GTAI GERMANY TRADE & INVEST

MEDICAL DEVICE MARKET ACCESS IN GERMANY

BEST PRACTICES, REGULATORY, AND REIMBURSEMENT UPDATE

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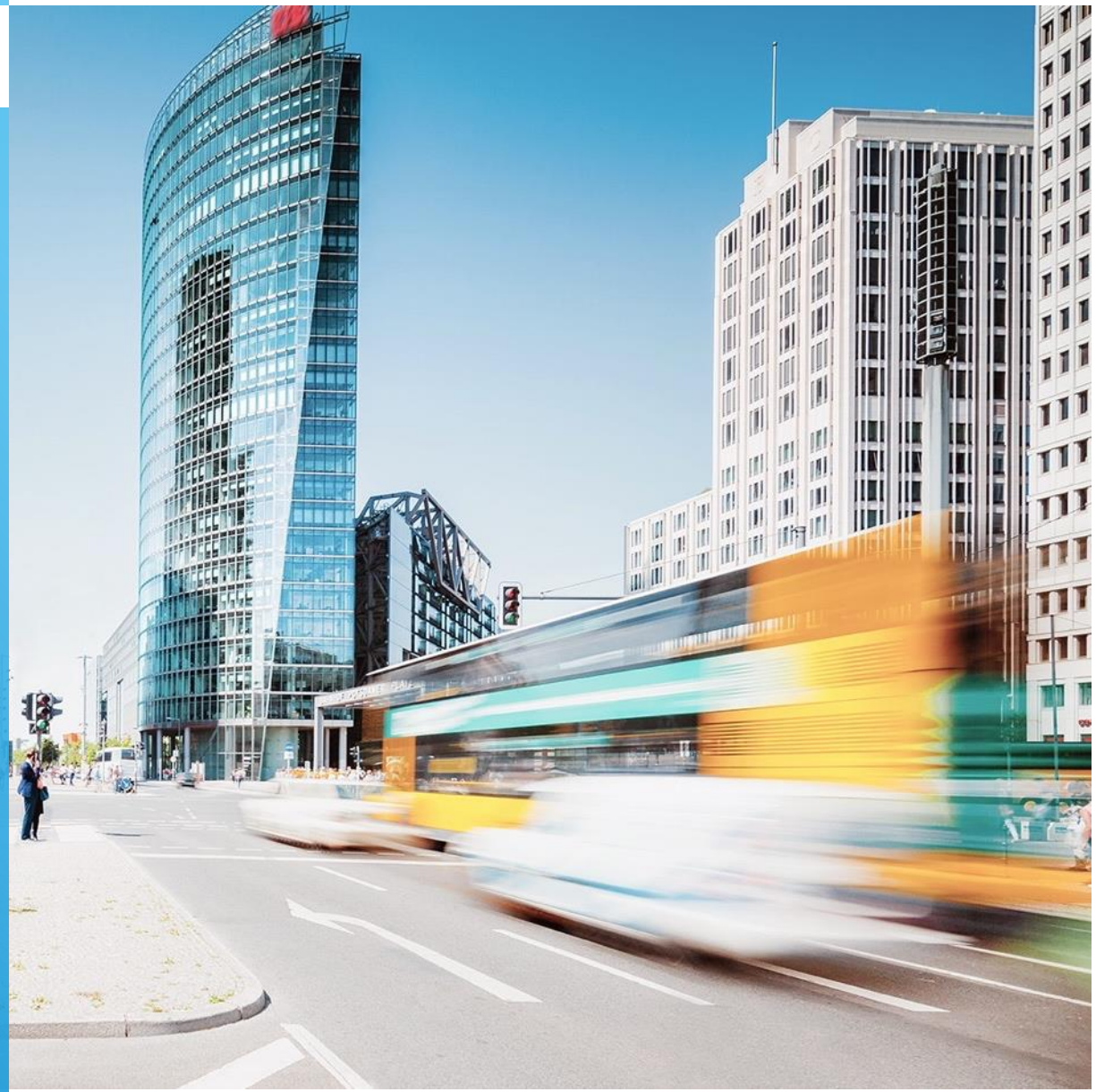
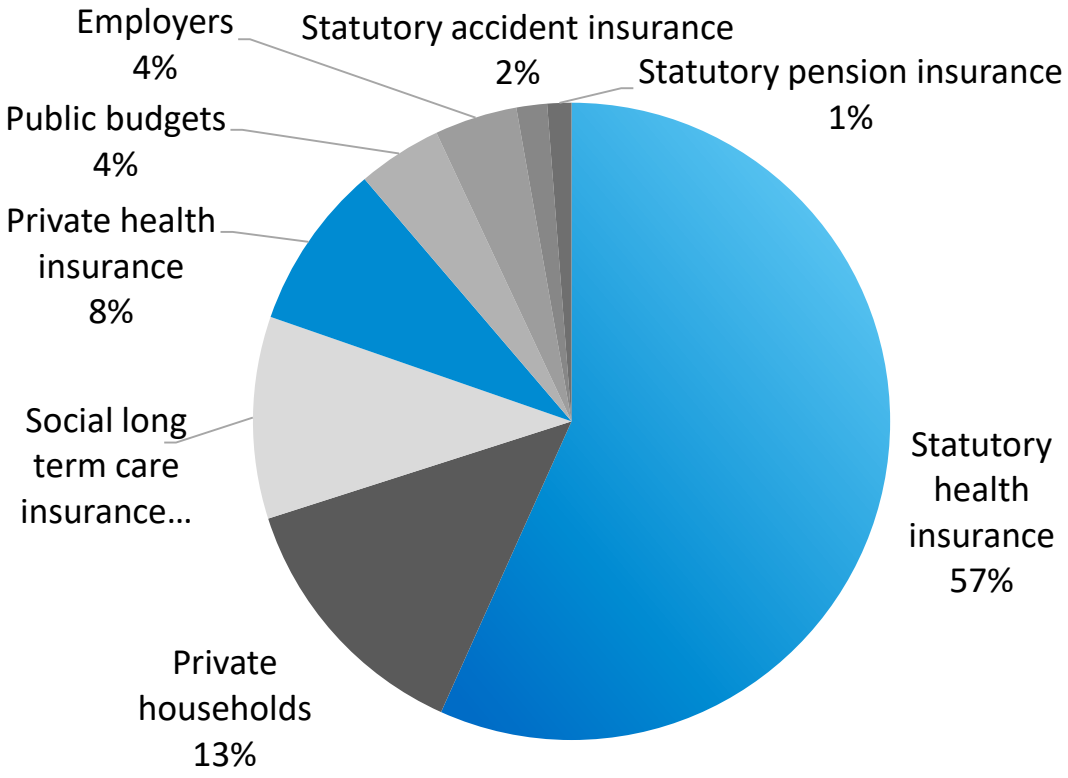
Investor Consulting

- Information about key industries
- Legal information
- Tax information
- Incentives and financing information
- Introduction to local partners
- Site selection support



German Healthcare is Financed by Multiple Sources

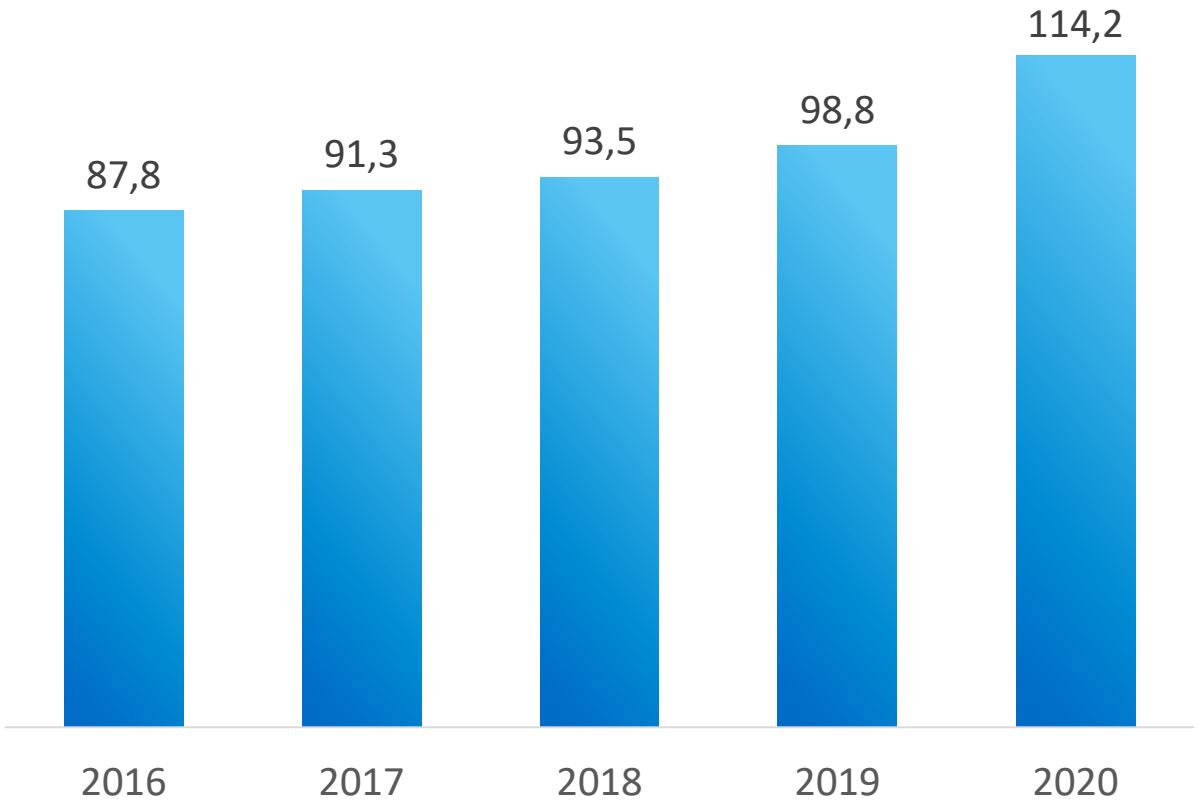


With a share of 57%, statutory health is most significant payer

Note: The item private households includes non-profit institutions serving households.
Source: German Federal Statistical Office 2021

German Hospital Spending is Increasing

Total spending of German hospitals 2016 – 2020 (in EUR bn)



- **1900+ hospitals**
- **EUR 5.088 per case (+5.5%)**

Source: Statista 2022

Market Access for Innovative Devices

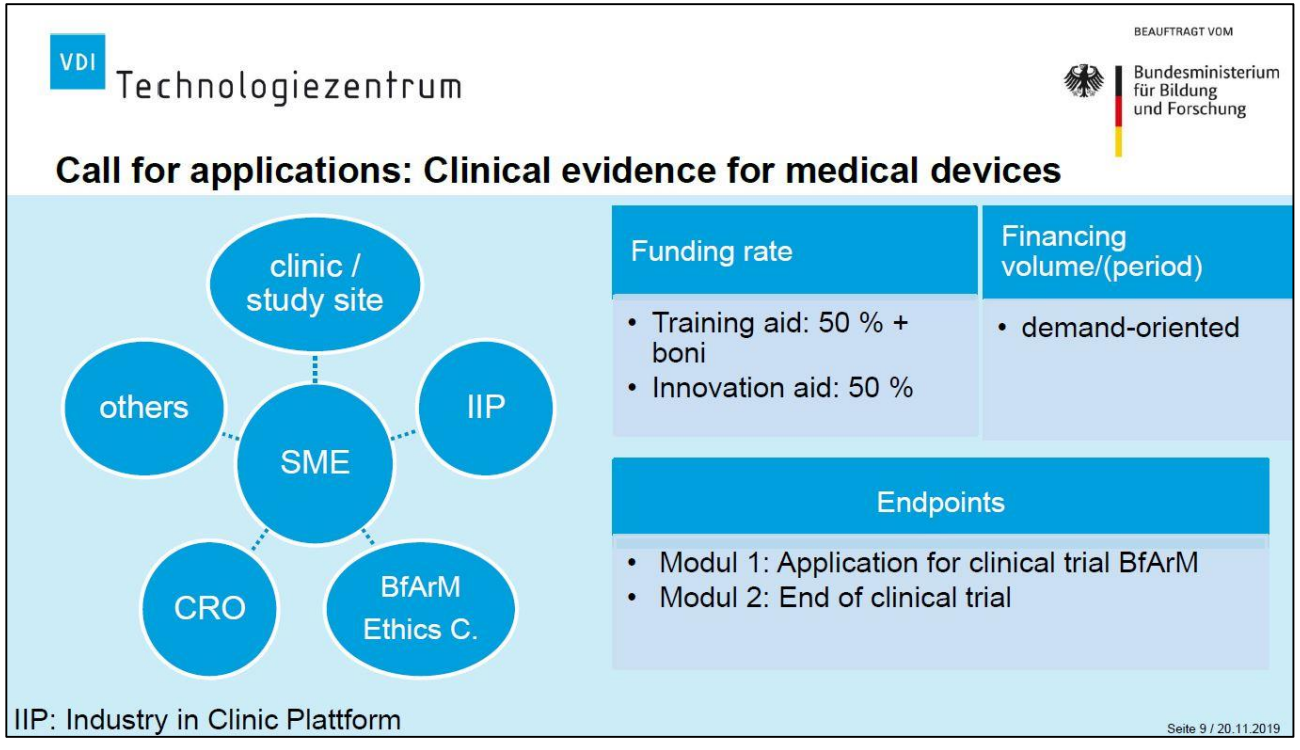
CE certification: MDR to replace MDD

- Latest expiry of CE marks via MDD in 2025
- Classification rules: Annex VIII of (EU) 2017/745 MDR
- EUDAMED is postponed
- German implementation “MPDG”
  - medical devices operators ordinance (*MPBetreibVg*)
  - medical product advisor (*Medizinproduktberater §83*)

Market Access for Innovative Devices

Clinical trials for CE (MDR) validation: Cash grants available

- For innovative class II/III
- Grant for training phase
- Grant for innovation phase
- Max. 70% of costs applicable



Source: VDI Technologiezentrum

Reimbursement Pathways in Germany

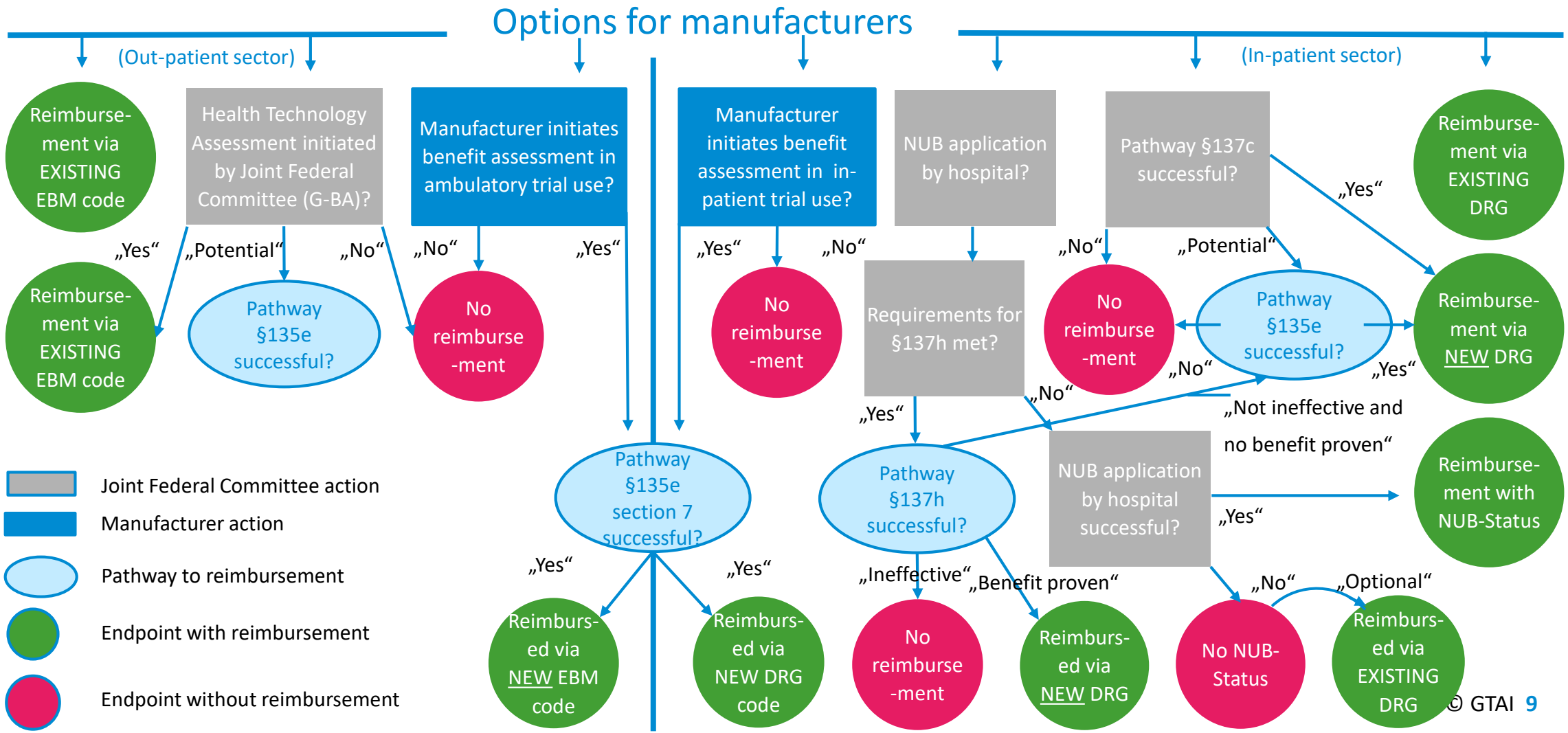
Ambulatory sector (out-patient)

- Doctor practices: reimbursed if listed in uniform evaluation standard (EBM)
- Medical supply stores: reimbursed if listed in medical aids register (HMV: GKV Spitzenverband)

Hospital sector (in-patient)

- G-DRG system: reimbursed unless barred
- Joint Federal Committee (G-BA)

Out-patient and in-patient reimbursement



Source: BVMed/Spectaris/VDGH/ZVEI

Hospital Reimbursement Requires Strategy

Option 1: use existing DRGs+OPS →	Quick access to the market (§137 c, SGB V)
Option 2: NUB track →	Register your individual OPS and DRG in case of new methods (§137 h, SGB V)
Option 3: coverage by evidence →	Receive reimbursement during clinical trial (§137 e, SGB V)

Clinical Trials can be Necessary

MDR: Class IIb+III →	New CE requires more individual clinical data. Equivalence via literature is limited
G-BA: potential to be proven →	Need to run clinical trials, will be reimbursed
New class III methods require RCT →	Only reimbursed when „HTA“ dossier provided by hospital and manufacturer, benefit assessment by IQWIG

Contact Us

Germany Trade & Invest is the economic development agency of the Federal Republic of Germany. The company helps create and secure extra employment opportunities, strengthening Germany as a business location. With more than 50 offices in Germany and abroad and its network of partners throughout the world, Germany Trade & Invest supports German companies setting up in foreign markets, promotes Germany as a business location and assists foreign companies setting up in Germany.

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