Market access and uptake of new antiviral drugs for the treatment of hepatitis

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The new therapies & diagnostics have the potential to completely change the HCV treatment paradigm in 2014-2017

<table>
<thead>
<tr>
<th>Therapies</th>
<th>Point of Care New Diagnostics</th>
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<tbody>
<tr>
<td>» simeprevir (TMC-435)</td>
<td>» Immunoassays – MBio</td>
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<tr>
<td>» sofosbuvir (GS-7977)</td>
<td>» Qualitative RNA tests – Daktari, Mbio, Wave 80</td>
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<tr>
<td>» ABT-333/ ABT-450/r/ ABT-267</td>
<td>» Quantitative RNA tests – Alere, Daktari, Iquuum, Wave 80</td>
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<tr>
<td>» faldaprevir (BI-201335)</td>
<td>» Genotyping – Celera, Wave 80, Cepheid</td>
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<td>» daclatasvir (BMS-790052)</td>
<td>• Testing done in the field of office</td>
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<td></td>
<td>• Higher cure rates</td>
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<td>• Shorter duration of treatment</td>
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<td>• Fewer side effects</td>
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<td>• All oral therapies</td>
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<td>• Potential for lower cost</td>
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Source: UNTAID Hepatitis C Medicines and Diagnostics in the Context of HIV/HCV Co-Infection: A Scoping Report
Even before the launch of the protease inhibitors, there was considerable variability in the number of treated HCV patients.

The number of treated patients declined in 2013 across most countries in anticipation of new therapies.

Source: CDA’s analysis of Peg-IFN sales data in each country. Presented at EASL 2012.
HCV treatment rate has historically been low due to its low priority, efficacy, side-effects of current therapies.

On average, only 50% of the treated patients were cured.

Source: CDA’s analysis of Peg-IFN sales data in each country & prevalence of HCV by country. Presented at EASL 2012.
However, the HCV infected patients are aging and progression to late stage liver diseases

The number of HCV related cirrhotic cases will increase by 20%, decompensated cirrhosis by 30%, HCC by 40%, and liver related deaths by 40%.
A patient with fibrosis will cost the healthcare system $200-700 annually.

A patient with compensated cirrhosis will cost the healthcare system $500-$2,000 annually.

A patient with compensated cirrhosis will cost the healthcare system $5,000-$20,000 annually.
A patient with HCC will cost the healthcare system $5,000-$25,000 annually.

A liver transplantation will cost the healthcare system $50,000-$250,000.

Drug prices – determines access but there are many factors that influence the final price

- The pharmacoeconomic

**Lifetime Cost of a Male 30-35 years old (in the US)**

<table>
<thead>
<tr>
<th>Stage of HCV Progression</th>
<th>F0</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>Cirrhosis</th>
<th>Decomp Cirrhosis</th>
<th>HCC</th>
<th>Liver Trans.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lifetime Cost</td>
<td>$76,000</td>
<td>$95,800</td>
<td>$124,800</td>
<td>$144,700</td>
<td>$163,100</td>
<td>$205,900</td>
<td>$89,000</td>
<td>$384,000</td>
</tr>
</tbody>
</table>

- Reference pricing
  - Romania uses the minimum drug price any of the following countries – Austria, Belgium, Bulgaria, Czech Republic, Germany, Greece, Hungary, Italy, Lithuania, Poland, Slovakia, and Spain.

- Rebates
The drug price is only part of the story

• Add-on support
  » Reimburse the countries for the cost of diagnosis
  » Provide medical education for physician and nurses
  » Patient hotline to help with side effects/compliance

• Reimbursements
  » Patient assistant programs
Access is also determined by the complexity of needed diagnostics and treatment.

Source: UNTAID Hepatitis C Medicines and Diagnostics in the Context of HIV/HCV Co-Infection: A Scoping Report
Treating HCV is not a simple task
How do we provide access to the new therapies and diagnostics?

- Education of the stakeholders – Governments, companies, and patients
- National and international guidelines
- Simplifying treatment and diagnosis