

# Addressing IP Barriers to Eliminate HCV as Public Health Problem in LATAM

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**DNDi**

Drugs for Neglected Diseases *initiative*



# SUSTAINABLE DEVELOPMENT GOALS (SDGs)



**“By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases.”**

GLOBAL HEALTH SECTOR STRATEGY ON

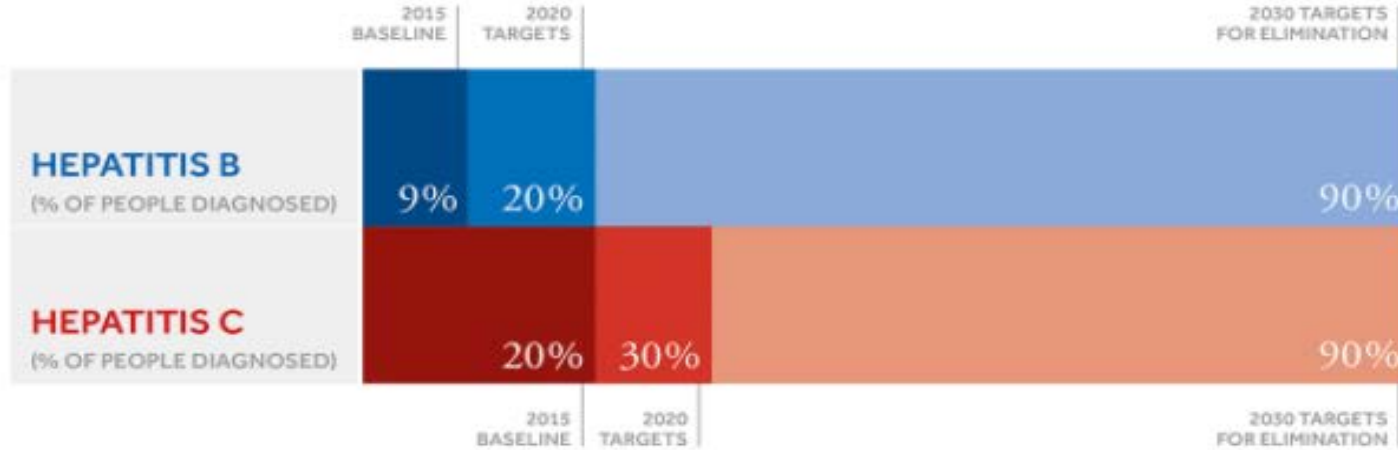
# VIRAL HEPATITIS 2016–2021

TOWARDS ENDING VIRAL HEPATITIS

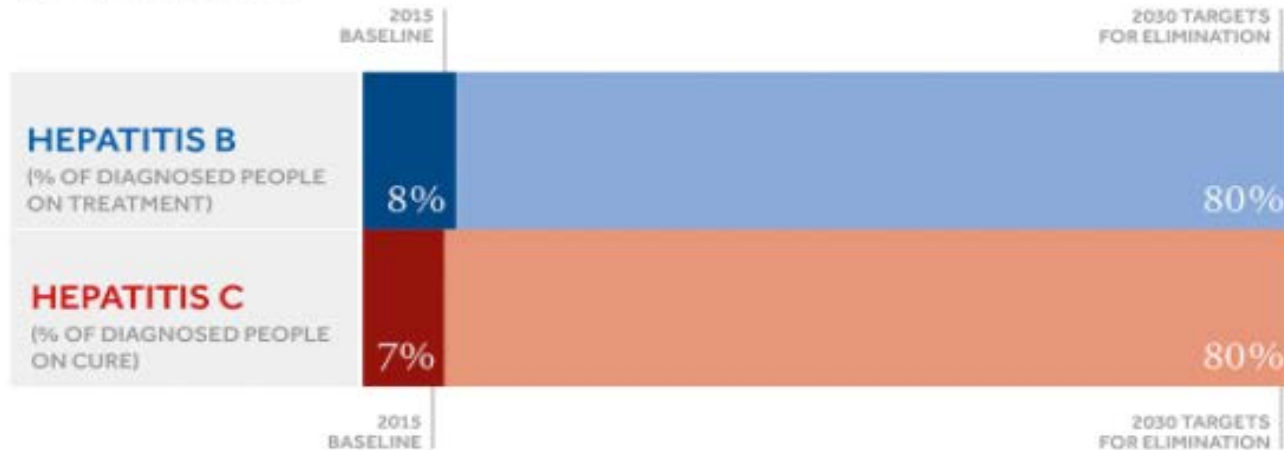
TARGET AREA	BASELINE 2015	2020 TARGETS	2030 TARGETS
<b>Impact targets</b>			
Viral hepatitis B and C diagnosis	<5% of chronic hepatitis infections diagnosed	30%	90%
Viral hepatitis B and C treatment	<1% receiving treatment	5 million people will be receiving hepatitis B virus treatment	80% of eligible persons with chronic hepatitis B virus infection treated
		3 million people have received hepatitis C virus treatment	80% of eligible persons with chronic hepatitis C virus infection treated
		(Both targets are cumulative by 2020)	

# MAJOR GAPS IN VIRAL HEPATITIS CARE

## TESTING GAP

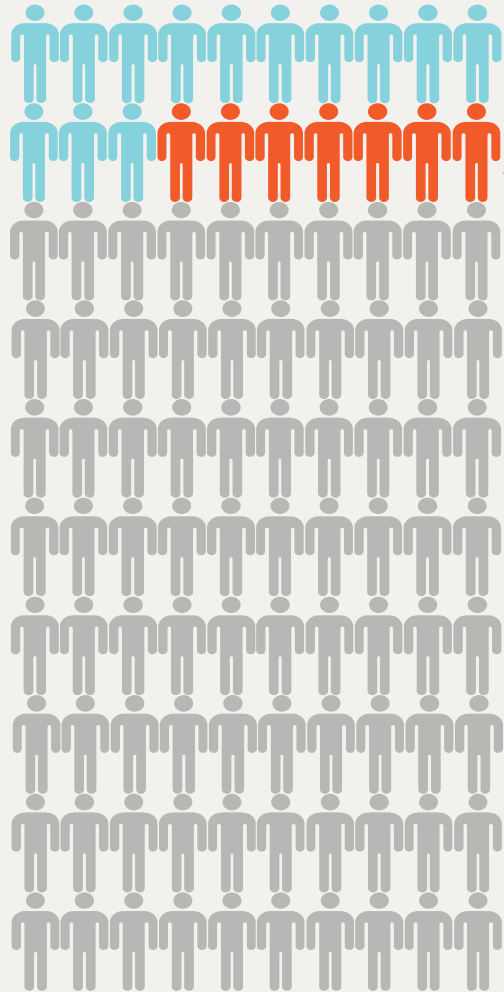


## TREATMENT GAP






# 71 million people worldwide

living with hepatitis C (HCV) infection in 2015



Only **2,86**  
**million**  
**people**  
**treated in**  
**2015-2016**

-  Infected, diagnosed but not treated
-  Diagnosed and treated
-  Infected, neither diagnosed nor treated

~ **400.000 deaths**  
a year mainly by cirrhosis /  
hepatocellular carcinoma

**1.1 million people**  
Treated in 2015

**1.75 million adults**  
New infections with HCV in 2015

# DNDi Hepatitis C Strategy: 3 pillars

**1**

**Accelerate  
R&D**

Accelerating the development of **promising drug candidates**



with



Pharma companies



Governments

**2**

**Catalyse  
ACCESS**

Supporting **affordable access to all DAAs**



with



Pharma companies



Civil Society organisations



Governments

**3**

**Simplify  
TREATMENT  
STRATEGIES**

Working with health providers to scale – up treatment



with

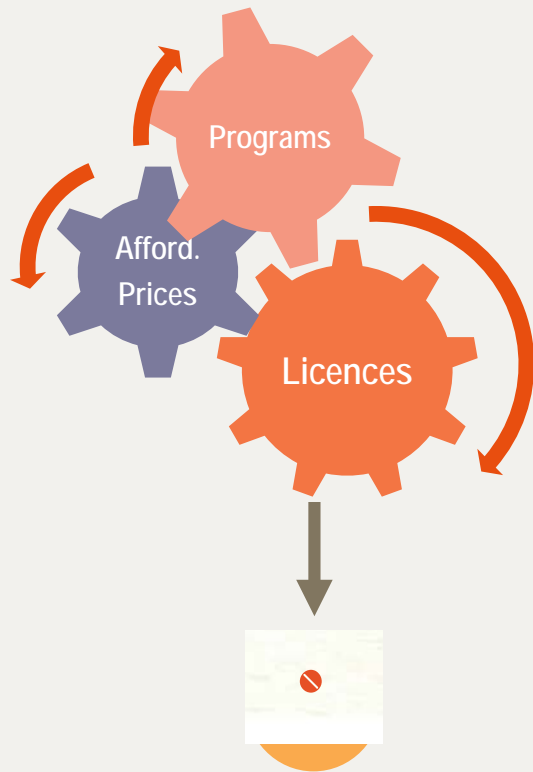


Primary healthcare doctors



Non Governmental Organizations

# DNDi Hep C Strategy: Contribute to HCV Elimination by 2030



- Raise political commitment & accountability
- Encourage policy change for the sustainable adoption of test & treat with DAAs
- Promote access to affordable, safe, quality and efficacious DAAs
- Address regulatory and intellectual property barriers for access to HCV diagnostics & medicines

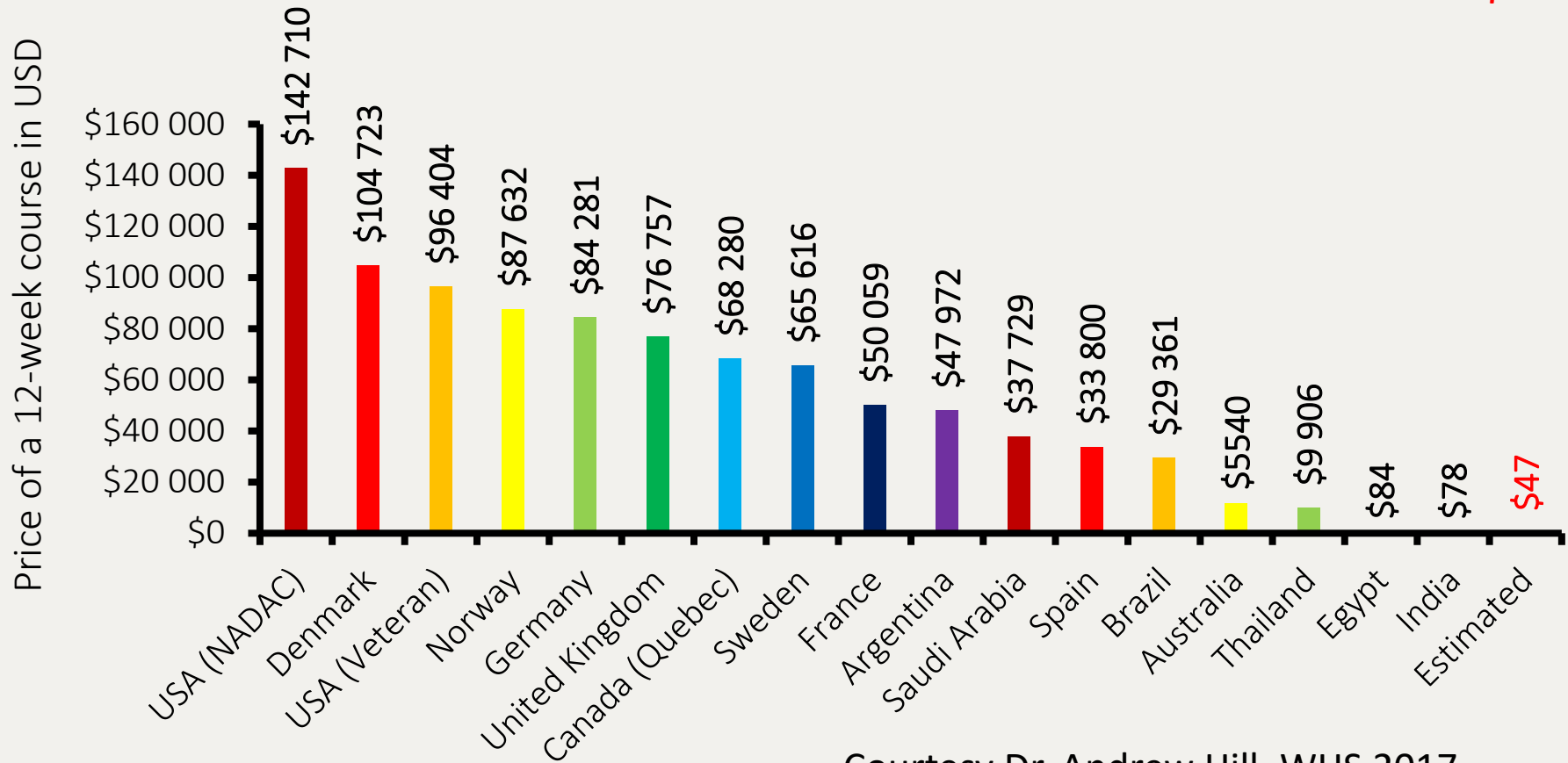
# Lowest prices of SOF/DCV in selected countries

**SOF/DCV:**

**Price in USA: \$143,000**

**Price in India: \$108**

**Production cost: \$47**



Courtesy Dr. Andrew Hill, WHS 2017



# Hepatitis C Treatment Gap

High prices impede access to hepatitis C treatments

## HEPATITIS C CASES



**Colombia**

378,000+ people

**Brazil**

657,000+ people

**Chile**

38,000+ people

**Argentina**

326,000+ people

Data source: Polaris/CDA

## PEOPLE TREATED

0.4%

9.3%

4.0%

0.6%

## TREATMENT PRICES

sofosbuvir + daclatasvir

USD 10,000

sofosbuvir + daclatasvir

USD 6,212

sofosbuvir + velpatasvir

USD 12,000

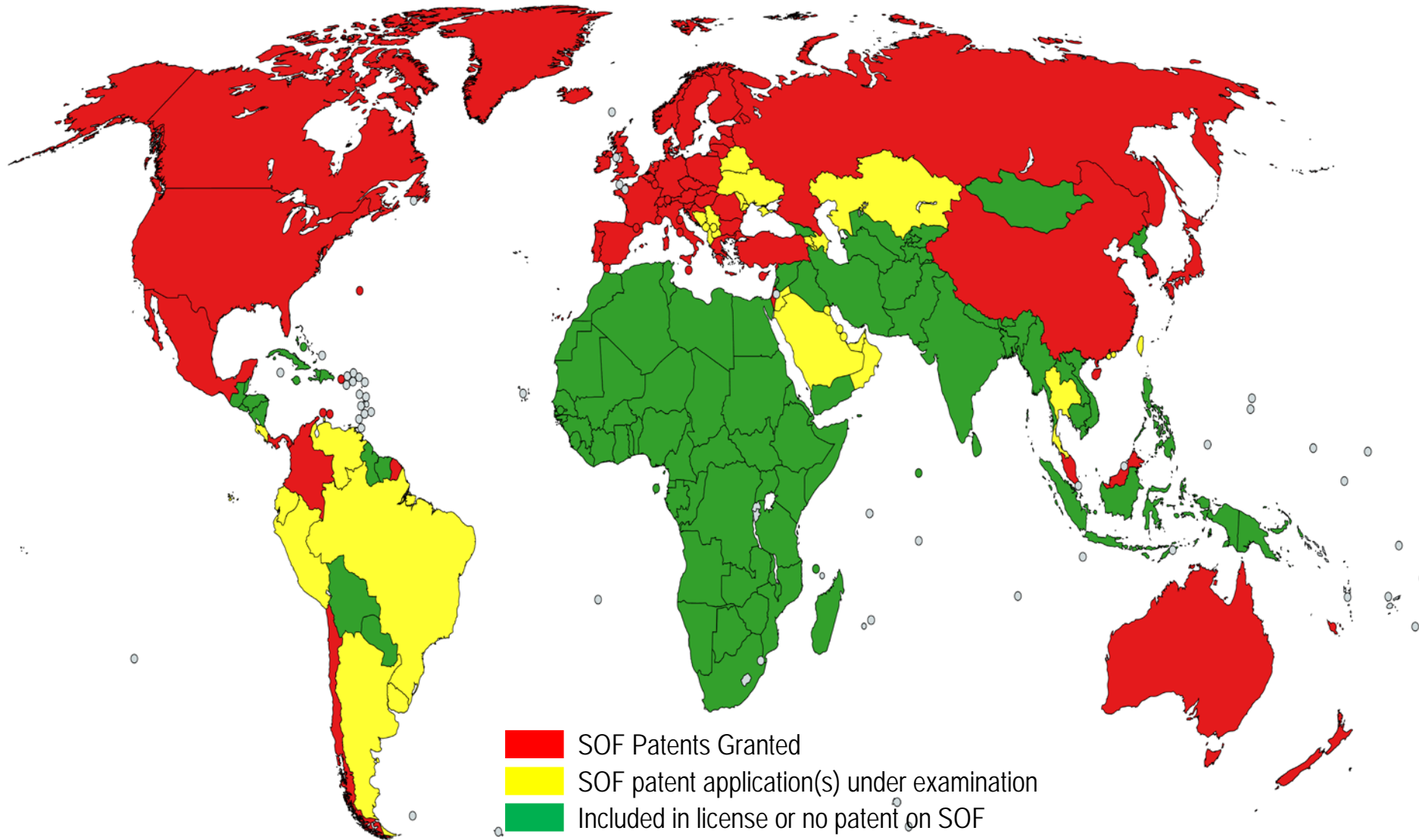
sofosbuvir + daclatasvir

USD 7,800

# Approved DAAs

API/Originator	FDA/EUA	EMA	Pan-genotypic	Patents (1 <sup>a</sup> and last expiry date)
sofosbuvir-Gilead	12-2013	1-2014	Combo	✓(2024-2032)
sofosbuvir+ledipasvir-Gilead	10-2014	11-2014	No	✓(2030-2034)
ombitasvir+paritaprevir+dasabuvir+ritonavir-AbbVie	12-2014	1-2015	No	✓(2030-2034)
daclatasvir-BMS	7-2015	8-2014	Combo	✓(2027-2033)
sofosbuvir+velpatasvir-Gilead	6-2016	7-2016	Yes	✓(2031-2034)
elbasvir +grazoprevir-Merck	1-2016	7-2016	No	✓(2032-2035)
sofosbuvir+velpatasvir+voxilaprevir-Gilead	7-2017	6-2017	Yes	✓(2031-2034)
glecaprevir/pibrentasvir-AbbVie	8-2017	7-2017	Yes	✓(2031-2034)

# Global SOF IP Landscape



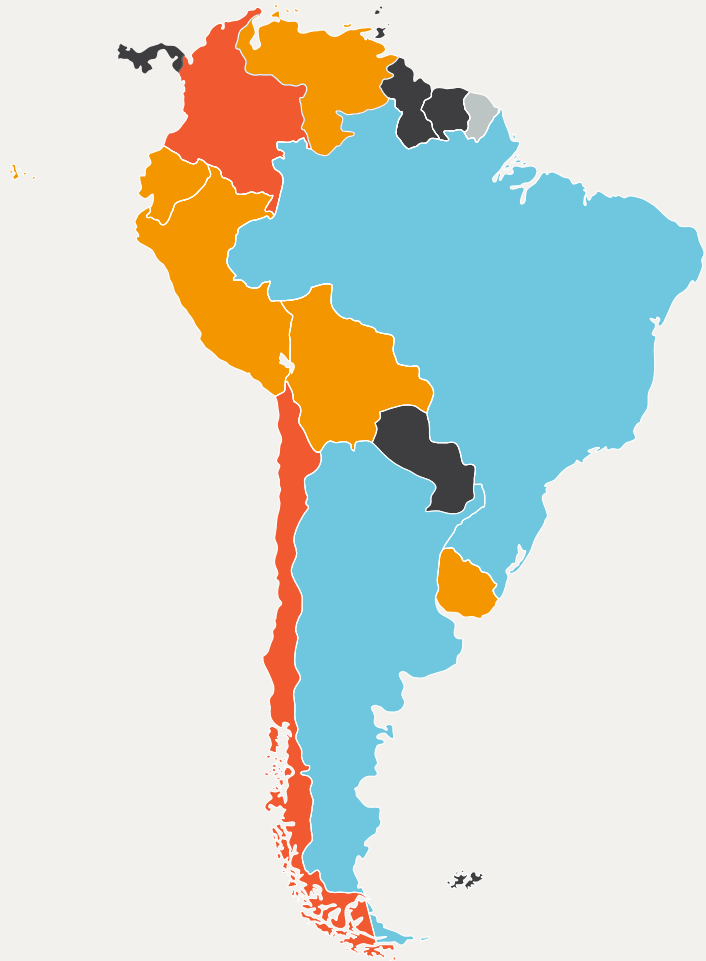
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# South America Scenario – Sofosbuvir IP Status

UNASUR countries: 12

Population: ~400 million

HepC Cases: predominance G1



Granted SOF Patents



No SOF Patents

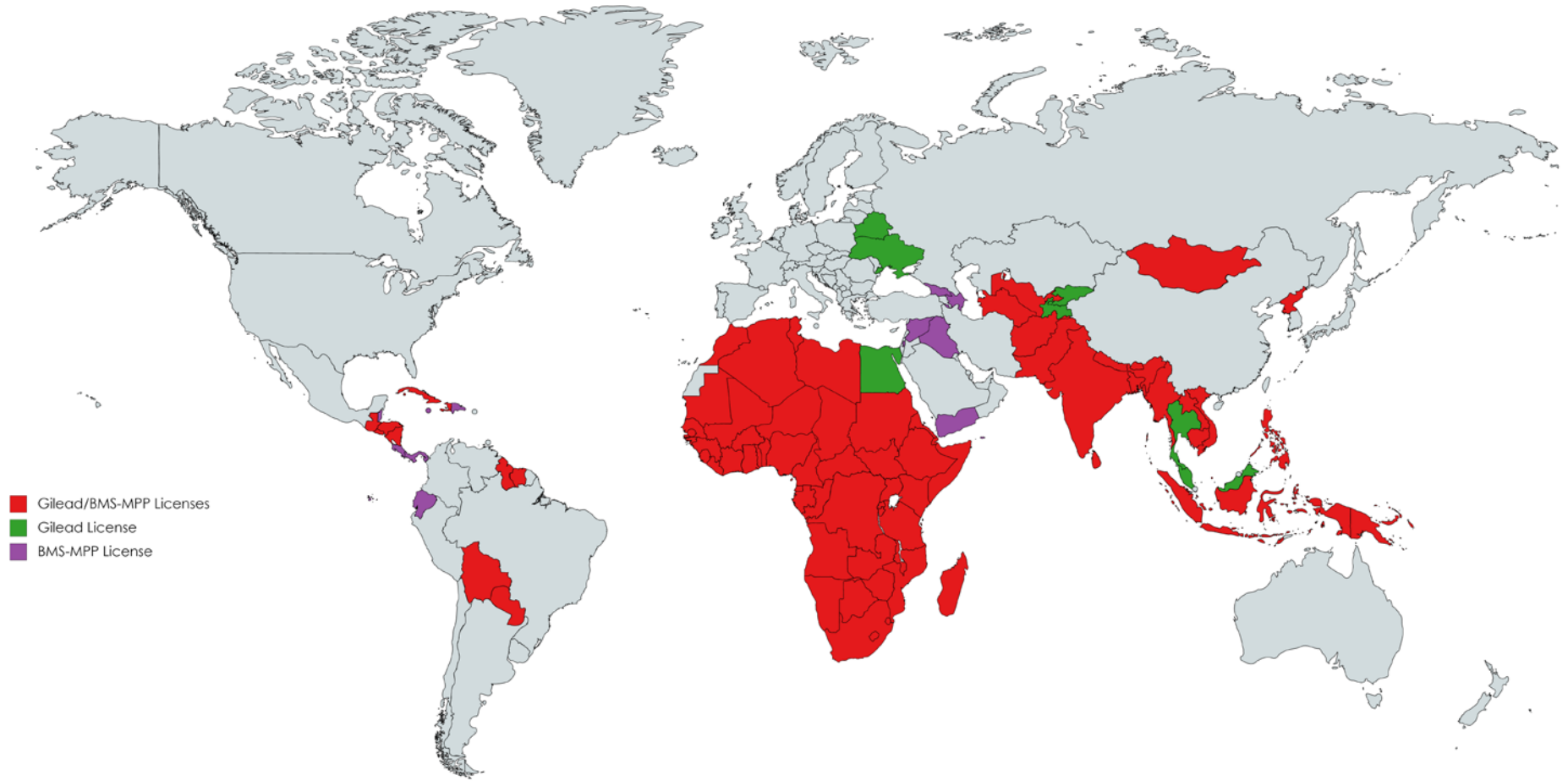


SOF primary pending patent applications



Only secondary SOF patent application pending

# Sofosbuvir and daclatasvir Voluntary Licenses: prevalent countries and Latin America excluded



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# DNDi's IP Policy

- The need to ensure that drugs are affordable to and access is equitable for patients who need them
- The desire to develop drugs as public goods when possible.

# DNDi's Strategy on IP related to HCV

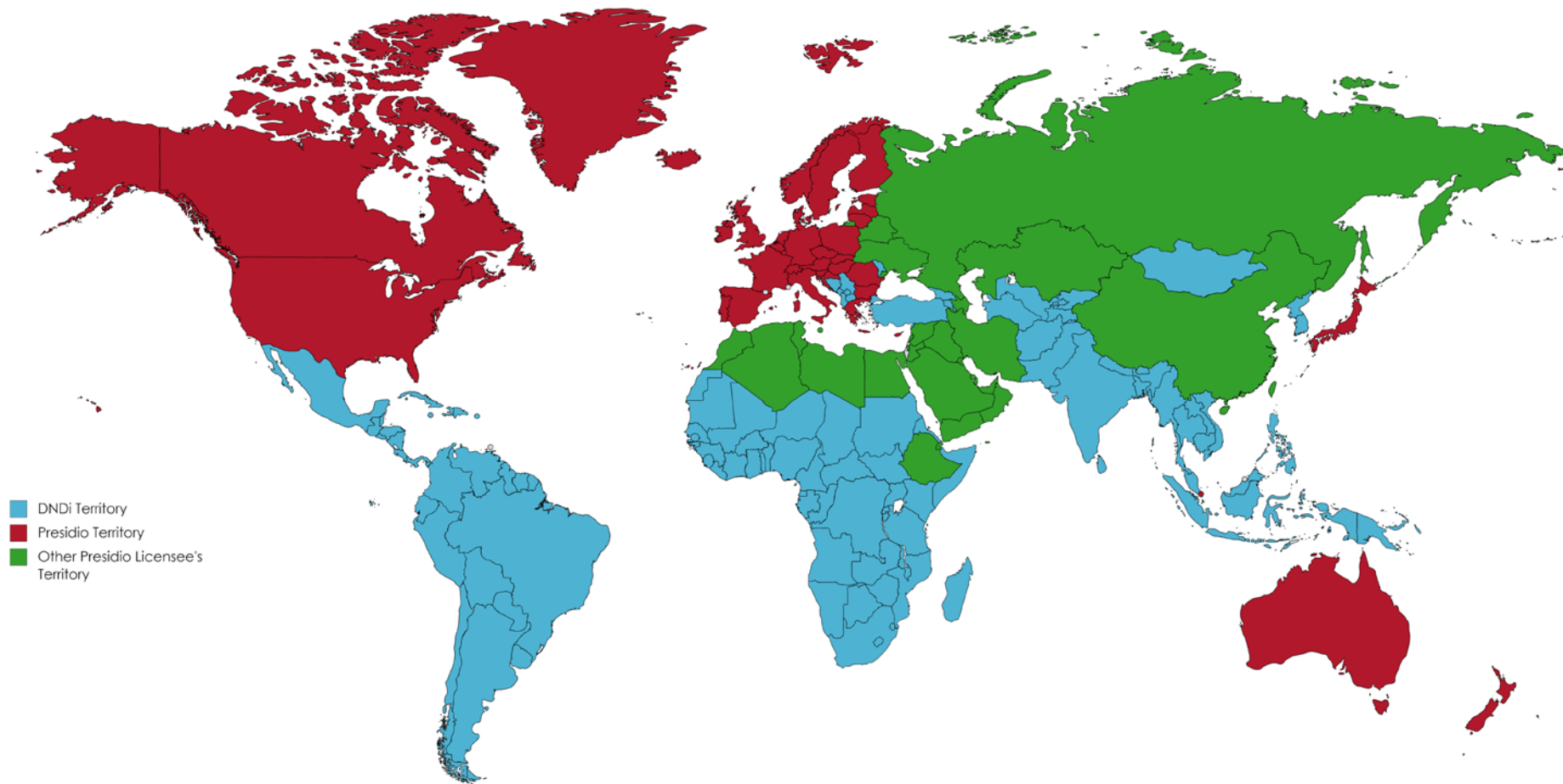
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Obtain and sublicense pro public health licenses related to the development of Ravidasvir

2

Advocate for removal of intellectual property barriers for access to all DAA's.

# 1 Ravidasvir license territory, March 2016

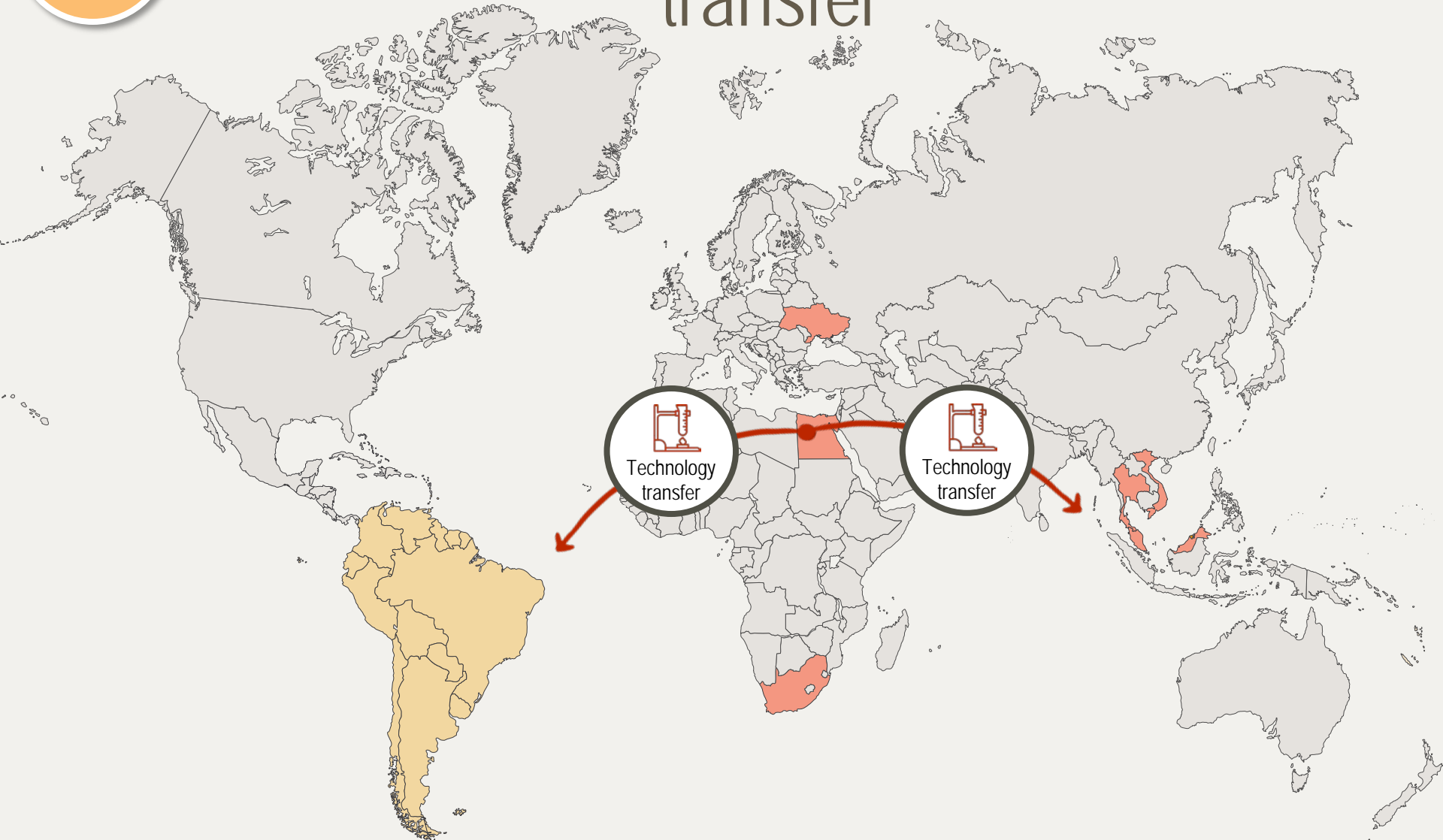


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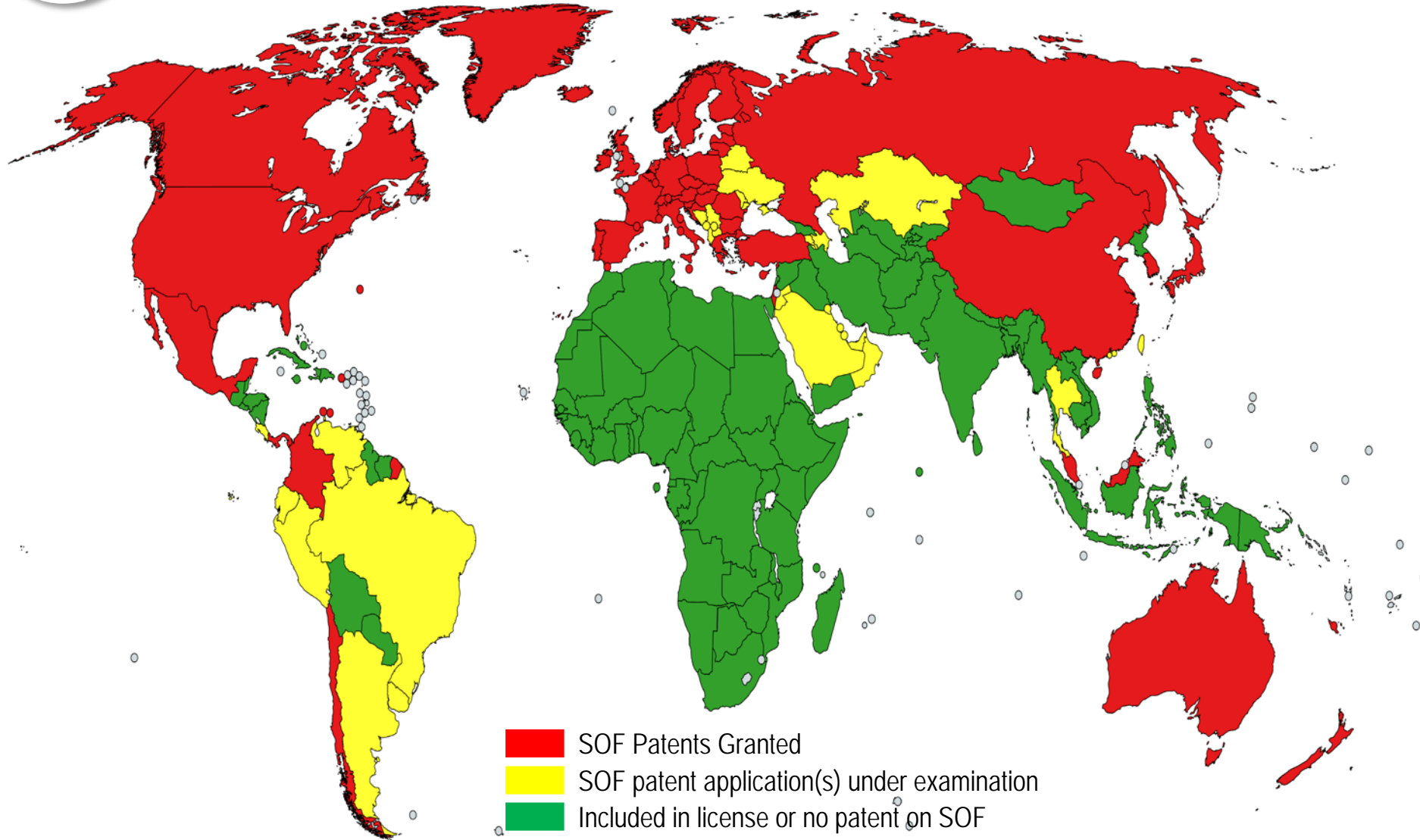
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# Non exclusive license – potential tech transfer



1

# RDV currently developed in combination with sofosbuvir (relevance of Sof IP landscape)



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2

# Partners engaged with DNDi to implement the HCV strategy

CSOs, Patient groups and NGOs: **MSF\*** South Centre\* C+, TWN, MTAAG+, MAC, TTAG, Ozone, Ifarma, DPN+, CoNE Manipur, MdM, TreatAsia

UNITAID & other donors

MoHs: Malaysia\* & Thailand\*

Other MoHs: Argentina Colombia

Regulatory Authorities

UNASUD & ISAGS

Presidio\*  
Regional Generic Malaysia\*  
Regional Generic LATAM\*  
Generic suppliers SOF/DCV  
Pharco\*

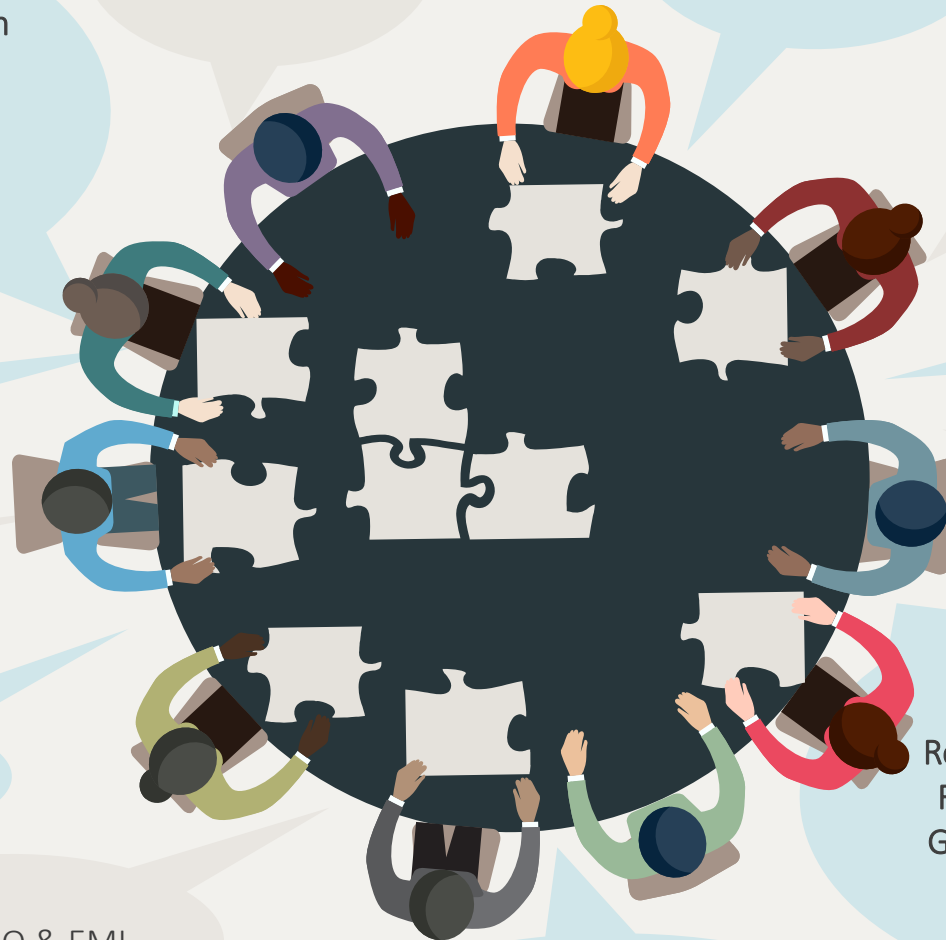
Research Partners\*  
CRM, PHPT, CRC

WHO-PQ & EML

PAHO Strategic Fund

MPP

FIND\*



2

## Countries tackling high prices

### Big pharma against CL move but WHO agrees

NATION

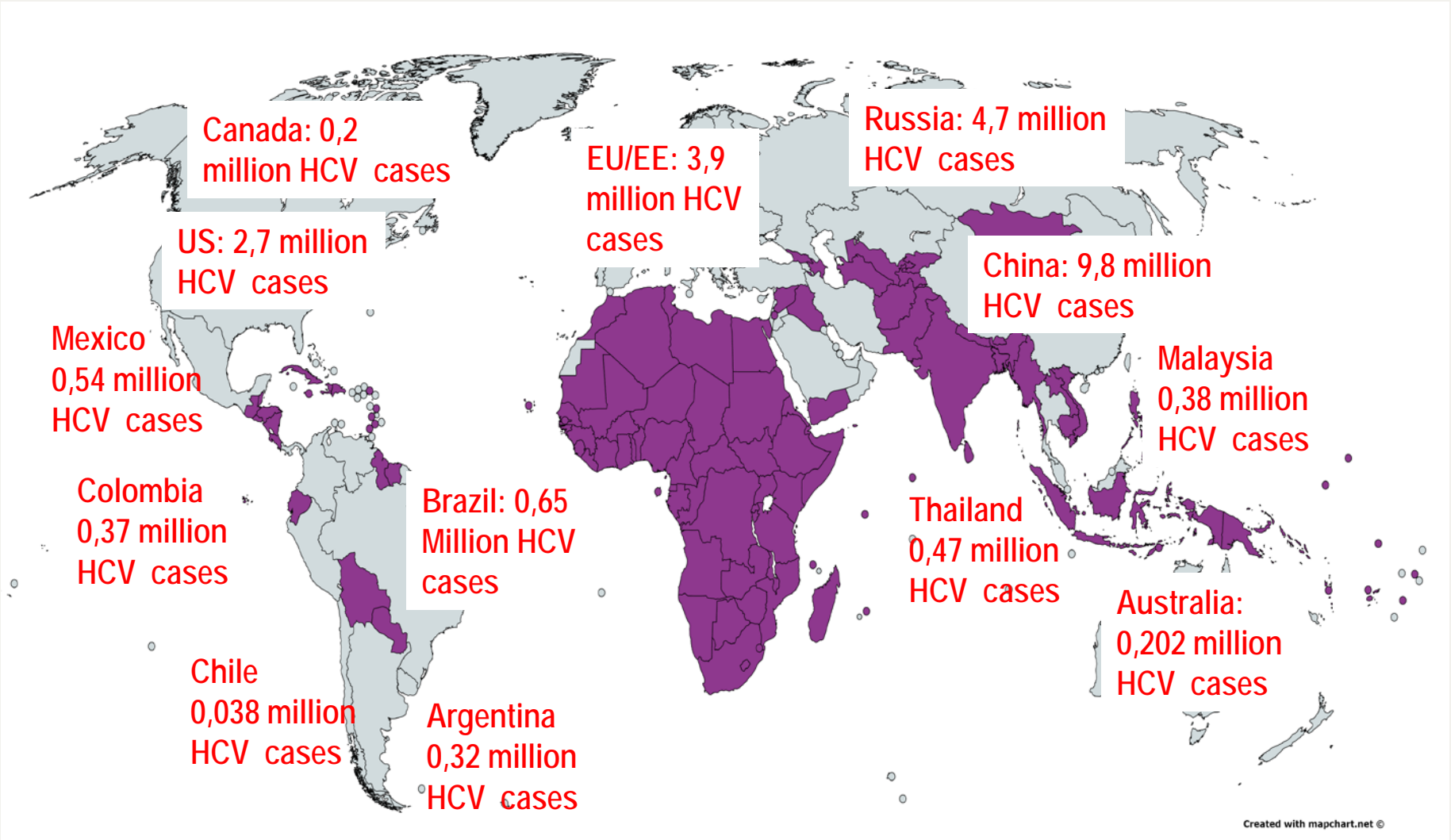
Friday, 2 Mar 2018



Right to get treatment: It was reported last year that there were 400,000 Hepatitis C sufferers in Malaysia, with only a fraction who could afford the RM300,000 cost. — AFP

2

# High Prevalence HCV countries excluded from affordable access : Need for action



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# THANK YOU

**DNDi**  
Drugs for Neglected Diseases initiative

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