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Options for countries without access to generic hepatitis medicines
Introduction to Intellectual Property

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The briefest introduction to intellectual property (well...patents really) you have ever heard.
Function of patents

... to encourage inventors to make an investment in time and money in research and development by providing exclusive rights for a limited time in exchange for an early public disclosure of the invention.

Patent system is a social policy tool meant to create benefits for society.

But, it comes with a price...
### Cost of production and price

**New WHO Essential Medicines**

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Originator price intro US</th>
<th>Cost of production¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>bedaquiline</td>
<td>$ 30,000 (6 month)</td>
<td>$ 48 - 101</td>
</tr>
<tr>
<td>sofosbuvir (SOF)</td>
<td>$ 84,000 (12 week)</td>
<td>$ 68 - 136</td>
</tr>
<tr>
<td>SOF+ledipasvir</td>
<td>$ 95,000 (12 weeks)</td>
<td>$ 193</td>
</tr>
<tr>
<td>simeprevir</td>
<td>$ 66,360 (12 weeks)</td>
<td>$ 130 - 270</td>
</tr>
<tr>
<td>daclatasvir</td>
<td>$ 63,000 (12 weeks)</td>
<td>$ 10 - 30</td>
</tr>
<tr>
<td>imatinib</td>
<td>$ 30,000 - &gt;$100,000 (1 y)</td>
<td>$ 119 - 159</td>
</tr>
<tr>
<td>trastuzumab</td>
<td>$54,000 (1 y)</td>
<td>$ 242</td>
</tr>
</tbody>
</table>

# Industrial Profit Margins

The Most Profitable Industries In 2015

- Health Technology: 21% Net Margin
- Finance: 18%
- Technology Services: 15%
- Electronic Technology: 13%
- Consumer Non-Durables: 12%
- Transportation: 10%
- Consumer Services: 8%
- Utilities: 7%
- Producer Manufacturing: 6%
- Communications: 5%
- Process Industries: 4%
- Commercial Services: 3%
- Consumer Durables: 2%
- Industrial Services: 2%
- Health Services: 2%
- Retail Trade: 2%
- Energy Minerals: 1%
- Distribution Services: 1%
- Non-Energy Minerals: 1%

- 21% average pharma profit margin
- 53% Gilead Sciences profit margin
Some practical guidance for the procurement of generic medicines when medicines are not affordable and patented.
Least Developed Country?  

Yes →  

LDC pharmaceutical waiver →  

Buy generic from quality source →  

No →  

Medicine patented?  

Yes →  

Patent license agreement and your country is part of the territory?  

No →  

License agreement allows generic supply to a country with TRIPS flexibility?  

Yes →  

Government non-commercial use  

No →  

Are there other sources of generic product?  

Yes →  

TRIPS 31bis special CL for export (today not relevant for Hep-B C medicines)  

No →  

Buy generic from licensee  

Government non-commercial use  

How to access generic hepatitis medicine  

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Has this happened before?
2001 – 2016 Use of TRIPS flexibilities

![Graph showing use of TRIPS flexibilities from 2001 to 2016. The graph indicates a significant increase in the use of flexibilities, particularly for HIV treatments. The data shows a peak in 2004, with a notable rise in the use of flexibilities for non-communicable diseases (NCDs) in 2009 and 2010.](image-url)
Govt allows cheaper versions of Hep-C drug imports

By LOH FOON FONG
fconfong@thestar.com.my

PETALING JAYA: The Cabinet has given approval for Malaysia to issue government-use licences to enable the import of generic versions of the Hepatitis C drug Sofosbuvir.

Confirming this, the Domestic Trade, Cooperatives and Consumerism Ministry said some 460,000 Hepatitis C patients in the country will be able to benefit from cheaper drugs for use in public hospitals.

According to information from the ministry, the Health Ministry tabled a Cabinet paper on the implementation of government rights under Section 84 of the Patents Act last month and that it had agreed to it.

“The Health Ministry got approval from the Cabinet on the execution of these rights,” it said in response to questions from The Star.

The Patents Act comes under the purview of the Intellectual Property Corporation of Malaysia – known as MyIPO – under the ministry.

The government-use licence is only for drugs to be used in public health facilities.

Clinical trials are being conducted in cooperation with the Neglected Diseases Institute and an Egyptian generic company in a project to make available a generic version of Sofosbuvir, combined with another drug.

Since Sofosbuvir is patented, a government-use licence is needed to waive the monopoly right and enable the sale of generic drugs, acting as a key to affordable treatment.

Spread through blood and semen, the disease is caused by a virus that infects the liver, with many patients not even aware of having it until they discover liver damage.

In July, The Star had carried a front-page report that about 460,000 Malaysians were suffering from Hepatitis C but only a fraction could afford the medication, which might cost up to RM300,000 for the full course of treatment.

Malaysia is not given special pricing for drugs by pharmaceutical companies because it is considered a middle-income country.

It was reported that Gilead Science, an American research-based bio-pharmaceutical company, had announced its decision on Aug 24 to expand its HIV and Hepatitis C generic licensing agreement to Malaysia, Thailand, Ukraine and Belarus.

Local think-tank Galen Centre for Health and Social Policy chief executive officer Azrul Mohd Khalib said the granting of a Sofosbuvir voluntary licence by Gilead Sciences meant that it would be possible for lower-cost generic versions of this life-saving drug to be made available in Malaysia.

Positive Malaysian Treatment Access and Advocacy groups director Edward Low said the Cabinet’s approval of the government-use licence was a good move.

“It is a milestone in making Hepatitis C treatment accessible to Malaysians,” he said.

Low also said that government-use licence was a better choice than voluntary licence as this allowed a broader option of drugs that could be used.

When contacted, the Health Ministry said it would prepare a statement on the issue soon.
2001-2016 Use of TRIPS Flexibilities to Procure Generic Medicines
Are patent holding companies going to like this?

Most likely not. But remember, they have the power to lower the price or offer a license to allow generic supply.
For more information and model Government public non-commercial use licenses.

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