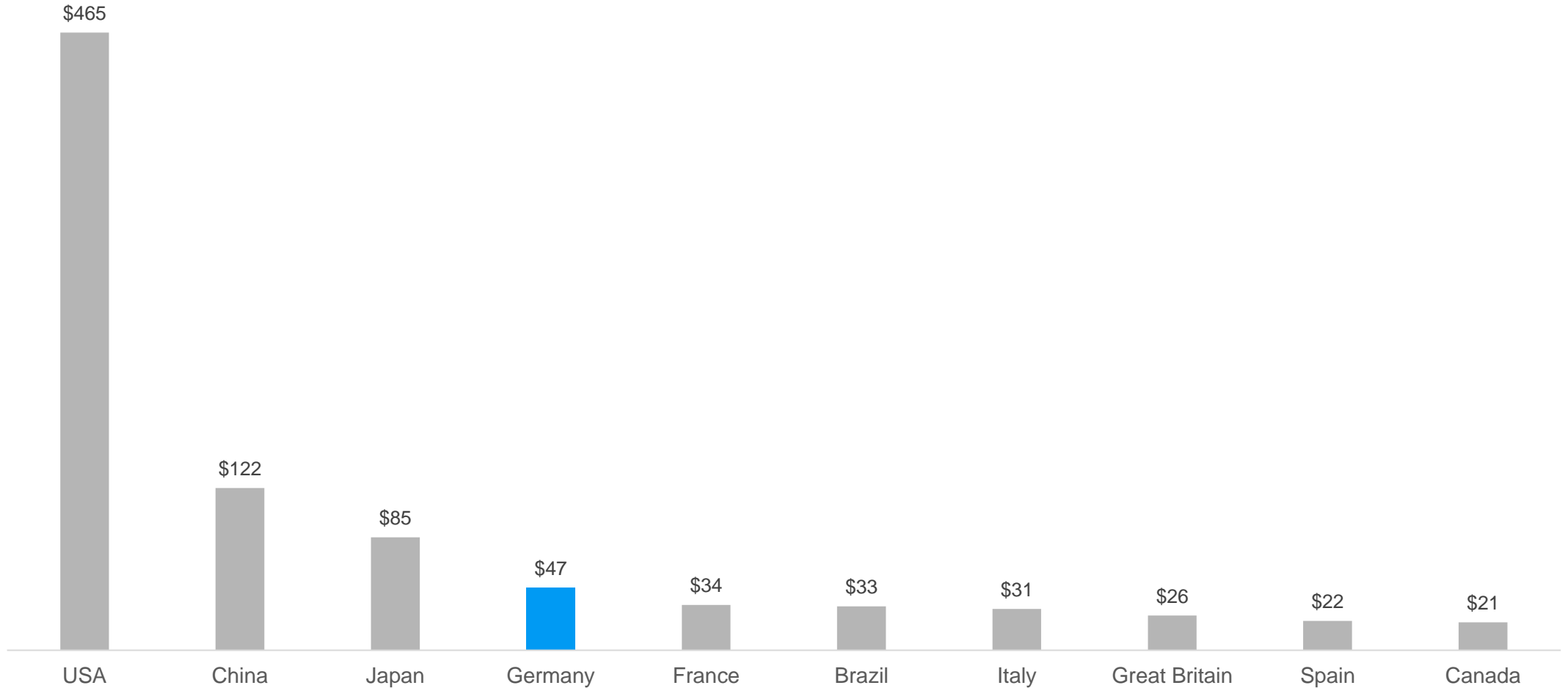
Reimbursement of innovative medical devices

How to find the best reimbursement strategy ?!



The German pharmaceutical market is the 4th largest worldwide

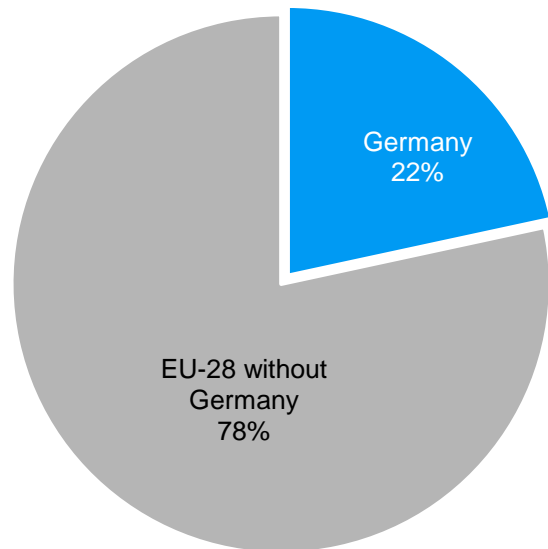
Turnover 2017 in Billion US-Dollar, TOP 10



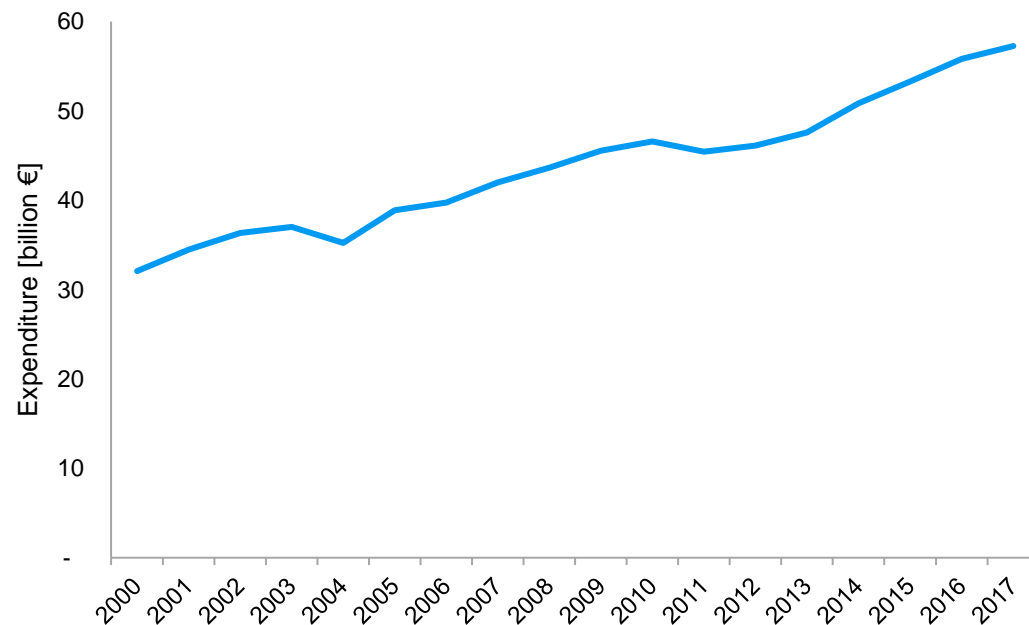


It accounts for 22% of the European pharmaceutical market ... and sales are on a high level

Turnover in % (2018), EU-28



Pharmaceutical expenditure in Germany (in Billion €)





The German health insurers have different instruments of pharmaceutical budget impact control in outpatient setting



- Price negotiated with payers (GKV-SV) based on early benefit assessment (AMNOG)
- Price set by pharmaceutical company
- Price freeze and mandatory discounts
- In case of new indication: early benefit assessment possible (“Kann-Regelung“)
- Reference pricing
- Price freeze and mandatory discounts
- Price set by pharmaceutical company
- No reimbursement by SHI (beside exception list)

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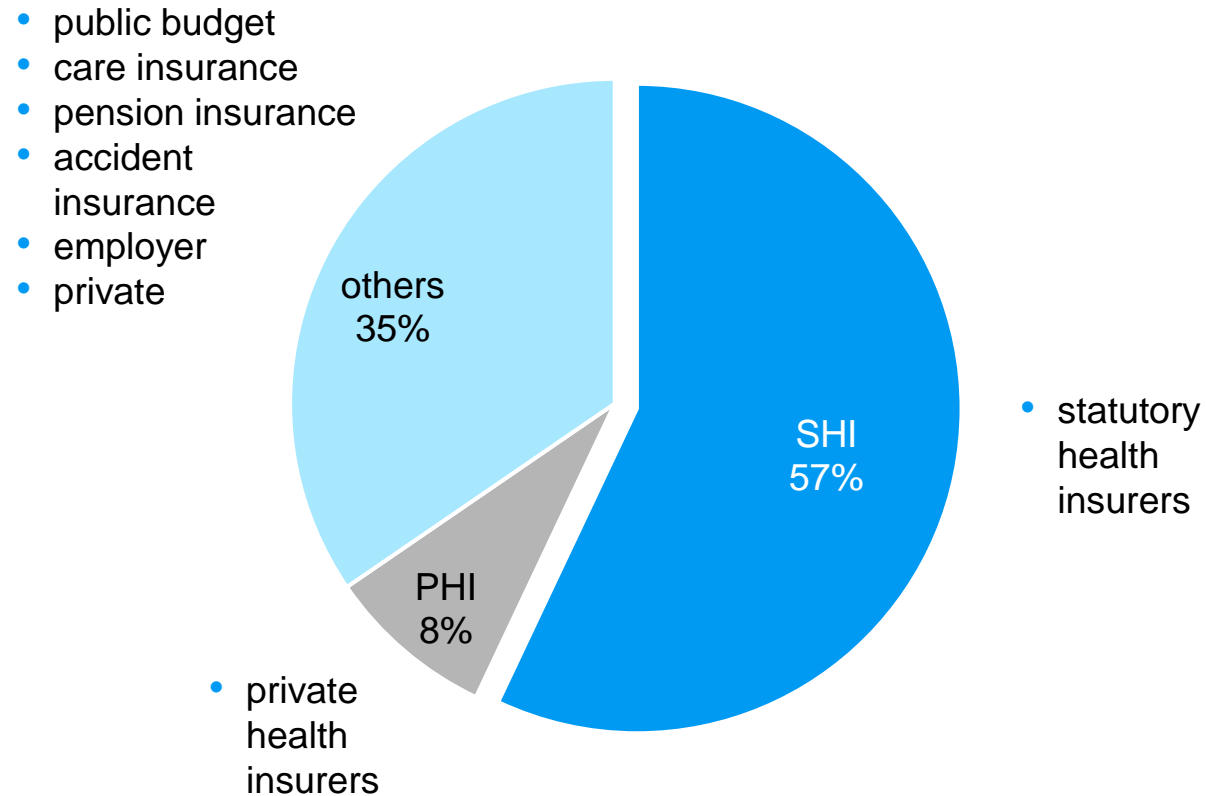
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How to find the best reimbursement strategy ?!

Healthcare in Germany is dominated by a system of statutory health insurers (SHI)

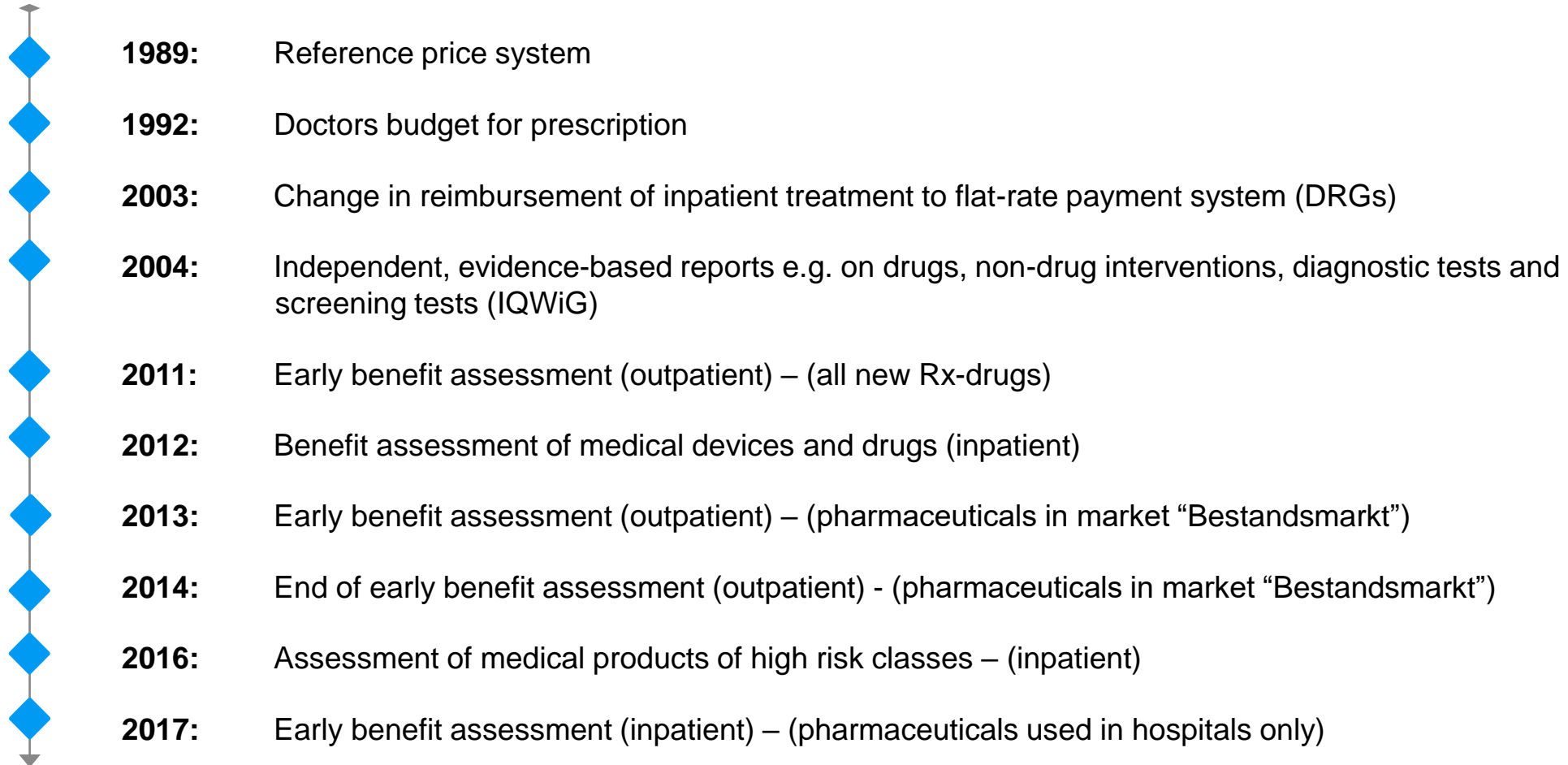
Expenditure on health in Germany 2017 (in %)





There is a trend to limit reimbursement of pharmaceuticals and medical devices

Last decade milestones





There is a handful of key institutions which define reimbursement for health care in Germany

G-BA, IQWiG, GKV-Spitzenverband, DIMDI, InEK and PKV-Verband



Federal Joint Committee

- Decides on coverage and reimbursement of most health care services in Germany (SHI only)
- Decides on early benefit assessment of innovative pharmaceuticals



Institute for Quality and Efficiency in Health Care

- Assesses the medical and economical advantages and disadvantages of pharmaceuticals on behalf of G-BA (e. g. benefit dossiers)



National Association of SHI Funds

- Price negotiations after early benefit assessment
- Decides about pharmaceutical reference prices and maximum amounts



German Institute of Medical Documentation and Information

- Cataloguing institute (e. g. ICD and OPS)
- HTA



Institute for the Hospital Remuneration System

- Implementation, further development and maintenance of the hospital payment system (DRGs)

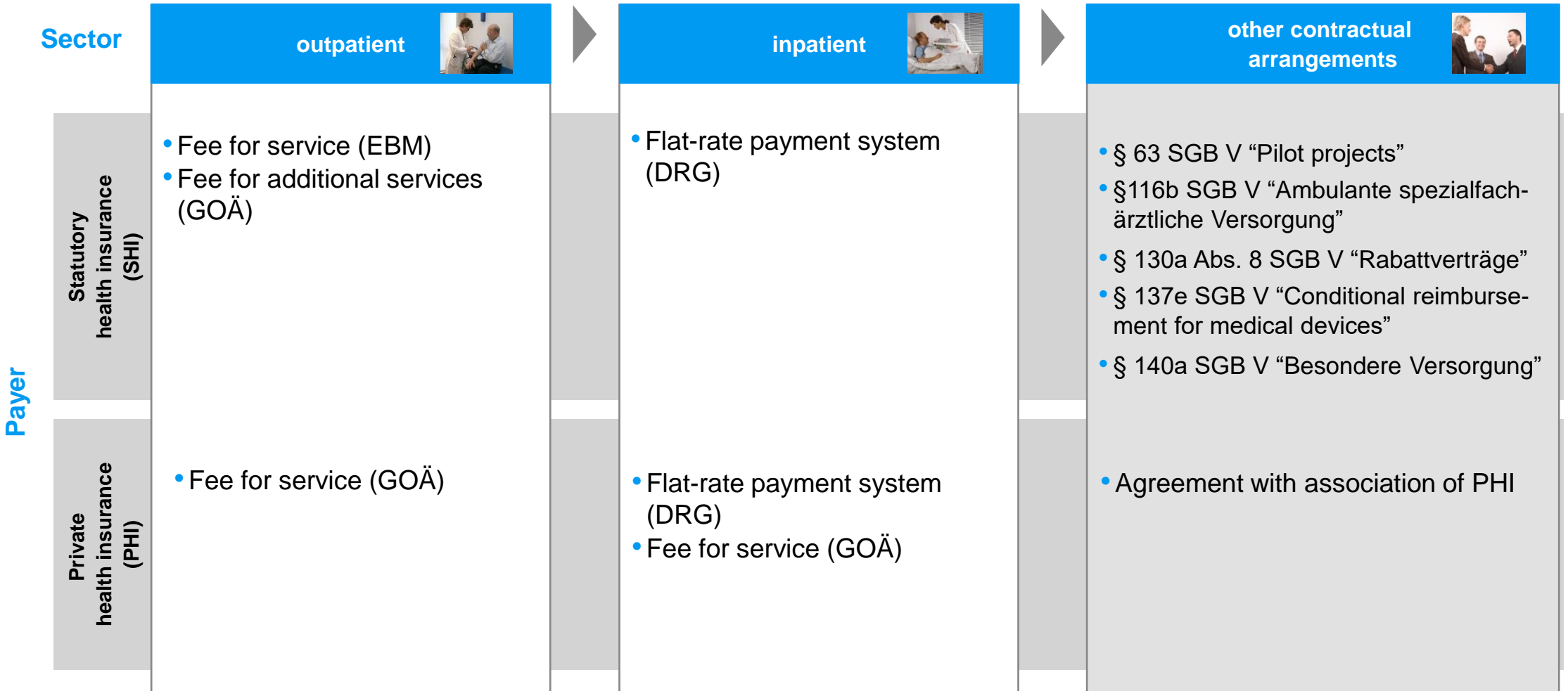


Private Health Insurance Association

- Effective lobbying (PHI only)
- Contract negotiations

Every sector and payer has its own reimbursement logic

Scheme of health care sector, market segments and payment





Outpatient reimbursement is based on a fee for service system

Outpatient

SHI: “Einheitlicher Bewertungsmaßstab“ (EBM)

- EBM is the Uniform Value Scale of the SHI for the payment of medical services
- EBM is regulated by German Social Code, Book V (SGB V) and the catalogue „EBM“ in its current version
 - Contains the catalogue of services, point value per service and time needed per service
 - Special chapter for each group of doctors

PHI: “Gebührenordnung für Ärzte“ (GOÄ)

- In Germany, doctors are not allowed to set their own prices, they have to charge in accordance with the German Medical Fee Schedule (GOÄ)
- In the GOÄ, nearly every medical service has a special number of points
- The monetary conversion factor is 0.0582873 per point

Most prescriptions are issued for outpatients, so EBM and GOÄ have an influence on prescription behaviour.



German hospital reimbursement is based on a flat-rate payment system

Inpatient

- The DRG system classifies patients into groups based on diagnosis, age, complications etc. and is mandatory for all hospitals
- For each group a flat-rate payment is defined
- There are additional payments on top of DRGs called “Zusatzentgelt“ (ZE) (e.g. dialysis and use of certain pharmaceuticals)
- In 2019, there are 1,318 different DRG codes and 214 ZE
- Reimbursement system is updated every year

Inpatient pharmaceutical pricing is nearly non-regulated but....

- no formal price regulation, but the hospital has to cover its pharmaceutical cost with the fixed reimbursement per case (with few exceptions)
- selling pharmaceuticals to hospitals for inpatient use requires a business case to buyer
- only 11% of all spendings for pharmaceuticals are in inpatient sector, but if a patient has been successfully treated with one medication, his willingness to switch is low

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How to find the best reimbursement strategy ?!

Reimbursement of innovative drugs works by early benefit assessment

Legal details of benefit assessment were defined in 2011

- Mandatory for all new pharmaceuticals (German market entry after 01.01.2011)
- „New pharmaceutical“ is defined as new active substance with existing data exclusivity
- Pharmaceutical company has to prove additional benefit (dossier needed)
- Additional benefit is assessed by IQWiG and proven by G-BA
- Price negotiation depends on the extent of additional benefit proven

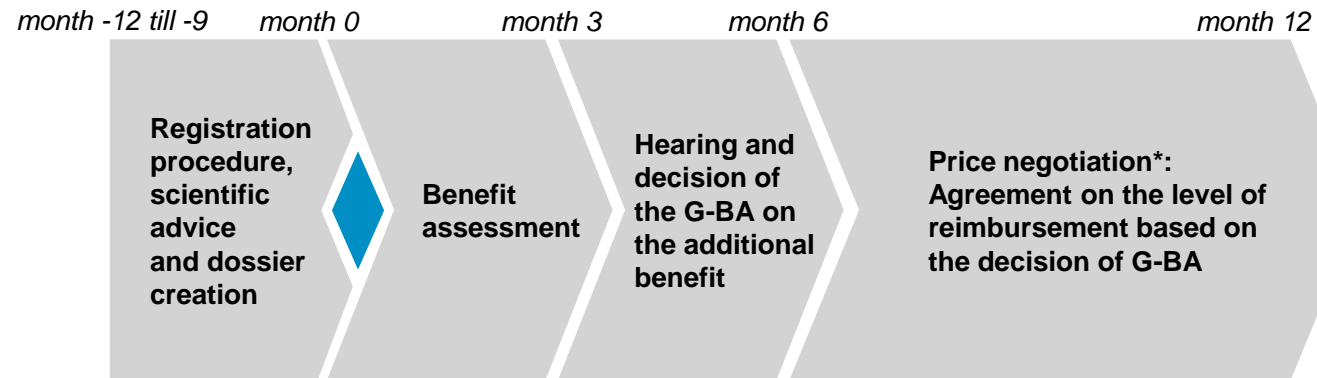
Note:

- Abbreviated assessment for orphan drugs
- Also assessment of drugs used only for inpatients (since 2017)

Early benefit assessment according to AMNOG follows clear rules

Main steps

- Overall process of benefit assessment and price negotiation takes about 12 months – plus about 12 months of preparation
- Pharmaceutical company can apply for new assessment after 12 months



* If price negotiation fails, the arbitration board makes price decision.

Basis of an early benefit assessment is the manufacturer's dossier

Manufacturers submit dossier to the Joint Federal Committee electronically.

- G-BA template for assessment dossier has unfilled 122 pages, filled up to 1000 pages!
- The dossier must be submitted at the time when a drug is first brought into German market and has to contain information on:
 1. Authorized application areas
 2. Medical benefit
 3. Medical additional benefit compared to the appropriate comparative therapy
 4. Number of patients and patient groups for which a therapeutically significant additional benefit exists
 5. Therapy costs for the SHI
 6. Requirements for a quality-assured application

New dossier template planned but not yet entered into force!

The burden of proof lies completely on the pharmaceutical company



The two most critical aspects of benefit assessment can be discussed with G-BA in advance

Scientific advice

Slicing of indication: not formalized, but 5 criteria used so far

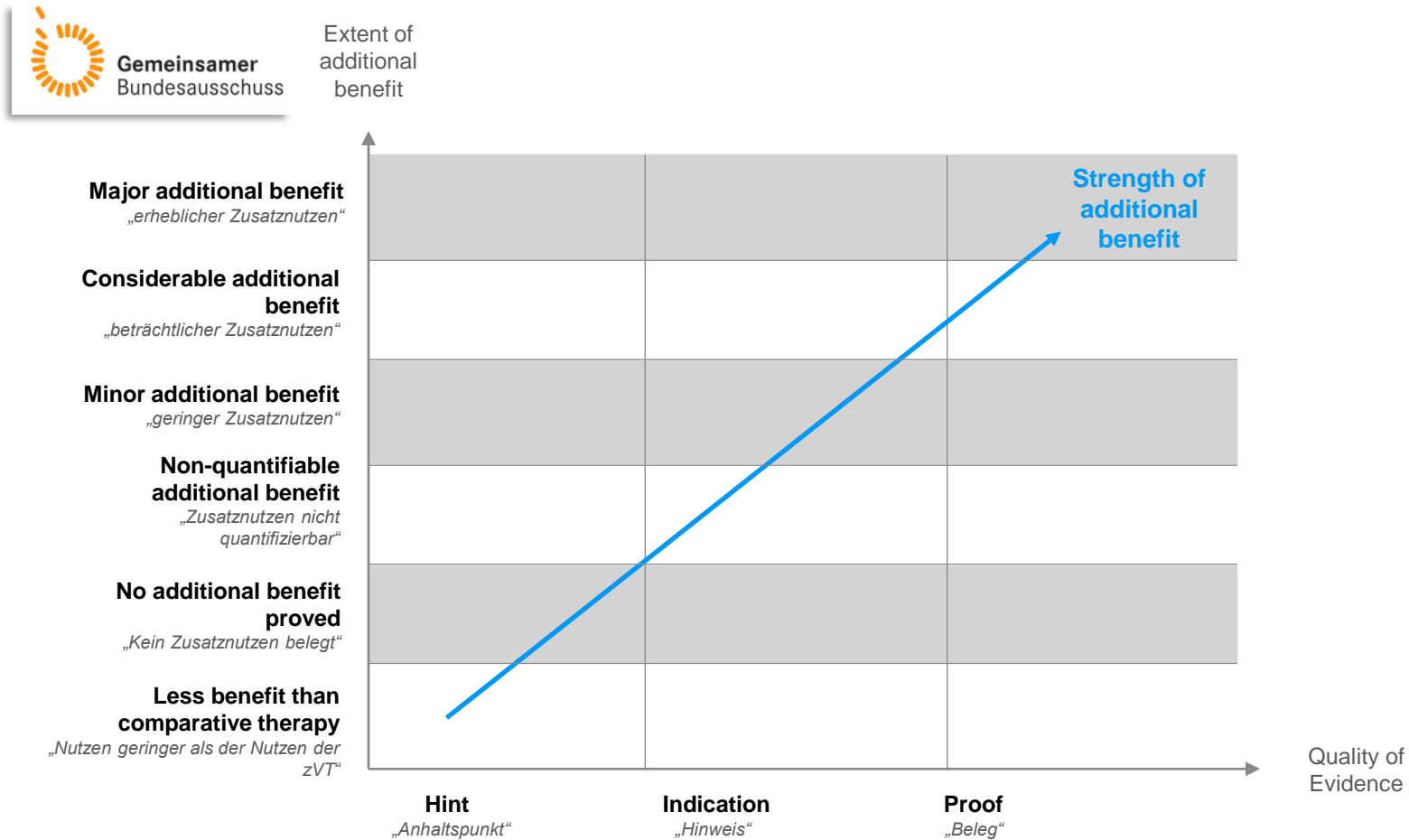
- Treatment scheme
- Naive vs. pretreated patients
- Mono vs. combination therapy
- Label comparator
- Enumeration in section 4.1 SmPC

Treatment comparator: 4 main criteria to be met

- Approved in the relevant indication(s)
- Reimbursable by SHI
- Adequate therapy according to medical standards
- Therapy attributed additional benefit to via AMNOG

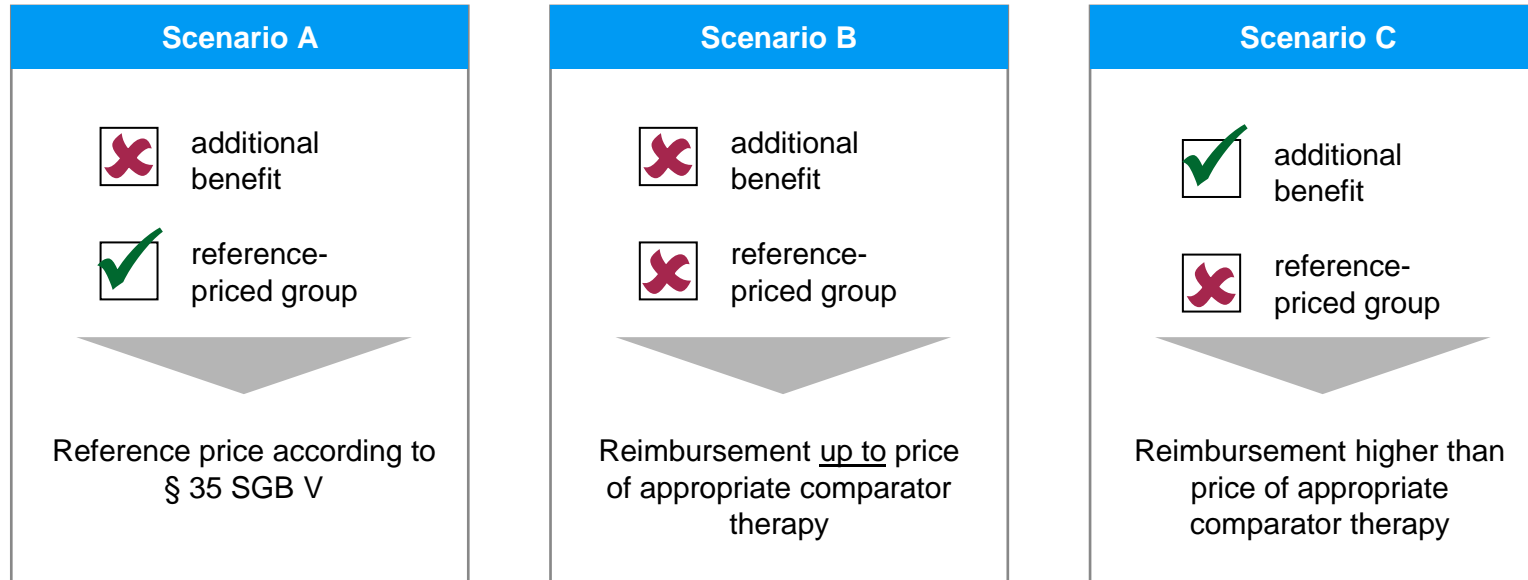
Every decision on additional benefit is made in two dimensions

Dimension of decision-making



Effective reimbursement follows benefit assessment

Additional benefit and reimbursement



- Additional benefit - Drugs with/without additional benefit in comparison to appropriate comparator therapy
- Reference-priced group - Drugs within or not within a reference-priced group

Prices and volumes are defined during negotiation with GKV-Spitzenverband

Details on reimbursement

Negotiation details

- Price negotiation with GKV-Spitzenverband can not be stopped (opt out only in the first 4 weeks)
- Negotiation is based on dossier, G-BA decision and “real-world data”
- Company has to submit the following data: treatment cost, expected volumes for their own product and relevant competitors (not only comparator)
- Company has to submit data on effective prices for their product in other European countries

Outcome:

- Negotiation is on price and volumes

Rebate details

If no inclusion in FRP group:

- Rebate will be negotiated
- Launch list price (AVP) is unchanged

Rebate level will depend on benefit evaluation:

- If additional benefit, then negotiations about mark up on appropriate comparators
- If no additional benefit, the net price to sick funds should not be higher than cost of comparative therapy

If no agreement:

- Rebate set by arbitration board

Outcome:

- Discount by rebate (list price is unchanged and rebate is negotiated on list price)
- Manufacturers provide rebate when selling the drug to wholesalers → wholesalers to pharmacies → pharmacies to sick funds



Benefit assessment has wider implications on German pricing, marketing and sales strategy

Implications

Implication 1

- Benefit assessment produces a clear statement by G-BA and IQWiG on additional benefit to comparator (available also in English). This statement will be actively used in the marketplace.

Implication 2

- G-BA has defined a new health standard for health economic analysis and definition of prices.

Implication 3

- In negotiation with SHI – group price and volume is fixed maybe at competitors' expense.

Implication 4

- Prescriber has to navigate between G-BA's decision and existing contracts with SHI.

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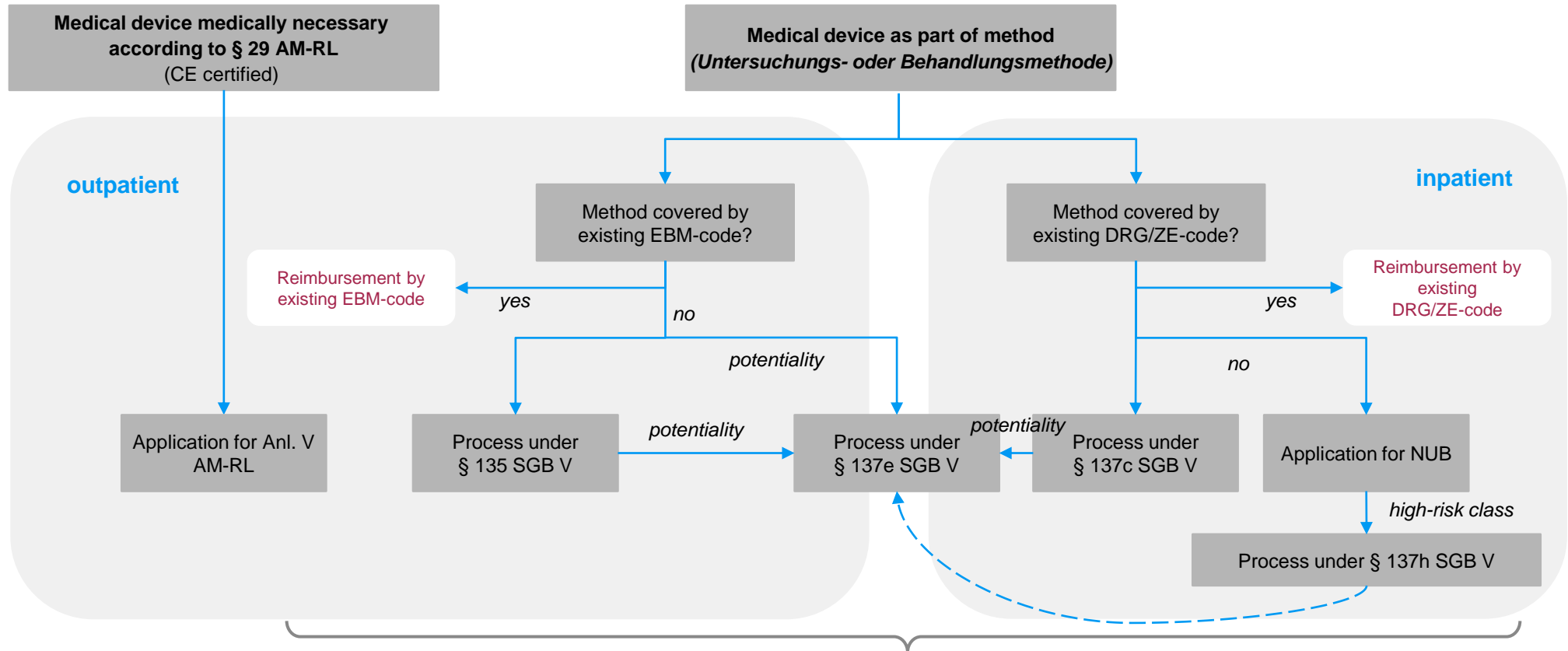
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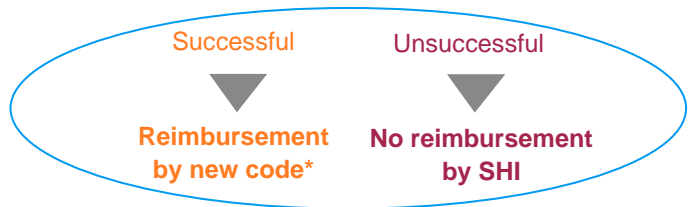
How to find the best reimbursement strategy ?!



Reimbursement of innovative medical devices is possible through different applications



*New code depending on outpatient (EBM-code) or inpatient care (DRG/ZE-code or NUB fee).
 EBM: Einheitlicher Bewertungsmaßstab; ZE: Zusatzentgelt; NUB: Neue Untersuchungs- und Behandlungsmethoden; SGB V: fünftes Sozialgesetzbuch, AM-RL Arzneimittel-Richtlinie
 Sources: G-BA, Bundesverband Medizintechnologie e. V., and Ecker + Ecker GmbH



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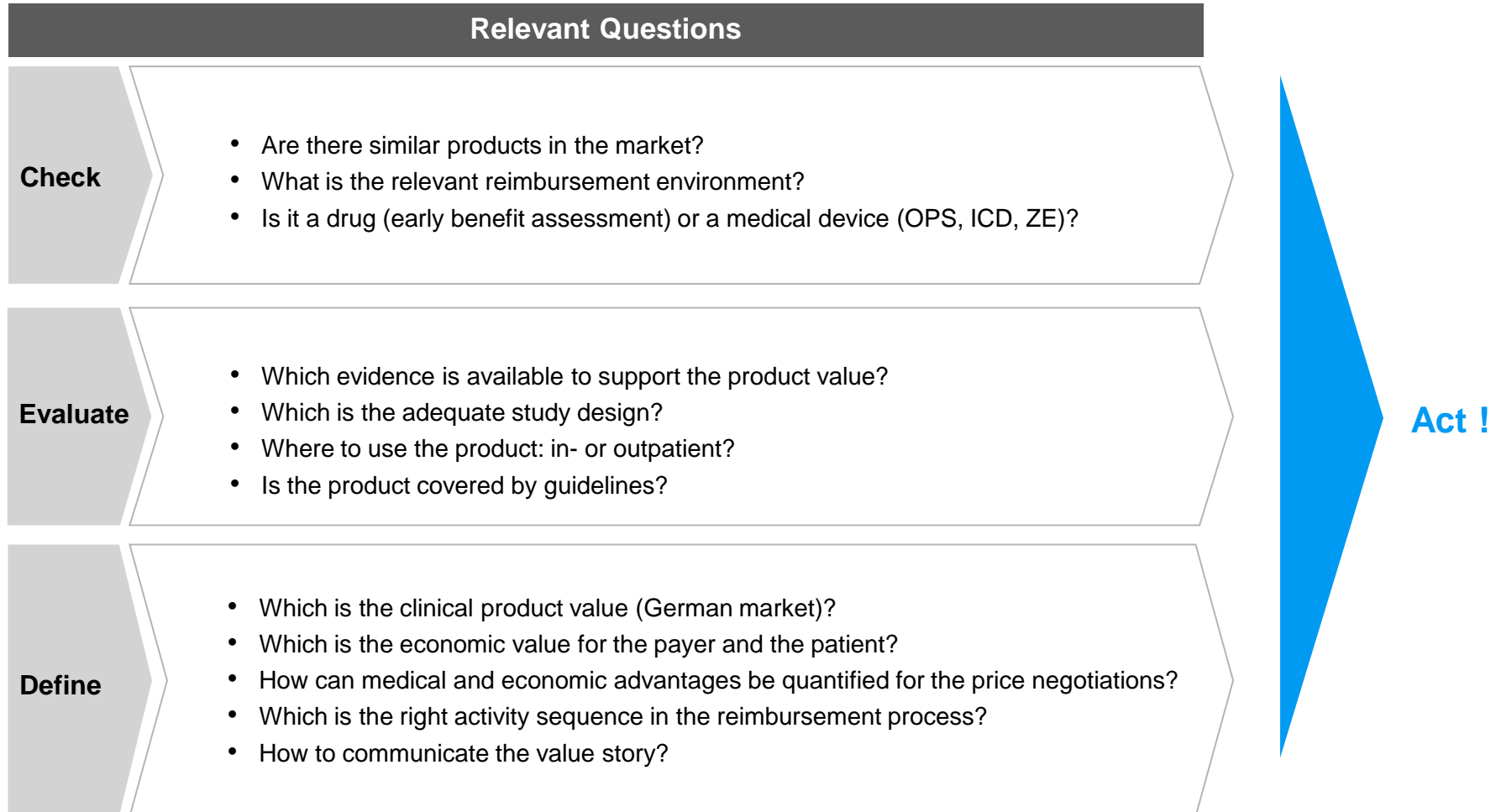
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How to find the best reimbursement strategy ?!



Check reimbursement situation for your innovative products and define strategy

Key questions





Consulting for the pharmaceutical industry,
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Thank you for your attention!