New treatments for hepatitis C: strategies for achieving universal access

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Médecins du Monde - Advocacy Officer
VHPB London Meeting - 5/6 June 2015
Prices of new DAAs are exorbitant

<table>
<thead>
<tr>
<th>Country</th>
<th>Sofosbuvir (SOVALDI®)</th>
<th>Sofosbuvir+Ledipasvir (HARVONI®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>84,000 USD</td>
<td>94,500 USD</td>
</tr>
<tr>
<td>UK</td>
<td>47,400 €</td>
<td>52,800 €</td>
</tr>
<tr>
<td>France</td>
<td>41,000 €</td>
<td>46,000 €</td>
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<tr>
<td>Germany</td>
<td>56,500 €</td>
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<tr>
<td>Switzerland</td>
<td>60,000 €</td>
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</tr>
<tr>
<td>Spain</td>
<td></td>
<td>33,000 €</td>
</tr>
</tbody>
</table>

Concerns over sustainability even in high income countries
Cost burden of new DAAs prices for national health systems

- Cost of providing SOVALDI® to all HCV patients in France
- Annual budget of Parisian public hospitals (2013)
- French public health insurance deficit (2013)
Lessons learned from HIV
Generic competition is the most effective way in driving the price of medicines down

Prices of the first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP) from 2000 to 2006

- Lowest Originator $10439
- Lowest Originator $727
- Brazil $2767
- Cipla $350
- Hetero $295
- Aurobindo $209
- Cipla $255
- Cipla $132
- Hetero $147
- Hetero $153
- Hetero $147

USS per patient per year

Jun 00, Mar 01, Sept 01, Jun 02, Dec 03, Apr 04, Jun 05, Jun 06

Médecins Sans Frontières, Untangling the web of antiretroviral price reduction 14th Edition July 2011, utw.msfaccess.org
Overcome patent barriers: Compulsory licensing (CL)

» A flexibility of the WTO TRIPS Agreement

» A public health safeguard

» A tool for balance between patent holder’s private right and public interest

» A leverage to reduce costs
  » Brazil CL on Efavirenz resulted in US$ 94,798,855 savings from 2007-2011
  » In 2001 USA obtain great price reduction for ciprofloxacin (Cipro) by threatening Bayer with a CL
Industry-driven access strategies

- Donations
- Price reduction
- Tiered pricing policies
- Voluntary licensing (VL)
Geographical scope of Gilead VL on HCV drugs
Armenia’s annual health expenditure vs. cost of universal access to SOF

- **Total expenditure on health in Armenia (2012)**
- **Cost of providing sofosbuvir to the estimated number of people living with HCV in Georgia at US$ 2,000 p/p**

State-driven access strategies

» Public pricing

» Paybacks

» Parallel import

» Pooled procurement and/or pooled negotiation

» Compulsory licensing
Patent challenges

» A way to get a patent revoked

» On industrial criteria only

- Egypt rejected sofosbuvir patent application

- February 2015: MdM filed an opposition to Gilead’s patent on sofosbuvir at the European Patent Office --> joined by 9 other opposants

- Mai 2015: 5 new oppositions including in Russia and Ukraine
Minimum target prices for production of new AAD

Summary

» Price of medicine is an essential factor for treatment access

» Relying only on industry-driven access strategies will not succeed to achieve universal access to new HCV treatment

» Several leverage – including legal tools recommended by the WTO – are available for States to control drug price
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New Treatments for Hepatitis C Virus:

Strategies for Achieving Universal Access

By Pauline Landelé, technical advisor to Médecins du Monde, co-founder of ACT UP-Beauvais and advisor for the International Treatment Preparedness Coalition (ITPC).

With the contribution of Olisa Fardet, HIV Reduction, HIV/AIDS & Viral Hepatitis Advocacy Officer, Médecins du Monde.

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Thank you!

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