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Medica 2019

Market access for medical aids in Germany

RAin Maria Heil

Agenda

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- Medical aids definition
- Legal framework for medical aids
- Regulatory market access
- Reimbursement market access
- Advertising framework
- Distribution framework

Medical Aids in Germany
Definition

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- Term „medical aids“ used in reimbursement regulations only
- Regulatory classification: medical device (besides )

Medical Aids in Germany
Definition

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Regulatory Access

- Medical aids have to follow general medical device market access requirements for EU

SHI access

- Differentation between various product categories (e.g. medical aids, wound dressings, practice supply etc.)

Medical Aids in Germany
Definition

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Goods which are necessary for the individual patient to

- ✓ **ensure** success of **medical treatment**,
- ✓ **prevent** an **threat of disability** or
- ✓ **compensate** for **disability**

by means of replacing, supporting or relieving effect

and which are **not**
X **every day items** or
X excluded according to § 34 para 4 Social Code V

Examples for medical aids

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No medical aids

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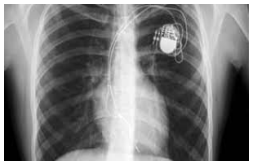

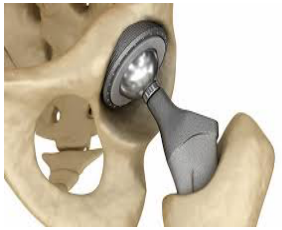

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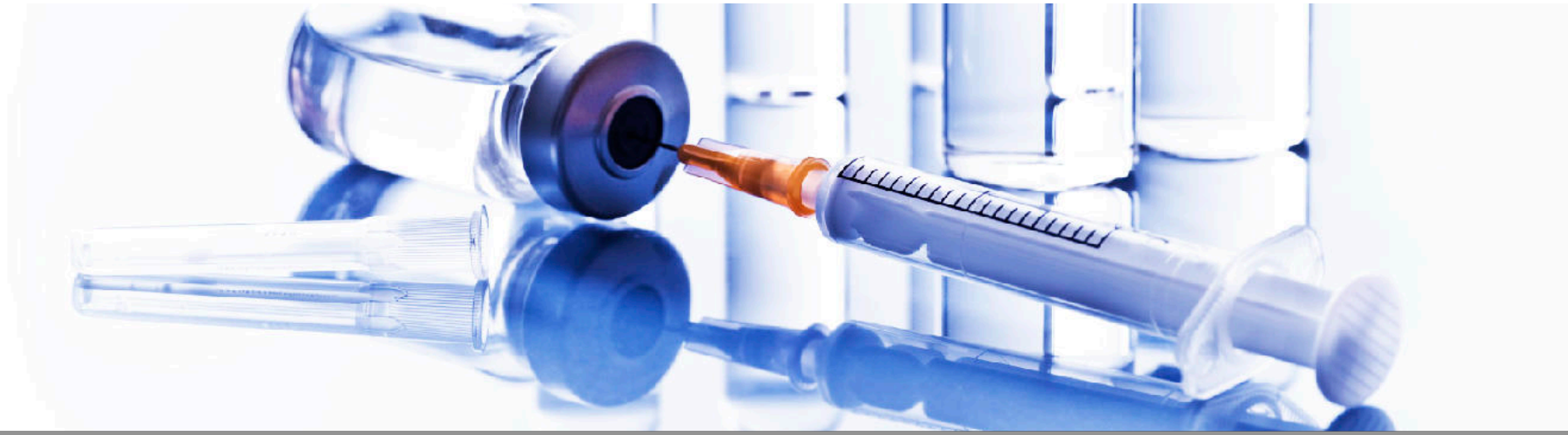

REGULATORY MARKET ACCESS

Regulatory Market Access

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- Legal basis
  - Medical Device Directive (MDD 93/42/EWG)
  - Medical Device Regulation (MDR 2017/745), has replaced MDD, date of application: May, 26th 2020
- Marketability in the EU requires „CE marking“

- CE-mark shows release for marketing within EU

Regulatory Market Access

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- CE-marking possible, if legal manufacturer has provided evidence for conformity with essential requirements for safety and reliability in a conformity assessment procedure
- Type of conformity assessment procedure depends on classification of product (risk classes I, IIa, IIb, III)
- Risk class IIa and higher: Notified Body has to be involved
  - Neutral and independent body
  - State-designated and state-supervised, but private company
  - Contracted by manufacturer

To-dos conformity assessment

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Definition medical device (delimitation to drugs, cosmetic etc.)

Classification according to risk classes (I, II a, II b, III)

Choice of conformity assessment procedure (depending on risk class)

Technical documentation

Audit of notified body (if required in procedure)

EU Authorized Representative

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- If company does not have physical location in EU
  - Authorised Representative is needed to sell medical devices in EU
  - Authorised Representative represents company to European authorities
  - Written mandate/agreement regulating allocation of responsibilities

Regulatory Market Access

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- Detailed labelling requirements, e.g.
  - *Name or trade name of **device***
  - *Name, registered trade name or registered trade mark of **Manufacturer** and the address of its registered place of business*
  - *Name of **authorised representative** and address of its registered place of business if manufacturer has its registered place of business outside EU*
  - *Lot number or the serial number of device preceded by the words **LOT NUMBER** or **SERIAL NUMBER** or an equivalent symbol, as appropriate*
  - ***Warnings** or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person*
  - *Indication of any **special storage** and/or **handling condition** that applies*

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ACCESS TO SHI REIMBURSEMENT

German Health Insurance Market

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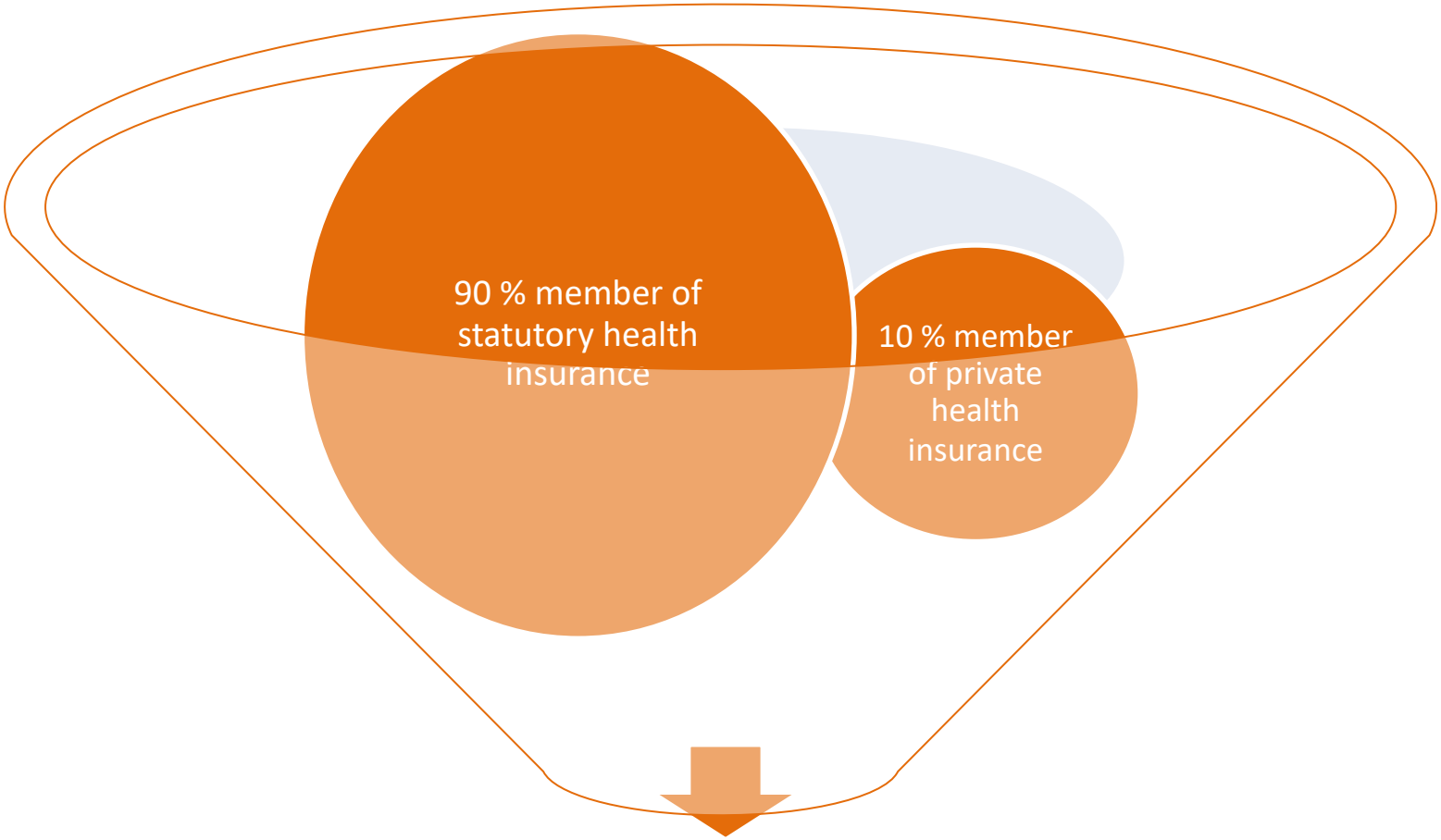

Reimbursement by health insurance very important for Manufacturer
Self-payer market alone would be insufficient

German Health Insurance Market

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- 90 % of population of Germany member of **statutory** health care insurance
  - Reimbursement principle
- Other 10 % of population of member of **private** health care insurance
  - Self-payer principle
- Therefore:
  - Reimbursement by statutory health insurance very important for Manufacturer
  - Self-payer market alone would be insufficient

Reimbursement requirements

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- Individual patient claim for medical aid vis-à-vis SHI
- Care agreement of care provider with patient‘s SHI
- Inclusion in medical aid register (not legally, but de facto mandatory)

Individual claim of patients vis-à-vis SHI

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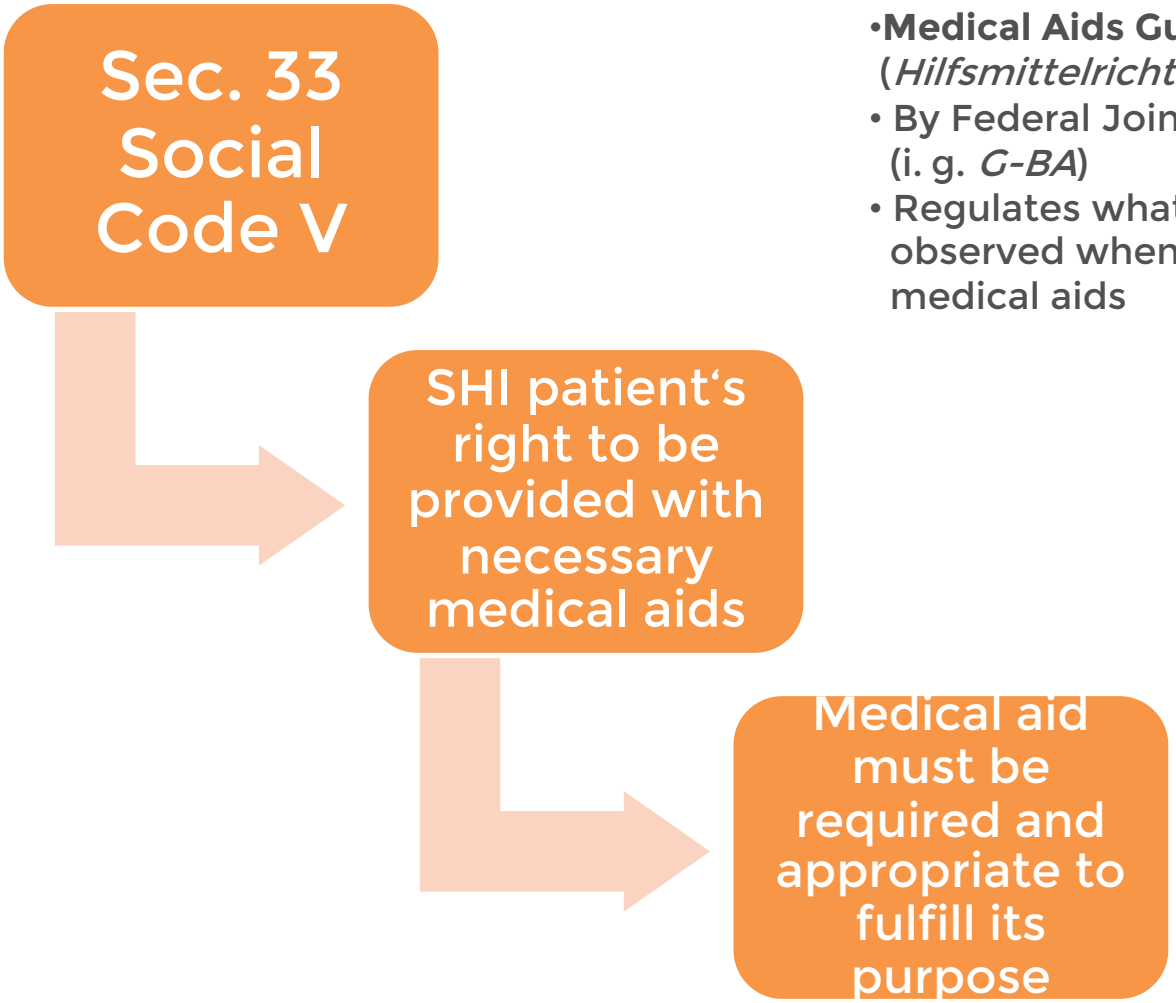

- **Medical Aids Guideline** (*Hilfsmittelrichtlinie*)
- By Federal Joint Committee (i. g. *G-BA*)
- Regulates what must be observed when prescribung medical aids

Right of medical aid provider to supply medical aid to individual patient

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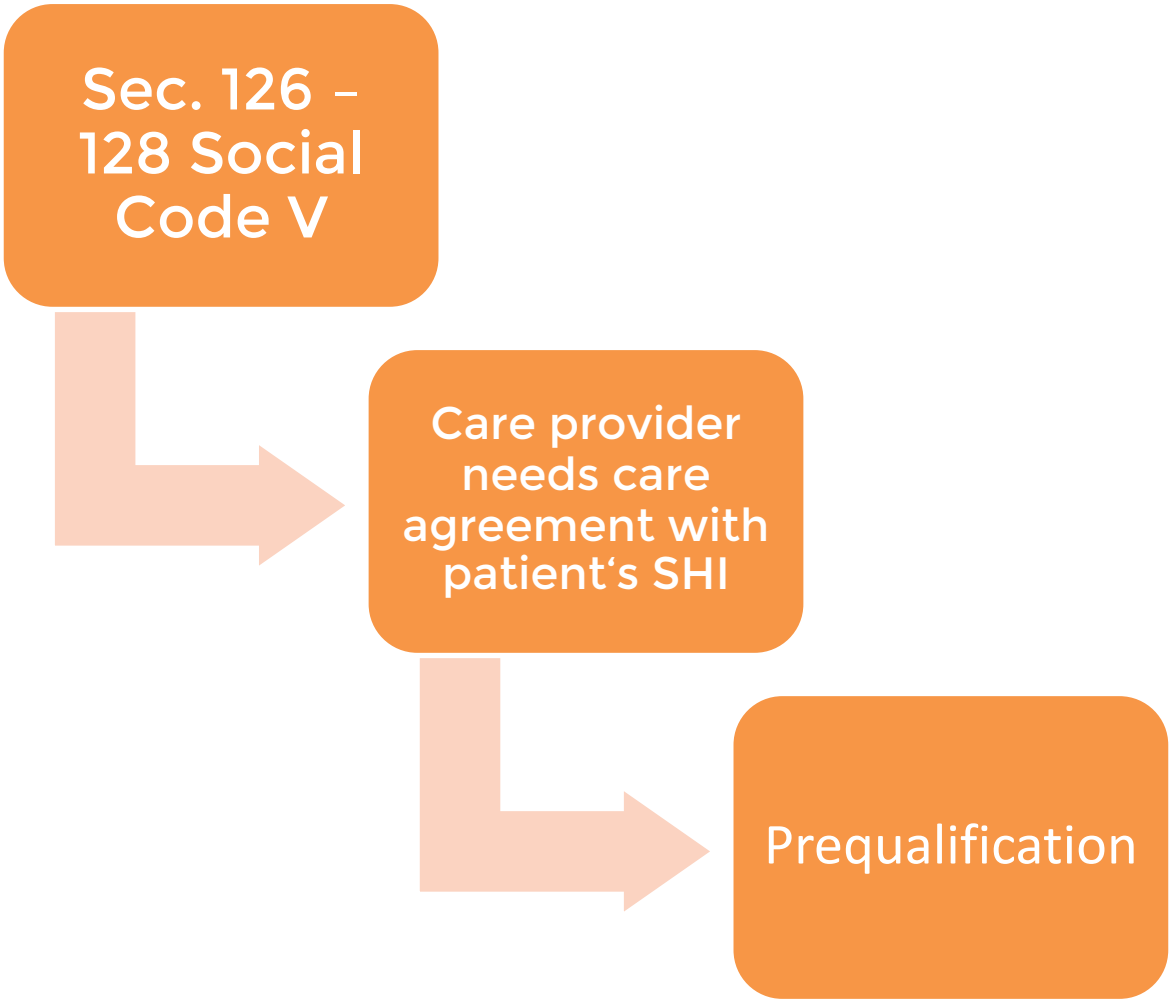

Access to care agreements

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- SHI has the obligation to negotiate (not conclude) care agreements with qualified service providers
- If care agreement has been concluded with a third party care provider, care providers may join the agreement accepting the same conditions as already agreed
- Right for information
- Recent development: Deletion of procurement right for SHIs

Reimbursement

Excursus: Conditions of Service Providers

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- Service providers need to fulfil conditions for:
  - ✓ **sufficient**, **appropriate** and **functional**
    - ✓ **production**,
    - ✓ **delivery** and
    - ✓ **adaptation** of medical aids
- Conditions need to be proofed by a **certificate** from a **prequalification body** (*Präqualifizierungsstelle*)

Medical aids register (*Hilfsmittelverzeichnis*)

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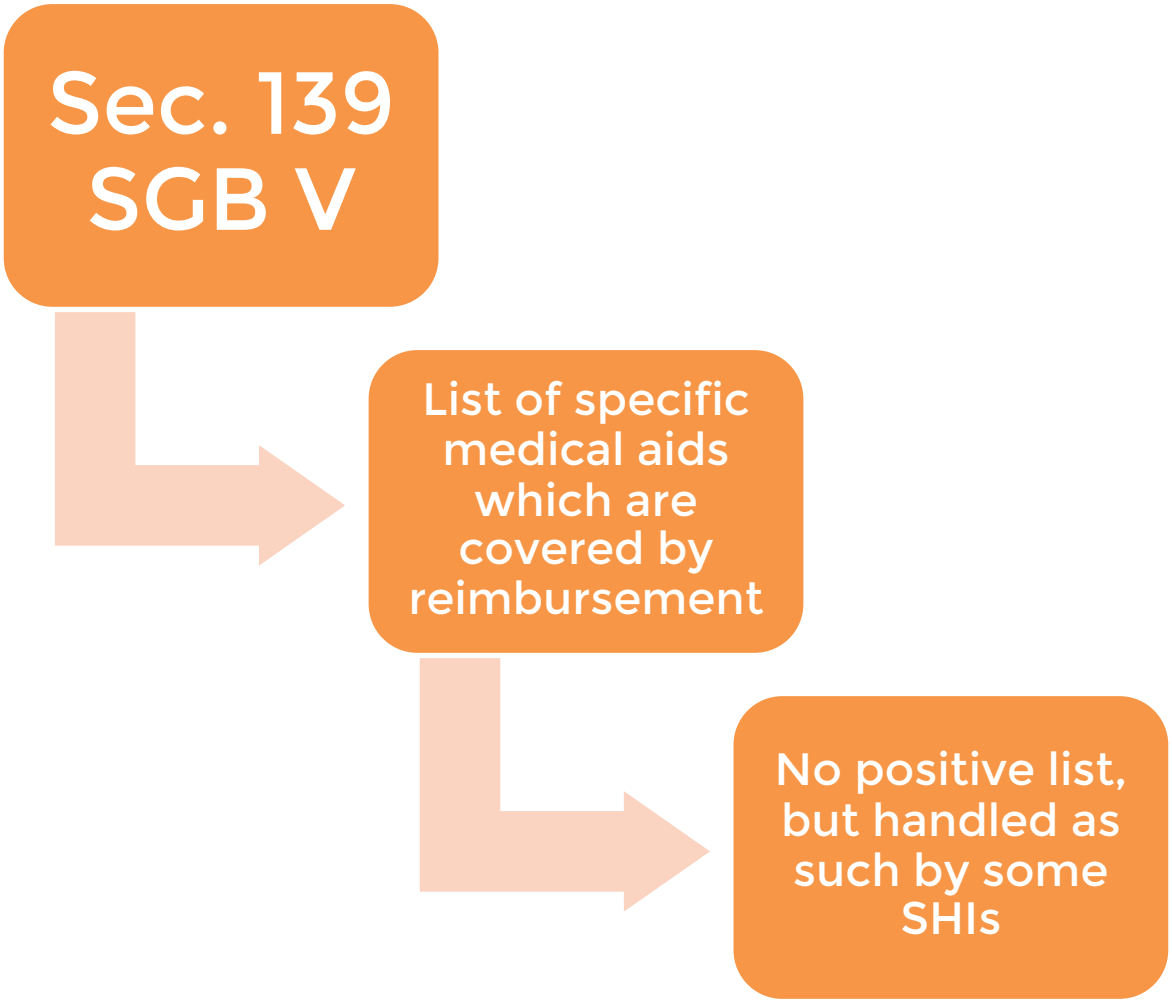

Reimbursement

Excursus: Medical Aids Register

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- Application for inclusion medical aid in Medical Aids Register
  - Who? Manufacturer
  - To Whom? National Association of Statutory Health Insurance
    - Needs to decide within 3 months after application by administrative act
- Legal claim for inclusion medical aid in Medical Aids Register if
  - **Functional capability** and **safety**, special quality requirements and, if necessary, medical need is proofed
    - With CE marking proof of functional capability and safety shall be deemed furnished
  - User manual in German language

Advertising restrictions for medical devices in Germany

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Misleading Advertisment

Restrictions on advertisment with expert opinions

Undue benefits

Mail order and teleshopping

Special prohibitions for advertising vis-à-vis public (non-HCP)

Distribution requirements

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- Distributor has own regulatory responsibilities
- In particular, control of regulatory compliance of manufacturer
- Recommended: Quality management system
- Contract with legal manufacturer and/or authorised representative including allocation of regulatory responsibilities
- Reimbursement: Distributor is care provider, i.e. has to conclude care agreements with SHI and to fulfill all legal requirements according to SGB V

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Thank you for your attention!

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Maria advises national and international pharmaceutical and medical device companies in all legal matters concerning the development, manufacturing, design, marketing and distribution of their products.

Maria is a founding partner of NOVACOS Rechtsanwälte. After her admission to the bar in 2004, Maria had been a lawyer for more than 11 years with the international law firm Clifford Chance in the „Healthcare, Life Sciences & Chemicals"-team.

A particular focus of her work is the advice on regulatory matters and sector specific contracts, health data protection and e-health. In addition, Maria represents companies in the healthcare sector regarding contractual relationships and the cooperation with medical institutions or physicians.

Finally, Maria has extensive experience in advising strategic clients, financial investors and financial institutions in national and international M&A projects with respect to the sector-specific characteristics of such transactions.

Maria is an external member of the legal working group of BVMed (AK Recht), the out-patient reimbursement working group of BVMed (German trade association of the medical device industry) and editor of a leading German Journal for Medical Device Law (Medizinprodukterecht) as well as regular speaker and author of legal publications in the healthcare sector.

Recent experience includes advising:

- A number of national and international medical device, pharmaceutical, life sciences and food companies on regulatory issues (e.g. clinical trials) and advertising questions (e.g. review of websites, storyboards etc.)

Maria Heil

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- A medical device company on the developments of the EU-Medical Device Regulation (MDR)
- An international medical device company on the draft of quality agreements according to MDR standards (intra-group, supplier, distributors)
- An international pharmaceutical company regarding e-health related questions (e.g. issues of delineation of new developed apps as medical devices)
- An international pharmaceutical company on regulatory and data protection questions regarding the transfer of products to another group-entity
- Performing an Compliance audit on a mid-size pharmaceutical and several medical device company
- Various pharmaceutical companies regarding cooperation with healthcare professionals and arbitration proceedings with industry associations (FSA)
- Medical device and pharmaceutical companies with regard to the European wide implementation of compliance programs, the development of internal guidelines and procedures covering interactions with health care professionals and their institutions as well as the set-up and implementation of compliance-guidelines and contract templates as well as the realization of related electronic processes
- Major pharmaceutical companies regarding Pharmaceutical companies regarding the advising and negotiating of clinical trial agreements with medical sites and/or CROs
- A US-based pharmaceutical company on proposed regulatory changes regarding use of genetic material in China
- Bayer on the acquisition of Germany-based Steigerwald Arzneimittelwerk GmbH, a family owned pharmaceutical company specializing in pharmacy-only herbal medicinal products.
- Financial investor 3i on the sale of betapharm to Dr. Reddy's Laboratories.
- Bridgepoint on the acquisition of Swiss Caps group, a Swiss contract manufacturer of pharmaceuticals and Dragenopharm, a German contract manufacturer of pharmaceuticals
- Merck KGaA in connection with a USD 4 Billion debut Yankee Bond issuance

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