

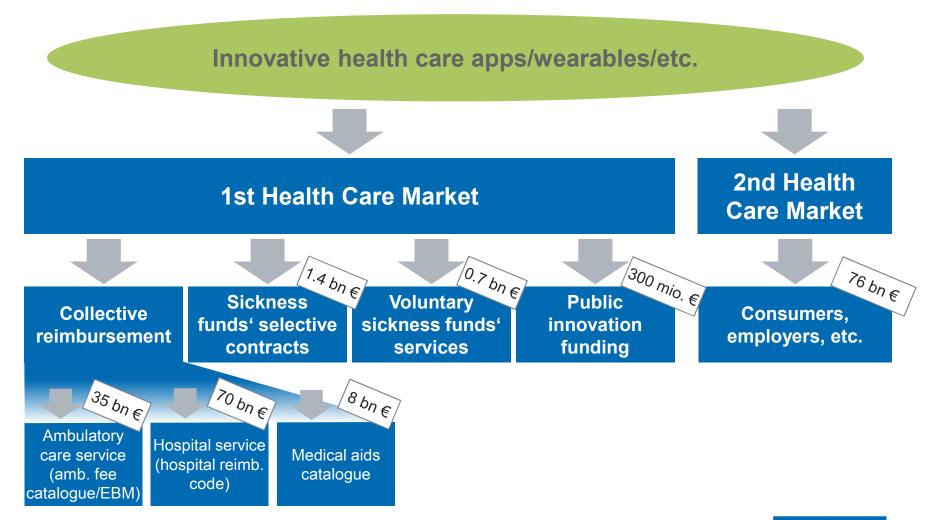
Apps and other Mobile Health Solutions

GTAI Webinar "Succeed in Germany's Healthcare Market"

Prof. Dr. Volker Amelung, President, German Managed Care Association

12 October 2016

How Do Innovations Enter the German Health Care Market?



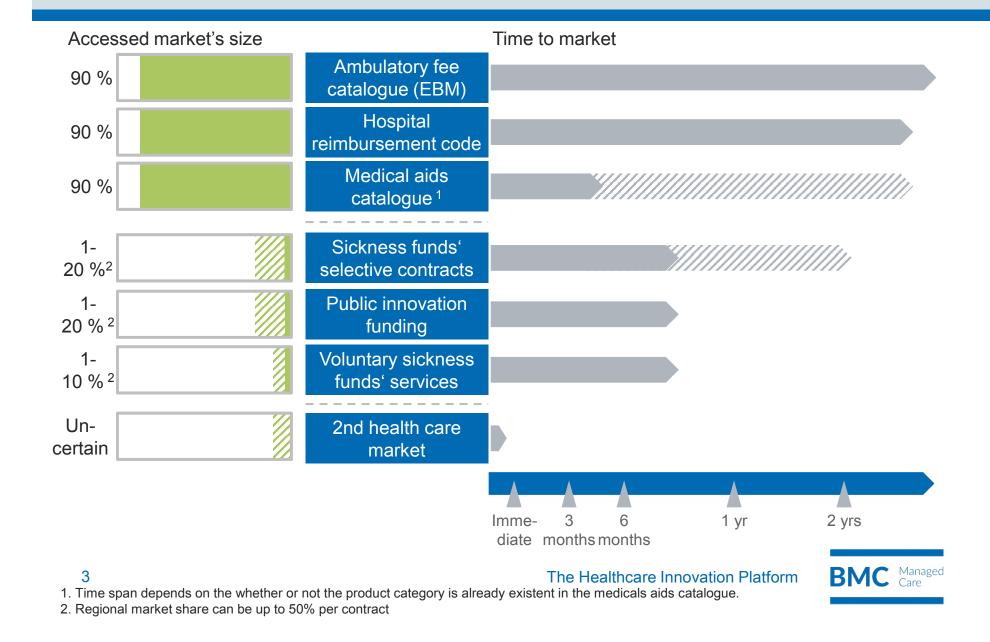


Different Market Access and Reimbursement Regulations per Instrument

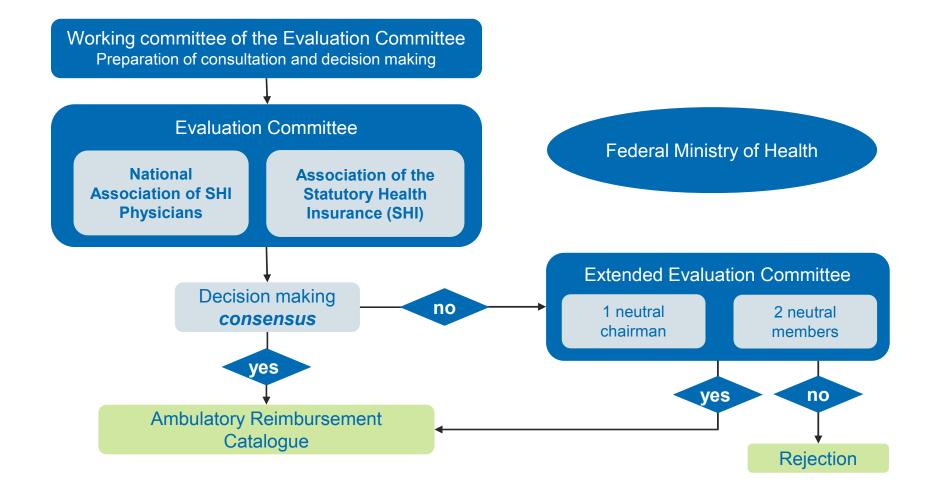
	Market size	Market access	Reimbursement
Ambulatory fee catalogue (EBM)	35 bn €	Collective positive vote	Fee for service
Hospital reimbursement code	70 bn €	Immediate access unless collective negative vote	DRG / code for innovative procedures (NUB)
Medical aids catalogue	8 bn €	Sickness funds' collective positive vote	Fee per device negotiated w/ each sickness fund
Sickness funds' selective contracts	1.4 bn €	Contracts with single sickness funds	Negotiated w/ each sickness fund (e.g. FFS, lump sum, etc)
Public innovation funding	300 mio. €	Public tender	Negotiated w/ participating sickness fund(s)
Voluntary sickness funds' services	0.7 bn €	Contracts with single sickness funds	Negotiated w/ each sickness fund (e.g. FFS, lump sum, etc)
2nd health care market	76 bn €	Immediate access (unless medical product)	Unrestricted market pricing



Long Time to Market Correlates With Larger Market Size



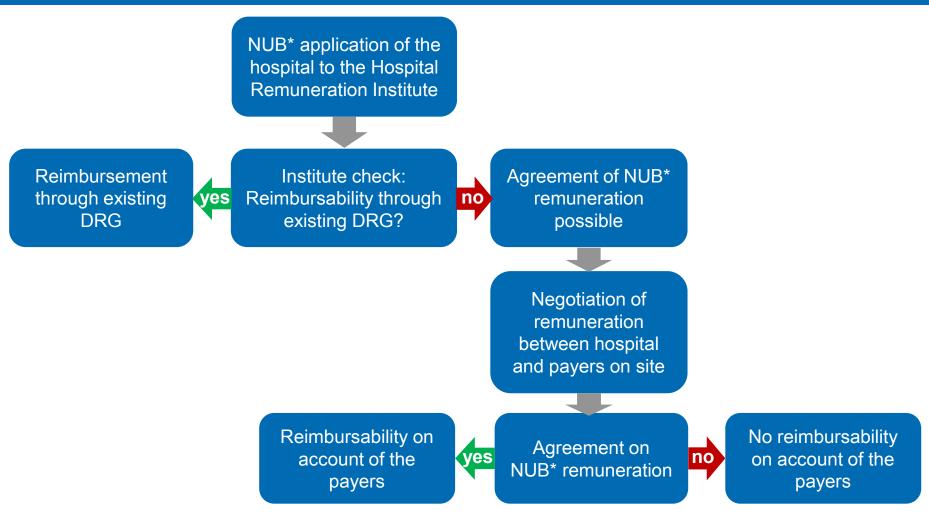
Pathway to Ambulatory Care Reimbursement





Pathway to Hospital Care Reimbursement

(Code for Innovative Procedures)



*New diagnostic and treatment methods Source: National Association of Statutory Health Insurance Physicians



Approval of medical devices is based on the risk class

Risk Classes of Medical Devices Examples Lowest risk classification. Non-sterile and /or non-Reading glasses, thermometers, measuring function; no notified body involvement wheelchairs Hearing aids, ultrasonic device, lla Medium risk. Manufacturing systems audit dental filling Medium risk. Manufacturing & product design Infusion pumps, X-ray apparatus, IIb audit (Technical File) condoms Hip implants, breast implants, drug-Ш High risk. Manufacturing & design dossier audit eluting stents



The German health care market is highly interesting, BUT...

- > Evidence-driven
- > Slow
- > Risk-averse
- > Partnership-driven
- ➤ German-speaking
- > "Old boys network"-driven





Thank you!

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