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Consulting for the pharmaceutical industry,
medical devices and diagnostics companies

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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

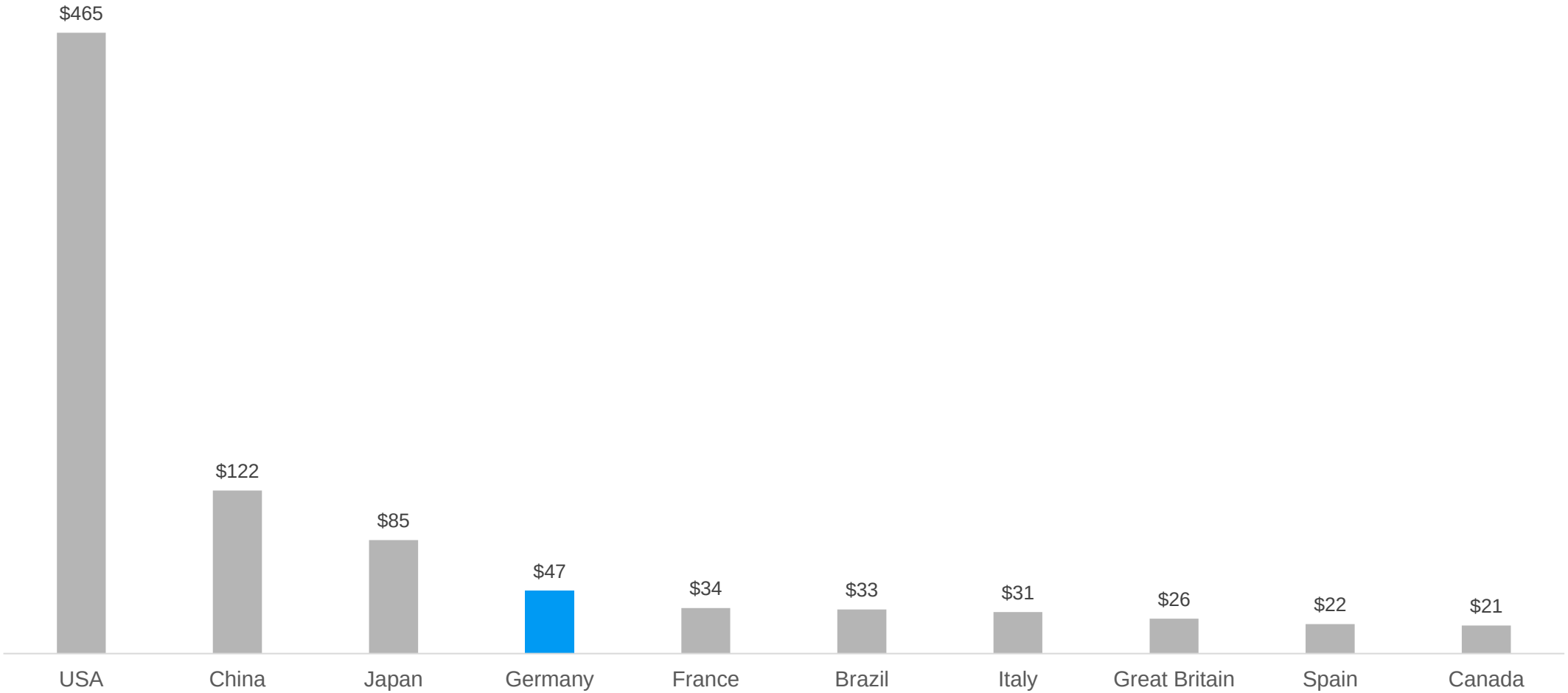
Reimbursement of innovative medical devices

Reimbursement of digital health applications (DiGA)

How to find the best reimbursement strategy ?!

The German pharmaceutical market is the 4th largest worldwide

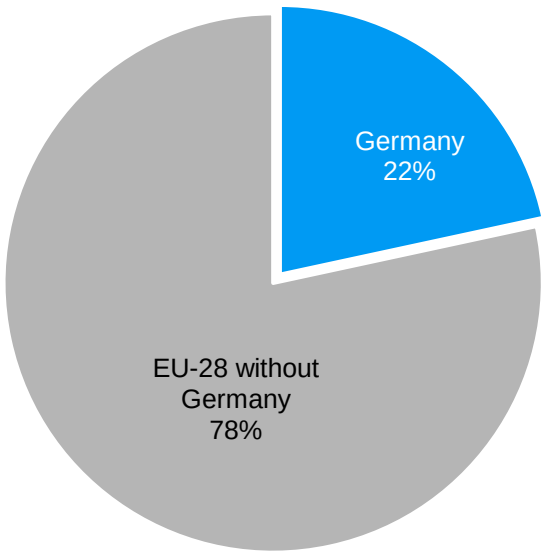
Turnover 2017 in billion U.S. dollars, TOP 10



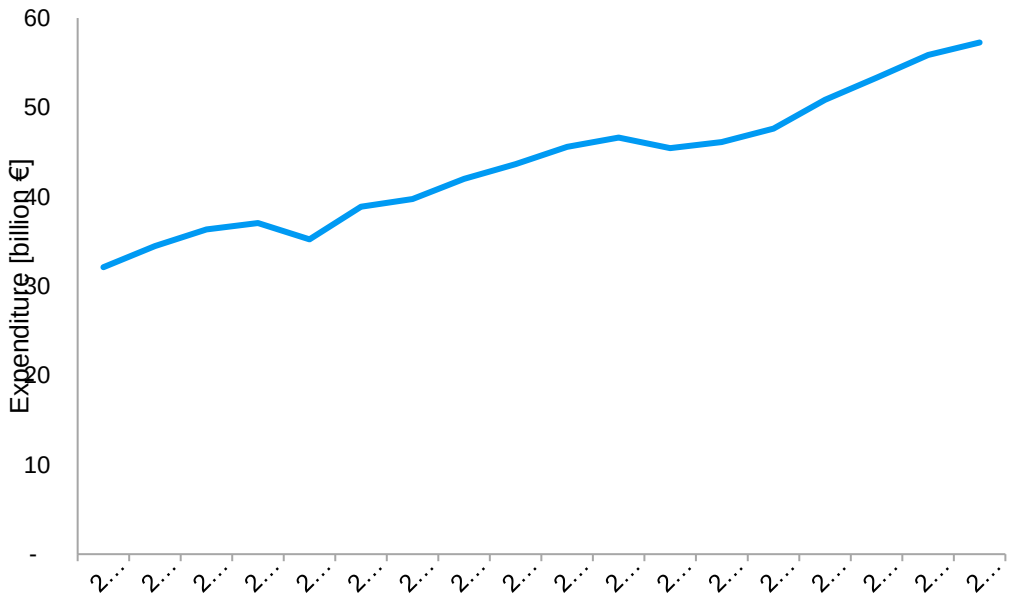
Source: BPI (2018), based on World Review Analyst 2018 (IQVIA)

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 €)



Sources: BPI (2018), based on World Review Analyst 2018 (IQVIA) and Statistisches Bundesamt 2017

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

New patented products

- Price negotiated with payers (GKV-SV) based on early benefit assessment (AMNOG)

„Old“ patented products*

- Price set by pharmaceutical company
- Price freeze and mandatory discounts
- In case of new indication: early benefit assessment possible (“Kann-Regelung“)

Generic Products
(and some „old“ patented)

- Reference pricing
- Price freeze and mandatory discounts

OTC products

- Price set by pharmaceutical company
- No reimbursement by SHI (beside exception list)

* launched before 2011
GKV-SV – National Association of Statutory Health Insurance Funds, SHI – statutory health insurance
Source: Ecker + Ecker GmbH

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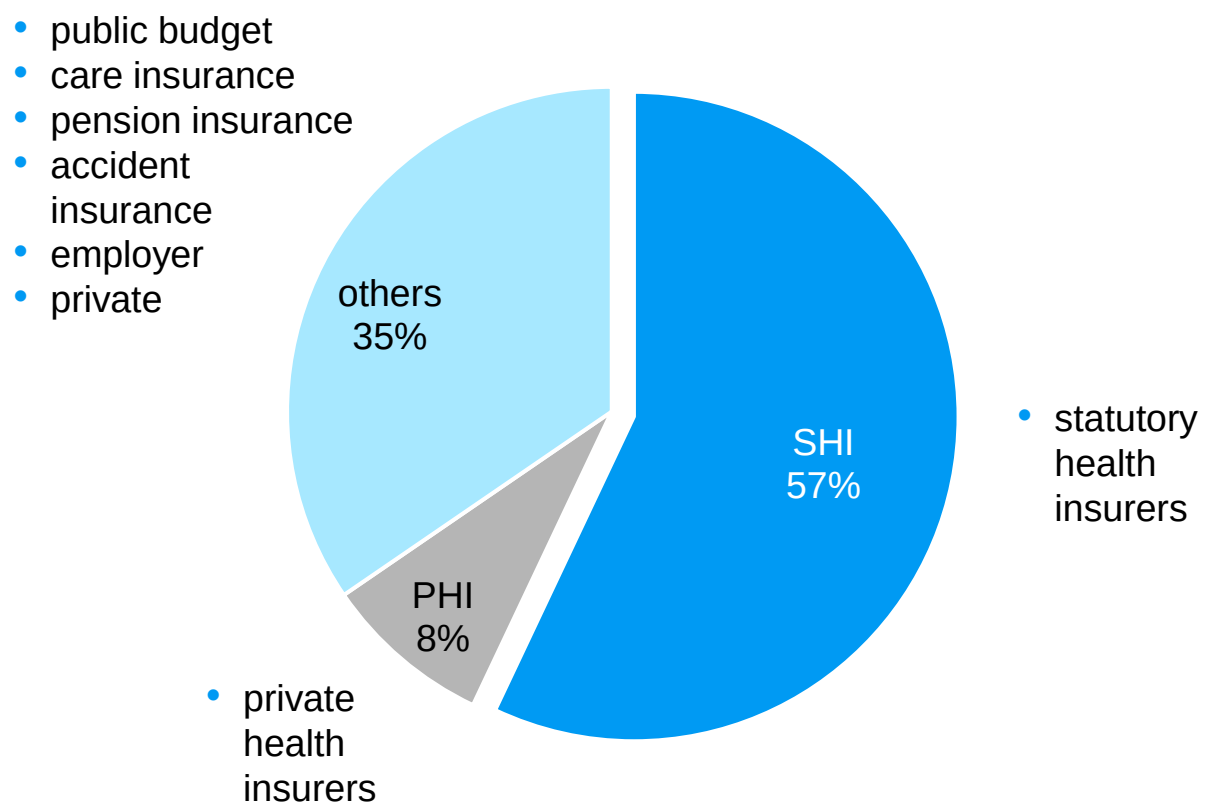
Healthcare in Germany is dominated by a system of statutory health insurers (SHI)

Expenditure on health in Germany 2018 in %



PHI – private health insurers
Source: Statistisches Bundesamt (2020)

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

Last decade milestones

1989: Reference price system

1992: Doctors budget for prescription

2003: Change in reimbursement of inpatient treatment to flat-rate payment system (DRGs)

2004: Independent, evidence-based reports e.g. on drugs, non-drug interventions, diagnostic tests and screening tests (IQWiG)

2011: Early benefit assessment (outpatient) – (all new Rx-drugs)

2012: Benefit assessment of medical devices and drugs (inpatient)

2013: Early benefit assessment (outpatient) – (pharmaceuticals in market “Bestandsmarkt”)

2014: End of early benefit assessment (outpatient) - (pharmaceuticals in market “Bestandsmarkt”)

2016: Assessment of medical products of high risk classes – (inpatient)

2017: Early benefit assessment (inpatient) – (pharmaceuticals used in hospitals only)

2019: Reimbursement of digital health applications (DiGA)

DRG – diagnosis related groups, Rx - only available by prescription
Source: Ecker + Ecker GmbH

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

- Participates in price negotiations after early benefit assessment
- Decides on pharmaceutical reference prices and maximum amounts

German Institute of Medical Documentation and **Information** and **Federal Institute for Drugs and Medical Devices**

- Institutes are joint since 2020
- Cataloguing institute (e. g. ICD and OPS)
- HTA
- Assessment procedure for digital health applications

Institute for the Hospital Remuneration System

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

Private Health Insurance Association

- Effective lobbying (PHI only)
- Contract negotiations

ICD – international classification of diseases, OPS – German procedure classification, HTA – health technology assessment
DiGA – Digital Health Applications
Source: Ecker + Ecker GmbH

Every sector and payer has its own reimbursement logic

Reimbursement by care sector and payer

Payer \ Sector	outpatient 	inpatient 	other contractual arrangements 
Statutory health insurance (SHI)	• Fee for service (EBM) • Fee for additional services (GOÄ)	• Flat-rate payment system (DRG)	• § 63 SGB V “Pilot projects” • §116b SGB V “Ambulante spezialfach-ärztliche Versorgung” • § 130a Abs. 8 SGB V “Rabattverträge” • § 137e SGB V “Conditional reimburse-ment for medical devices” • § 140a SGB V “Besondere Versorgung”
Private health insurance (PHI)	• Fee for service (GOÄ)	• Flat-rate payment system (DRG) • Fee for service (GOÄ)	• Agreement with association of PHI

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 values for each service and time needed per service
  - Separate chapter for each speciality 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 is assigned a certain 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 homogeneous groups based on diagnosis, procedures, 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 2021, there are 1,285 different DRG codes and 226 ZE
- Reimbursement system is updated on a yearly basis

Inpatient pharmaceutical pricing is almost unregulated 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 on pharmaceuticals arise in the inpatient sector. Yet, if a patient has been successfully treated with a certain medication, his willingness to switch is low

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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

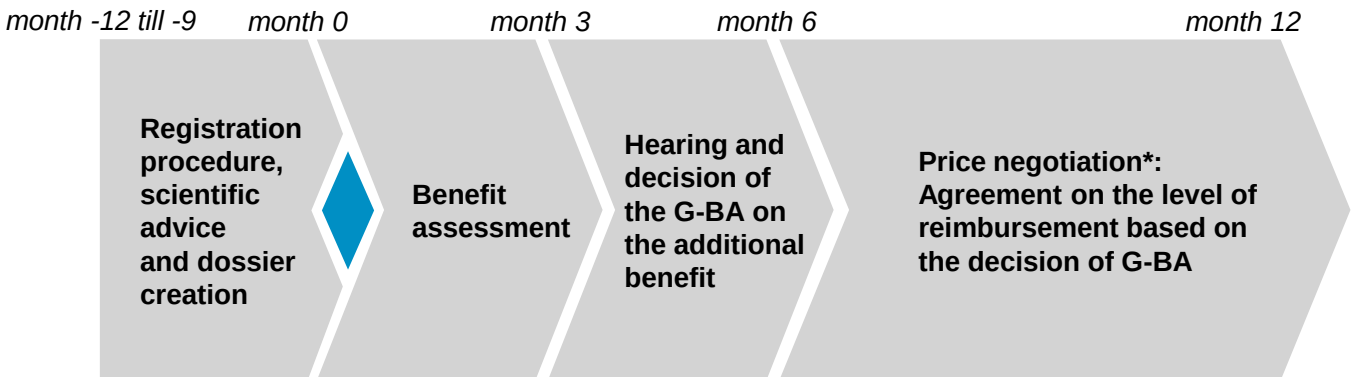
Note:

- Abbreviated assessment for orphan drugs
- Also assessment of drugs used only in the inpatient sector (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 abitration board makes price decision.

Sources: SGB V, Verfahrensordnung G-BA and Rahmenvereinbarung zu § 130b Abs. 9 SGB V

The manufacturer’s dossier constitutes the basis for early benefit assessment

Manufacturers submit dossier to the Joint Federal Committee electronically.

- G-BA template for assessment dossier has unfilled 122 pages, filled up to 1000 pages!

New dossier template planned but not yet entered into force!

- 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

The burden of proof lies completely on the pharmaceutical company

Sources: § 35a SGB V and Ecker + Ecker GmbH

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

Scientific advice

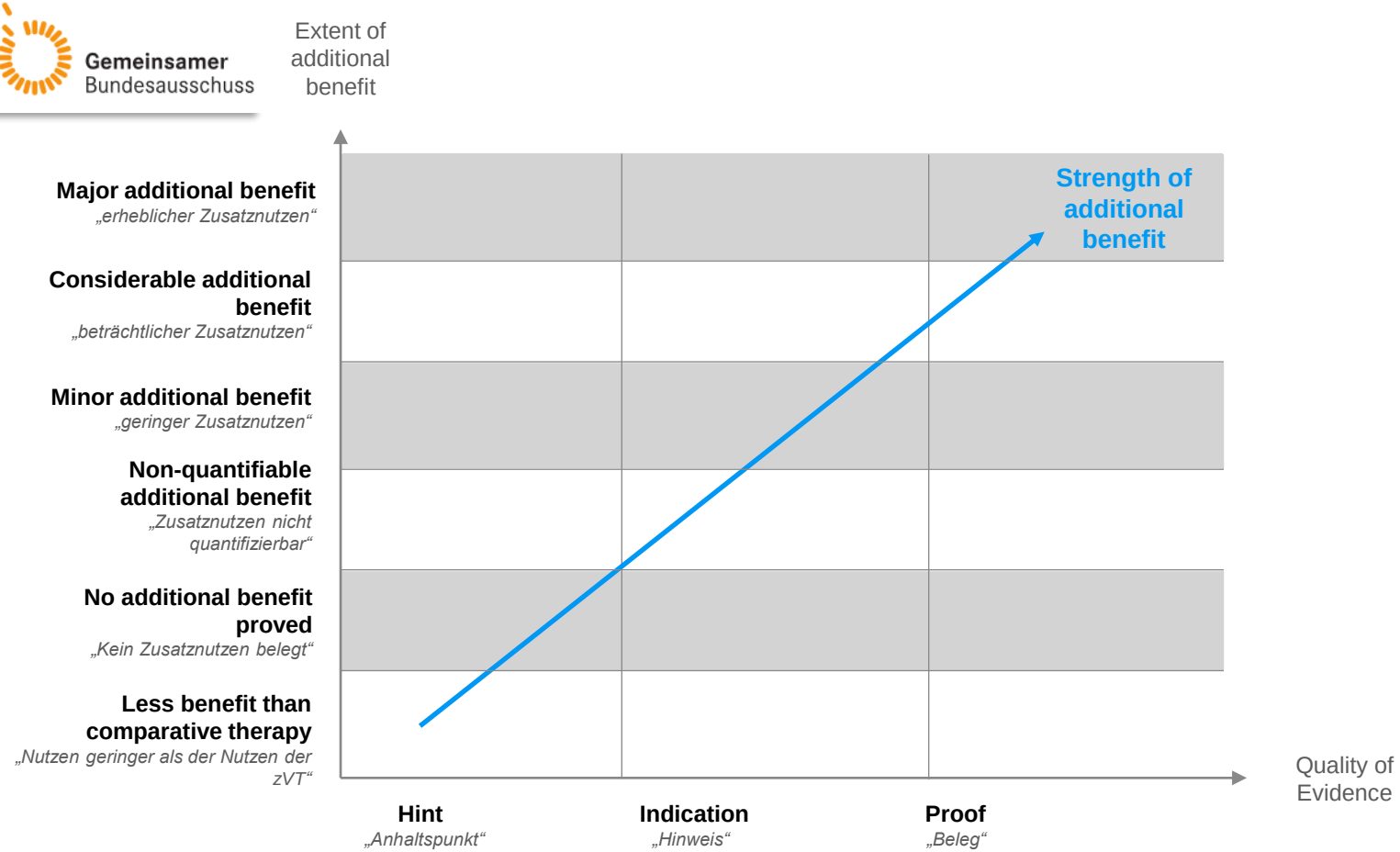
Slicing of indication: not formalized, but 5 criteria used so far
• Treatment scheme • Naive vs. pretreated patients • Mono vs. combination therapy • Label comparator • Enumeration in section 4.1 SmPC

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

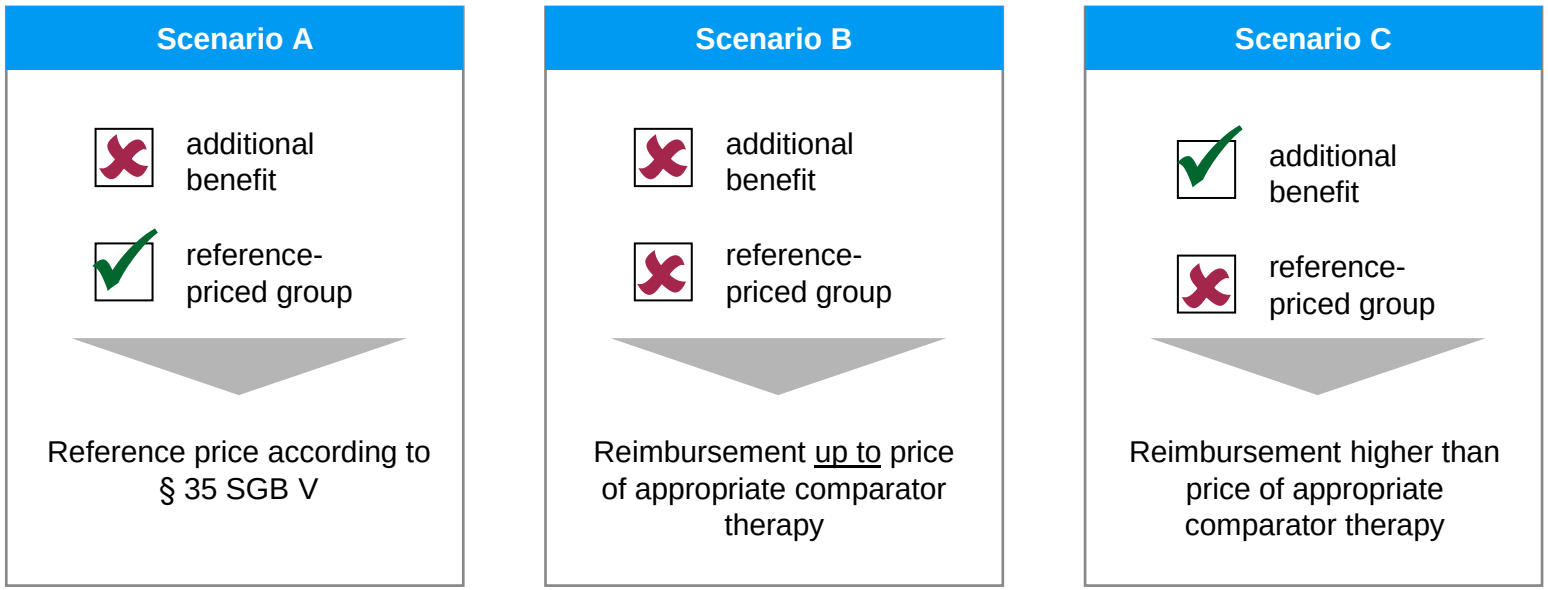
Gemeinsamer Bundesausschuss



zVT: Zweckmäßige Vergleichstherapie (engl.: appropriate comparator)
Sources: Verfahrensordnung G-BA and Ecker + Ecker GmbH

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

Sources: Rahmenvereinbarung zu § 130b Abs. 9 SGB V and Ecker + Ecker GmbH

Prices and volumes are defined during negotiation with GKV-Spitzenverband

Details on the reimbursement process

Negotiation details

- Price negotiations with GKV-Spitzenverband can not be abandoned (opt out only during 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 appropriate comparator)
- Company has to submit data on effective prices for their product in other European countries

Outcome:

- Price and volumes are subject to negotiation

Rebate details

If no inclusion in FRP group:

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

Rebate level will depend on benefit evaluation:

- If additional benefit is proven, negotiations about mark up on appropriate comparators
- If additional benefit is not proven, the net price to sickness funds should not be higher than the cost of the comparative therapy

If no agreement:

- Rebate is set by arbitration board

Outcome:

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

FRP – Fixed reference price, AVP – pharmacy retail price
Sources: Rahmenvereinbarung zu § 130b Abs. 9 SGB V and Ecker + Ecker GmbH

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.

Source: Ecker + Ecker GmbH

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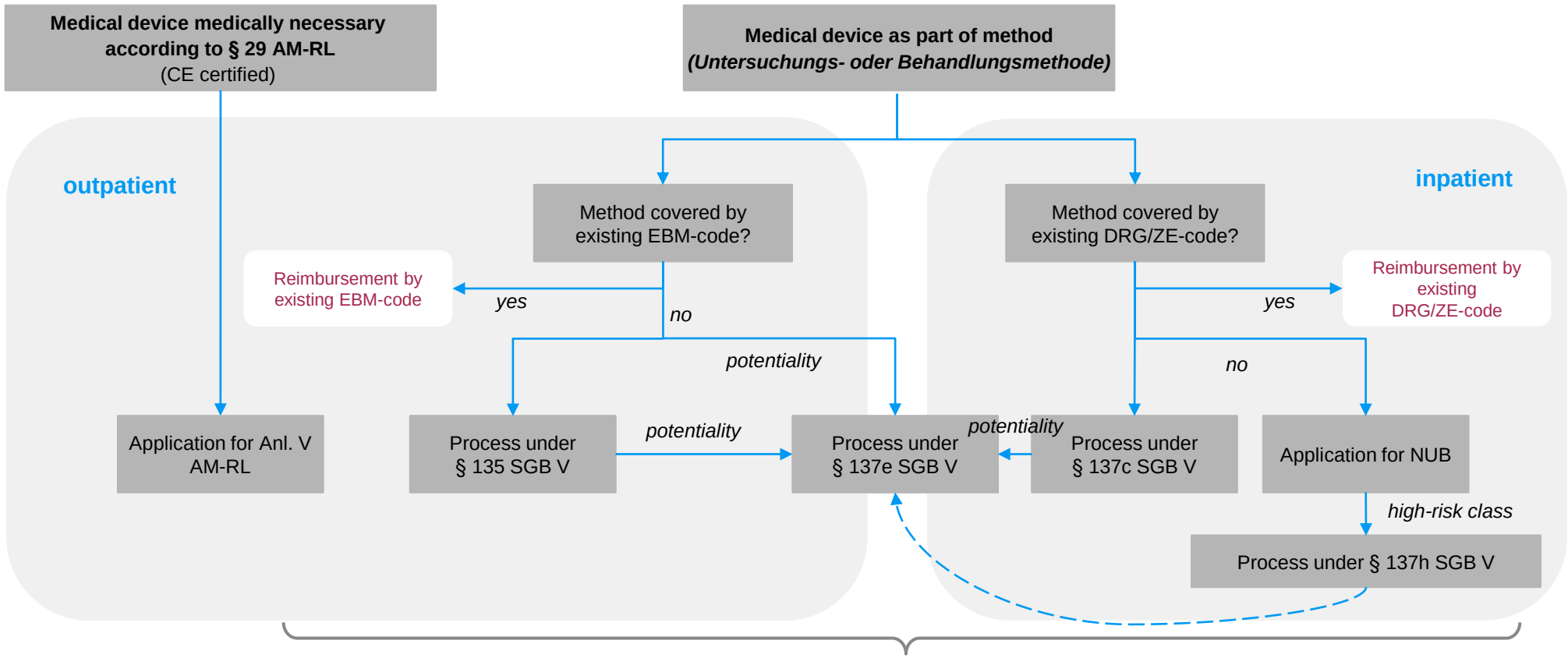
Reimbursement of innovative medical devices is possible through different applications



*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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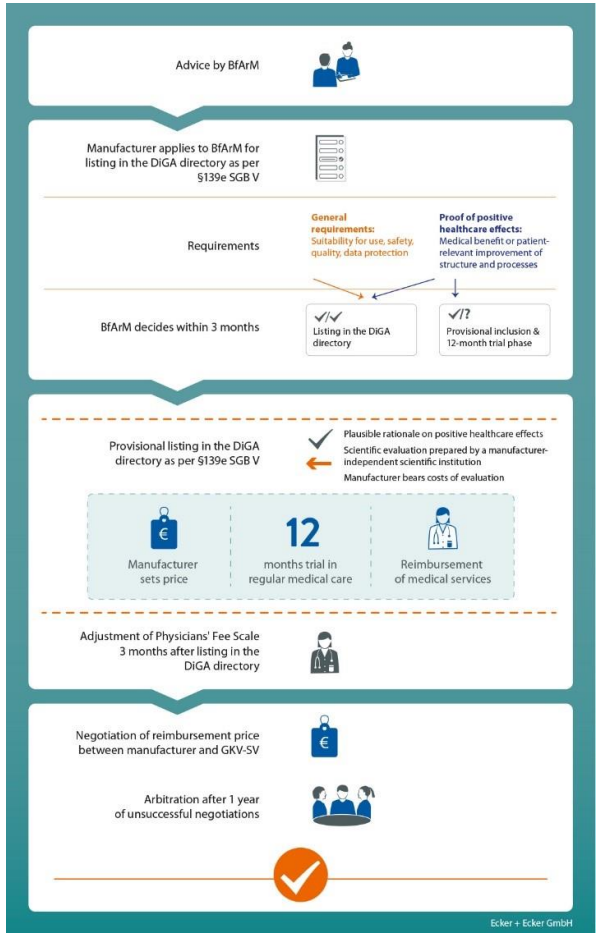
By the Digital Healthcare Act the reimbursement of digital health applications (DiGA) by the German statutory health insurance is possible

- DiGA may only be prescribed at the expense of statutory health insurance (SHI), if they are listed in the DiGA directory
- In order to be listed in the DiGA directory, the manufacturer has to officially apply to the Federal Institute for Drugs and Medical Devices (BfArM)
- Requirements to be assessed:
  - Safety, suitability for use, quality data protection and data security
  - Evidence for positive healthcare effects
  - Manufactures can apply for provisional inclusion, if evidence for positive healthcare effects has not been gathered yet
- After listing in the DiGA directory:
  - DiGA is reimbursed based on the actual price of manufacturer for 12 months
  - Within the first year manufacturer and SHI negotiate remuneration sum



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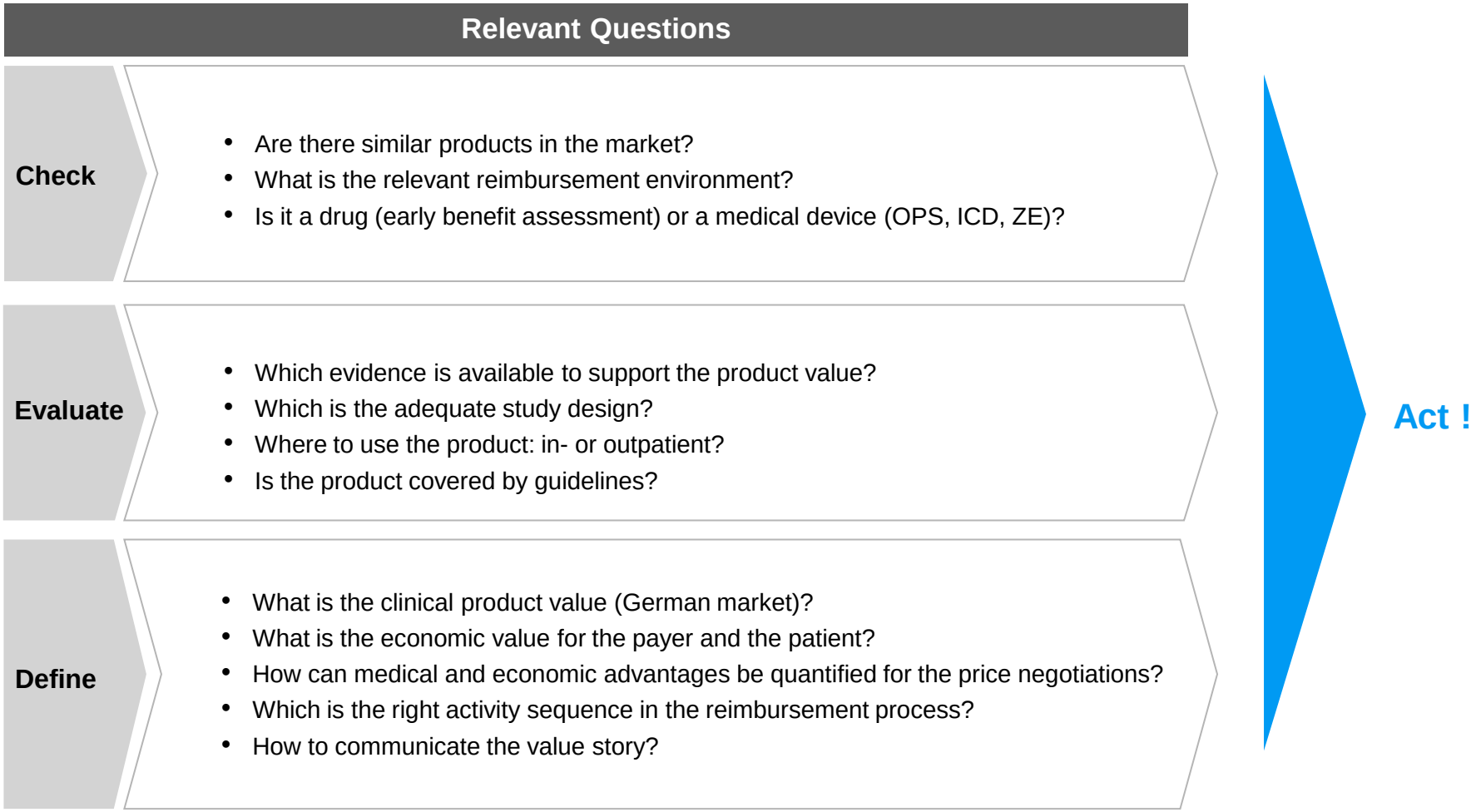
Check reimbursement situation for your innovative products and define strategy

Key questions



Source: Ecker + Ecker GmbH

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Thank your for your attention!