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

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“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

<table>
<thead>
<tr>
<th>TARGET AREA</th>
<th>BASELINE 2015</th>
<th>2020 TARGETS</th>
<th>2030 TARGETS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact targets</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Viral hepatitis B and C diagnosis</td>
<td>&lt;5% of chronic hepatitis infections diagnosed</td>
<td>30%</td>
<td>90%</td>
</tr>
<tr>
<td>Viral hepatitis B and C treatment</td>
<td>&lt;1% receiving treatment</td>
<td>5 million people will be receiving hepatitis B virus treatment</td>
<td>80% of eligible persons with chronic hepatitis B virus infection treated</td>
</tr>
<tr>
<td></td>
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<td>(Both targets are cumulative by 2020)</td>
<td></td>
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<tr>
<td>3 million people have received hepatitis C virus treatment</td>
<td></td>
<td>80% of eligible persons with chronic hepatitis C virus infection treated</td>
<td></td>
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</tbody>
</table>
MAJOR GAPS IN VIRAL HEPATITIS CARE

TESTING GAP

<table>
<thead>
<tr>
<th></th>
<th>2015 BASELINE</th>
<th>2020 TARGETS</th>
<th>2030 TARGETS FOR ELIMINATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HEPATITIS B</strong></td>
<td>9%</td>
<td>20%</td>
<td>90%</td>
</tr>
<tr>
<td>(% OF PEOPLE DIAGNOSED)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HEPATITIS C</strong></td>
<td>20%</td>
<td>30%</td>
<td>90%</td>
</tr>
<tr>
<td>(% OF PEOPLE DIAGNOSED)</td>
<td></td>
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<td></td>
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</tbody>
</table>

TREATMENT GAP

<table>
<thead>
<tr>
<th></th>
<th>2015 BASELINE</th>
<th>2020 TARGETS</th>
<th>2030 TARGETS FOR ELIMINATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HEPATITIS B</strong></td>
<td>8%</td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td>(% OF DIAGNOSED PEOPLE ON TREATMENT)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HEPATITIS C</strong></td>
<td>7%</td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td>(% OF DIAGNOSED PEOPLE ON CURE)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
71 million people worldwide living with hepatitis C (HCV) infection in 2015

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

Only 2,86 million people treated in 2015-2016

~ 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

Source WHO http://www.who.int/mediacentre/factsheets/fs164/en/
DNDi Hepatitis C Strategy: 3 pillars

1. Accelerate R&D
   - Accelerating the development of promising drug candidates
   - with Pharma companies and Governments

2. Catalyse ACCESS
   - Supporting affordable access to all DAAs
   - with Pharma companies, Civil Society organisations, and 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

**PEOPLE TREATED**
- **Colombia**: 0.4%
- **Brazil**: 9.3%
- **Chile**: 4.0%
- **Argentina**: 0.6%

**TREATMENT PRICES**
- Sofosbuvir + daclatasvir
  - **Colombia**: USD 10,000
  - **Brazil**: USD 6,212
  - **Chile**: USD 12,000
  - **Argentina**: USD 7,800

Data source: Polaris/CDA

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

1. 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.
Ravidasvir license territory, March 2016
Non exclusive license – potential tech transfer
RDV currently developed in combination with sofosbuvir (relevance of Sof IP landscape)

- SOF Patents Granted
- SOF patent application(s) under examination
- Included in license or no patent on SOF
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

**PAHO Strategic Fund**

**UNAID & 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*

**MPP**

**Research Partners***

CRM, PHPT, CRC

**WHO-PQ & EML**
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
High Prevalence HCV countries excluded from affordable access: Need for action

- Brazil: 0.65 million HCV cases
- China: 9.8 million HCV cases
- Thailand: 0.47 million HCV cases
- Argentina: 0.32 million HCV cases
- Mexico: 0.54 million HCV cases
- Colombia: 0.37 million HCV cases
- Chile: 0.038 million HCV cases
- Canada: 0.2 million HCV cases
- EU/EE: 3.9 million HCV cases
- Russia: 4.7 million HCV cases
- Malaysia: 0.38 million HCV cases
- Australia: 0.202 million HCV cases
- US: 2.7 million HCV cases
THANK YOU