Access to hepatitis C treatment

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TREAT Asia/amfAR

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Outline

• Progress on policy
• What needs to happen to improve access
• Direct-acting agents (DAA)
  • Regulatory status of Indian generic DAAs
  • Pricing
• Regional treatment programs
• Alternate approaches to accessing DAAs
• Conclusion
Progress on policy

• Global Fund
  – September 2016: Expert review panel of Global Fund approves first generic sofosbuvir

• WHO
  – October 2015: WPRO approves regional action plan
  – May 2016: Release of global health sector strategy on viral hepatitis
  – April 2017: SEARO approves regional action plan
  – Ongoing: Prequalification assessments of sofosbuvir and daclatasvir, updates of guidelines
What needs to happen to improve access

• Find the patients and link them to care
• Register the drugs
• Make drugs more affordable
  – Egypt and India examples of major pricing reductions
• Expand pool of treating providers
  – Improve skills of non-specialist healthcare professionals to manage liver disease and implement treatment
DAAs for HCV in the region

- Sovaldi® (sofosbuvir)
- Harvoni® (ledipasvir/sofosbuvir)
- Daklinza®
- Generic sofosbuvir
- Generic ledipasvir/sofosbuvir
- Generic daclatasvir
## DAAs in the region: SEARO

<table>
<thead>
<tr>
<th>Country</th>
<th>Sofosbuvir</th>
<th>Ledipasvir/sofosbuvir</th>
<th>Daclatasvir</th>
<th>Olysio®</th>
<th>Velpatasvir/sofosbuvir</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>✓</td>
<td>Widely available</td>
</tr>
<tr>
<td>India</td>
<td>✓**</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>✓</td>
<td>Widely available</td>
</tr>
<tr>
<td>Indonesia</td>
<td>✓**</td>
<td>X</td>
<td>X</td>
<td>✓*</td>
<td>X</td>
<td>Limited availability through referral hospitals as part of “special assistance scheme”</td>
</tr>
<tr>
<td>Myanmar</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>X</td>
<td>Widely available</td>
</tr>
<tr>
<td>Nepal</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>✓</td>
<td>Widely available</td>
</tr>
<tr>
<td>Thailand</td>
<td>✓*</td>
<td>✓#</td>
<td>✓*</td>
<td>X</td>
<td>X</td>
<td>Widely available, except for Harvoni®</td>
</tr>
</tbody>
</table>

All DAAs are generic versions unless otherwise noted.

*Branded product  **Both branded and generic products  #Registered but not available
## DAAs in the region: WPRO

<table>
<thead>
<tr>
<th>Country</th>
<th>Sofosbuvir</th>
<th>Ledipasvir/sofosbuvir</th>
<th>Daclatasvir</th>
<th>Viekira pak®</th>
<th>Velpatasvir/sofosbuvir</th>
<th>Zepatier®</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodia</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>x</td>
<td>✓</td>
<td>x</td>
<td>Widely available</td>
</tr>
<tr>
<td>Malaysia</td>
<td>✓*</td>
<td>x</td>
<td>x</td>
<td>✓</td>
<td>x</td>
<td>x</td>
<td>Widely available</td>
</tr>
<tr>
<td>Philippines</td>
<td>✓*</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>Widely available</td>
</tr>
<tr>
<td>Vietnam</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>x</td>
<td>✓*</td>
<td>Limited availability through referral hospitals as part of “special import quota”</td>
</tr>
</tbody>
</table>

All DAAs are generic versions unless otherwise noted.
*Branded product  **Both branded and generic products
Indian generic DAA access: Licensed countries vs. actual registrations

- Sovaldi® FDA approval: Dec 2013
- Generic licenses signed: Sep 2014
- Harvoni® FDA approval: Oct 2014
- Daklinza® FDA approval: July 2015
- Licenses through MPP: Nov 2014

Sources: [http://www.gilead.com/responsibility/developing-world-access/viral%20hepatitis](http://www.gilead.com/responsibility/developing-world-access/viral%20hepatitis) and Indian generic manufacturers
# Sofosbuvir: Indian generic regulatory status

<table>
<thead>
<tr>
<th>Region</th>
<th>Completed drug registration</th>
<th>Drug registration under review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asia-Pacific</td>
<td>Bhutan, Cambodia, India, Indonesia, Mongolia, Myanmar, Nepal, Sri Lanka (8)</td>
<td>Pakistan, Philippines, Vietnam (3)</td>
</tr>
<tr>
<td>Africa and Middle East</td>
<td>Chad, Congo Republic, Cote d’Ivoire, Ethiopia, Gabon, Ivory Coast, Malawi, Mozambique, Nicaragua (9)</td>
<td>Benin, Botswana, Burkina Faso, Cameroon, Ghana, Guyana, Kenya, Liberia, Madagascar, Morocco, Mali, Namibia, Nigeria, Rwanda, Senegal, Sierra Leone, South Africa, Sudan, Tanzania, Togo, Tunisia, Uganda, Zambia, Zimbabwe (24)</td>
</tr>
<tr>
<td>Eastern Europe</td>
<td>Kazakhstan, Kyrgyzstan, Turkmenistan, Uzbekistan (4)</td>
<td>Belarus, Tajikistan (2)</td>
</tr>
<tr>
<td>Latin America</td>
<td>El Salvador, Guatemala (2)</td>
<td>Bolivia, Nicaragua, Honduras (3)</td>
</tr>
</tbody>
</table>

Source: Indian generic manufacturers
# Ledipasvir/sofosbuvir: Indian generic regulatory status

<table>
<thead>
<tr>
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<th>Completed drug registration</th>
<th>Drug registration under review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asia-Pacific</td>
<td>Cambodia, India, Mongolia, Myanmar (4)</td>
<td>Sri Lanka, Vietnam (2)</td>
</tr>
<tr>
<td>Africa and Middle East</td>
<td>Chad, Cote d’Ivoire, Gabon, Ivory Coast, (4)</td>
<td>Burkina Faso, Burundi, Cameroon, Congo, Liberia, Malawi, Mali, Mozambique, Senegal, Zambia (10)</td>
</tr>
<tr>
<td>Eastern Europe</td>
<td>Kyrgyzstan, Turkmenistan, Uzbekistan (3)</td>
<td>Tajikistan (1)</td>
</tr>
<tr>
<td>Latin America</td>
<td>El Salvador (1)</td>
<td>Guatemala, Nicaragua, Honduras (3)</td>
</tr>
</tbody>
</table>

Source: Indian generic manufacturers
# Daclatasvir: Indian generic regulatory status

<table>
<thead>
<tr>
<th>Region</th>
<th>Completed drug registration</th>
<th>Countries under review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asia-Pacific</td>
<td>Cambodia, India, Myanmar, Nepal (4)</td>
<td>Sri Lanka, Mongolia, Vietnam (3)</td>
</tr>
<tr>
<td>Africa and Middle East</td>
<td>Chad, Gabon (2)</td>
<td>Congo Republic, Benin, Burkina Faso, Cameroon, Mali, Liberia, Mozambique, Madagascar, Senegal, Togo (10)</td>
</tr>
<tr>
<td>Eastern Europe</td>
<td>Kyrgyzstan, Turkmenistan, Uzbekistan (3)</td>
<td>Tajikistan (1)</td>
</tr>
<tr>
<td>Latin America</td>
<td></td>
<td>Bolivia, Costa Rica, El Salvador, Nicaragua, Honduras, Guatemala (6)</td>
</tr>
</tbody>
</table>

*Source: Indian generic manufacturers*
## Velpatasvir/sofosbuvir: Indian generic regulatory status

<table>
<thead>
<tr>
<th>Region</th>
<th>Countries approved</th>
<th>Countries under review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asia-Pacific</td>
<td>Cambodia, India, Nepal (3)</td>
<td>Myanmar (1)</td>
</tr>
</tbody>
</table>

Source: Indian generic manufacturers
Price reductions in Indian generic HCV medicines for private purchase

Source: [www.hepcasia.com](http://www.hepcasia.com) in collaboration with community networks in India
Price reductions in Indian generic HCV medicines for government purchase

Source: Government of Punjab, India
Pricing variations between countries

USD per bottle

- India: SOF 60, LDV/SOF 83, DAC 23
- Indonesia: SOF 289, LDV/SOF 469, DAC 135
- Myanmar: SOF 220, LDV/SOF 300, DAC 90
- Vietnam: SOF 570, LDV/SOF 808, DAC 288
- Cambodia: SOF 280, LDV/SOF 705, DAC 288

Source: www.hepcasia.com
Personal communications, regional civil society organizations
Pricing in non-licensed countries

Source: www.hepcasia.com
Thailand and Malaysia prices: Gilead
Hong Kong SAR prices: Personal communications, local providers
National treatment programs

• Thailand
  – Provided under Universal Health Care from 2012 for Thai citizens above 18 years
  – Uses pegylated interferon and ribavirin regimen
  – Coverage criteria
    • Genotypes 1,2,3,6
    • HIV co-infection: CD4 more than 350 if on ART and 500 if not on ART
    • Fibrosis stage of F2 and above by FibroScan®
  – Have provided treatment to 4503 patients through 2016
National treatment programs

• India: Example of Punjab state
  – Approximately 600,000 viremic cases in the state
  – Initiated program in June 2016
  – Uses all oral DAAs
  – Coverage criteria
    • All fibrosis stage and all genotypes
    • If non-cirrhotic; 12 weeks daclatasvir and sofosbuvir
    • If cirrhotic; then genotyping is done and either ledipasvir/sofosbuvir OR daclatasvir/sofosbuvir given
  – 25,217 people treated as of April 2017
National treatment programs

• Mongolia
  – Coverage scheme: National health insurance covers 30-62% of medicine costs which are all oral DAAs
  – Rapid national registration process facilitated active price negotiations and promotion of generic competition

• Indonesia
  – National program for 6000 patients
  – Uses sofosbuvir, simeprevir, and ribavirin
  – Currently limited to Jakarta

• Vietnam
  – Coverage scheme: National health insurance covers 30% of treatment using peg-interferon
Alternate procurement methods of DAAs

- At the hospital level
  - Special import license
- At the patient level
  - “Named patient import”
  - ‘Buyers’ clubs
  - Large pharmacies in India
Conclusions

- Regional policy developments support expansion of treatment programs
- National health programs slow to meet need
  - Leadership
  - Fast-track drug registrations
  - Pricing negotiations
- Growing but limited availability of generic medications
- Broader prescriber pool to reach elimination targets
- More affordable price of medications
THANK YOU