

# Regulatory Update: Telemedicine in Germany

DMEA - Connecting Digital Health

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Peter Schüller – Partner | Attorney

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# Agenda

Dierks+Company, who?

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Telemedicine – Regulatory Framework in Germany

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Recent Challenges and New Solutions

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Implications for the Providers

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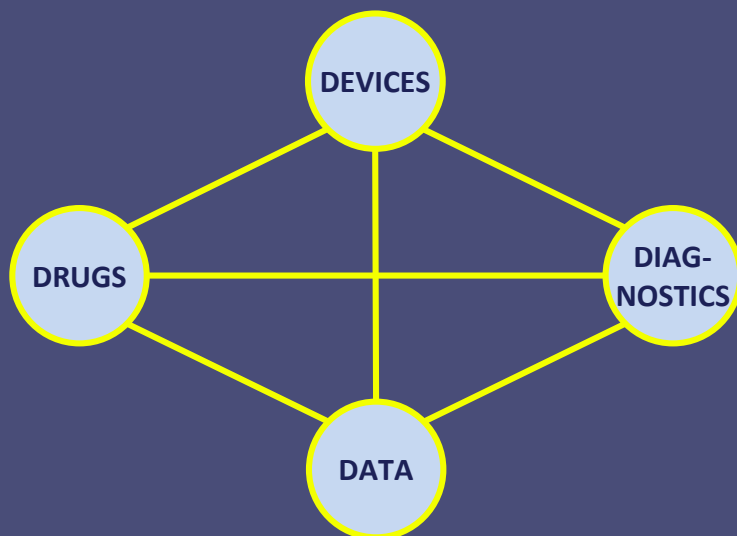
Conclusion

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# Dierks+Company – who?

## who we serve



## what we offer



## where we live



# How we work

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## HELIX HUB

The innovation space  
for healthcare and  
life sciences





**"Why us? Because we combine deep legal knowledge with real leadership experience in the healthcare industry."**

**PROF. DR. MED. DR. IUR. CHRISTIAN DIERKS**

One of the leading lawyers for medical law in Germany and Europe.

Trained physician, expert in regulatory issues, reimbursement, and digital health.

**JULIANA DIERKS**

Extensive experience in various top management positions in the pharmaceutical and healthcare industry.

Expert in organizational transformation, patient experience design, and marketing & sales excellence. Innovative thinker.







# Who are the potential customers?

## Patients

- Total population of 83 Mio
- Expect for insurance to pay for telemedicine services

## Pharma

- Willing to pay for beyond the pill, e.g. patient centric models
- Drug specific offerings, exclusivity requirements are common

## Providers

- 150.000 physicians, 1.900 Hospitals
- Limited willingness to pay in exchange for increased volume and lower cost

## Health Insurance

- 90% of patients insured with Statutory Health Insurance (GKV)
- **UNDERSTANDING THE RULES OF REIMBURSEMENT ARE KEY**



# Essential rules of reimbursement



- Outpatient services need positive listing for reimbursement
- Telemedical services of a hospital to be financed from the DRG system
- „Selective Contracting“ is a limited competitive tool only
- Telemedical services require panel doctors
- Applications for medical purposes need CE certificate

# Finally, the Germans move forward ...

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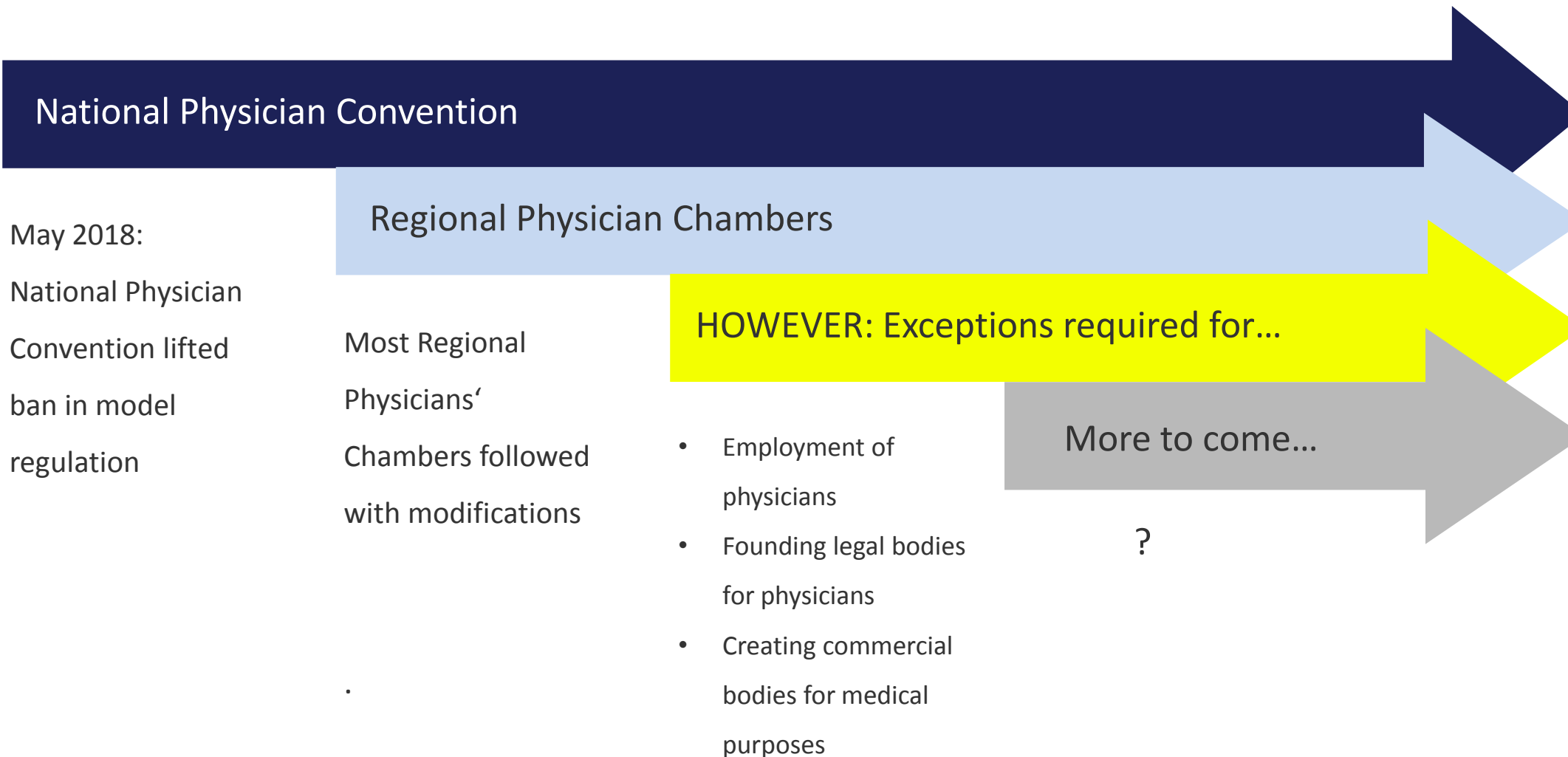
## Current barriers to keep in mind...

- Remote prescription not to be served by pharmacist
- Advertisement ban for telemedicine
- Applications require evidence for patient related benefit endpoints
- Bottleneck: Notified Bodies will slow down certification

## Solutions coming up

- Will be lifted with upcoming reform
- Hopefully to be erased with „Digitization Act“
- Experimental clauses might allow a wider market access
- New processes of certification under debate (precertification pilot)

# Recent regulatory events





- Essentially the same requirements throughout the EU
- Partial deviations and differences in Germany and its „Länder“
- Risk assessment for telemedical services most likely required
- Special attention to information, documentation etc.
- Right to data portability
- Know Your Customer – identifying the patient
- No storage of personalized health data outside the adequacy countries without consent

# Implications for Telemedicine Companies

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- Identify customer: Physician, Industry, Patient, Hospital, Insurance Fund ...?
- Assess the pathway of reimbursement and pricing
- Determine ways of integrating physicians or Decision Support Systems
- Identify the criteria for admission to the market
- Develop study design for proof-of-concept for
  - a) CE Certification and
  - b) Generating evidence for benefit
- Contract Notified Body
- Apply for contracts or reimbursement procedures

# In Summary...

## Enjoy the ride

We can make a difference –  
we can shape, we can innovate



## Market is attractive

German market is worth the effort to  
“crack” its complexity... with patience.



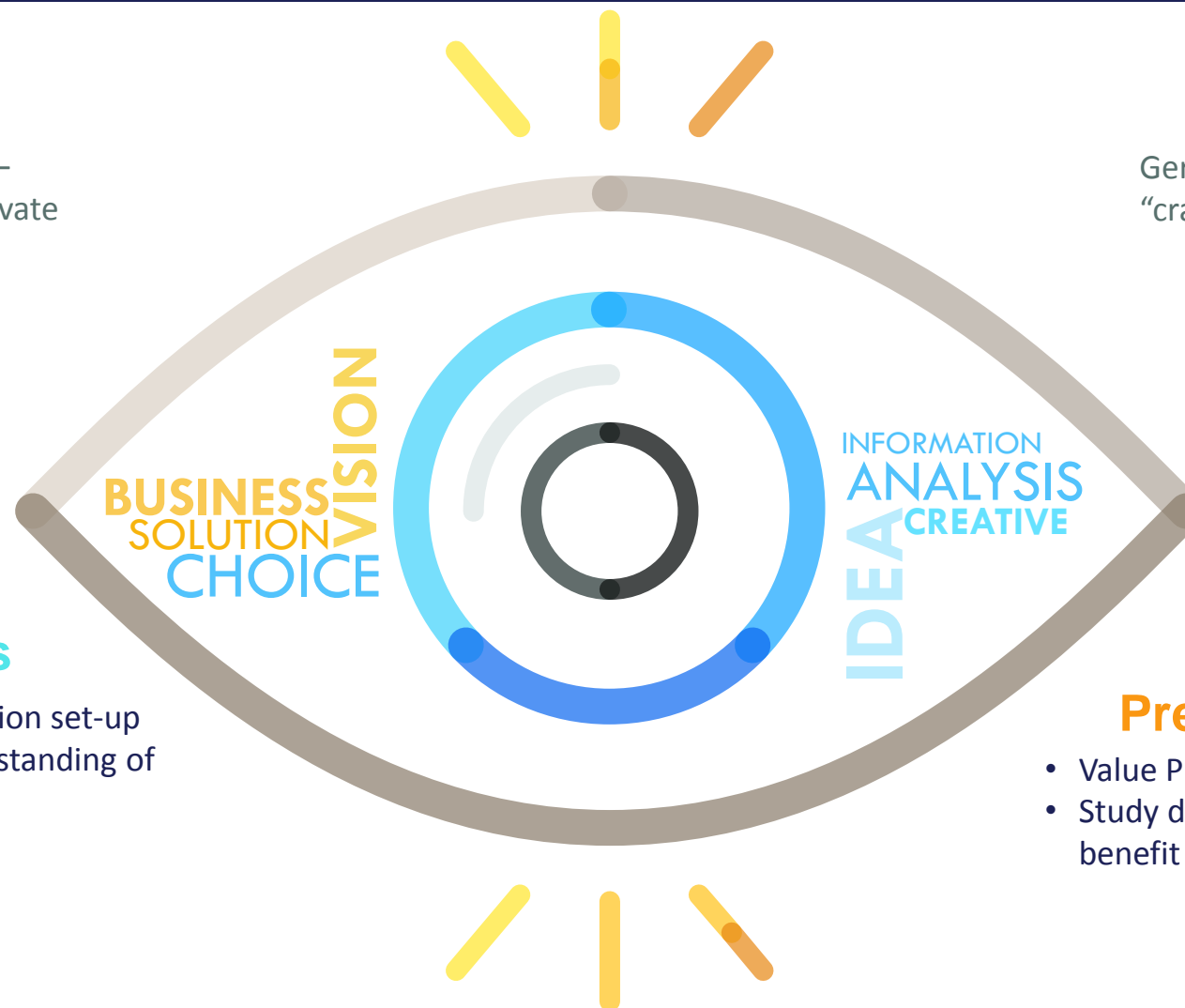
## Understand the rules

- Check country specific data protection set-up
- Contracts with funds require understanding of fund's perspective



## Preparation is required

- Value Proposition needs to address B2B models
- Study design for CE has to deliver evidence for benefit as well





## It will work:

To get good products into the market  
requires solid preparation,  
a profound understanding of the system  
and a joint effort  
to fulfil the preconditions  
for reimbursement in the  
Statutory Health Insurance.

## Thank you!

**Peter Schüller**

**Attorney-at-law (Rechtsanwalt) | Partner  
Head of Digital Health**

[peter.schueller@dierks.company](mailto:peter.schueller@dierks.company)