

# How to improve access to therapy ?

## A round the World Table: GERMANY

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# Situation of Hepatitis C in Germany

- Low endemic area
- Prevalence still under debate: 0.4 % in healthy blood donors
- Still to convince that HCV is a major health burden
- Peak of endstage liver disease still ahead:
  - Cirrhosis
  - HCC
  - Liver transplantation

# HCV drugs available in Germany

- 2001 PEG-IFN a2a / RBV
- 2002 PEG-IFN a2b / RBV
  
- 05/2011 Boceprevir/P/R
- 07/2011 Telaprevir/P/R
  
- 01/2014 Sofosbuvir: SOF/P/R or SOF/R
- 05/2014 Simeprevir: SMV/P/R or IFN intol + SOF
- 08/2014 Daclatasvir: DCV/SOF
  
- 11/2014 Sofosbuvir/Ledipasvir (FDC)

# Latest recommendations: DGVS 12 September 2014

**after DCV before SOF/LDV !!!**



April 2014: [www.easl.eu](http://www.easl.eu)

**bng**

Berufsverband Niedergelassener  
Gastroenterologen Deutschlands e.V.



Deutsche  
\_Leberstiftung

12 September 2014: [www.dgvs.de](http://www.dgvs.de)

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**MONTHLY UPDATE NEEDED !!**



Deutsche  
**Leberstiftung**

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# Germany: Access to Treatment

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- Health insurance coverage:
  - regular social health insurance (~ 80 %)
  - private health insurance (< 20 %)
- Social welfare
- Special populations
  - refugees
  - prisoners
- Clinical trials

# Germany: Access to Treatment

1. EMA approval
2. Reimbursement by health insurance



# Germany: Nomenclature

1. **AMNOG**: Arzneimittelneuordnungsgesetz
2. **GB-A**: Gemeinsamer Bundesausschuss
3. **IQWiG**: Institut für Qualitätssicherung und Wirtschaftlichkeit im Gesundheitswesen

# Germany: Access to Treatment

- Pricing according to the AMNOG law
- 1 year drug price according to pharmaceutical industry
- After first year pricing as a results of
  - GB-A judgement whether new therapy has additional benefit (Zusatznutzen) over standard of care (SOC) based on IQWiG (Institut für Qualitätssicherung und Wirtschaftlichkeit im Gesundheitswesen) evaluation
  - Final pricing following negotiations with the pharmaceutical industry based on GB-A judgement

# Situation of Hepatitis C in Germany:

## Present Discussion

- Is HCV therapy too costly ?
- Prioritization of HCV therapies
  - F3/F4 ?
  - Transplant populations: all ? HCC/Child A ? Child B/C post LTX ?

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- 3. Improved eligibility and tolerability of novel IFN free therapies:**
  - Maasoumy et al Plos One 2013
  - Siederdisen et al Liv Int 2014

# Germany: How to improve access to HCV therapy

1. Guidelines and recommendations
2. Definition how and who should treat HCV: primary care physician versus specialized centers
3. Improved eligibility and tolerability of novel IFN free therapies
- 4. Effective screening programmes !**

PEG-IFN/RBV

95% SVR

95% SVR  
And increase of diagnosis

All  
HCV  
patients

100%

100%

100%

DIAGNOSIS  
and therapy

20%

20%

90%

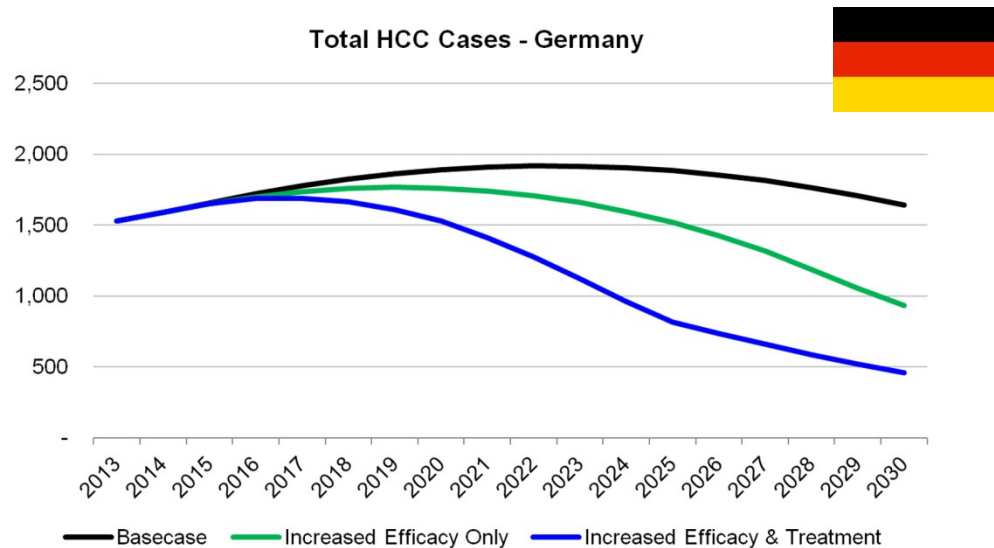
Cure

10%

19%

85%

# Strategies to manage hepatitis C virus (HCV) disease burden



- Old standard Peg-IFN/RBV
- SVR 90%
- SVR 90%, Increase of Treatment uptake by 75%



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Congress President

[www.isvhld2015.org](http://www.isvhld2015.org)

Berlin, Germany  
**June 26-28, 2015**



- Public Health
- Basic Science
- Prevention
- Diagnosis
- Treatment

# The Global Viral Hepatitis Summit

15<sup>th</sup> International  
Symposium on Viral Hepatitis  
and Liver Disease

Deutsche  
Leberstiftung  
German Liver Foundation



**Joint Meeting with**  
12<sup>th</sup> International HepNet Symposium (German Liver Foundation) and  
1<sup>st</sup> International Hepatitis Symposium of the German Center for Infection Research (DZIF)