

Malaysia's Experience towards Access to Hepatitis C Treatment (Sofosbuvir – Compulsory License)

Tilak Ramanaidu

Hepatitis C : Public Health Issue



500,000 PATIENTS
WERE INFECTED
WITH **VIRAL**
HEPATITIS C
Genotype 1 (39%)
Genotype 3 (56%)

2000

ESTIMATED
NEWLY
DIAGNOSED
PATIENTS PER
YEAR



1:10 PATIENTS
ARE **FEMALE**

73%

PATIENTS WERE
THOSE IN THE
PRODUCTIVE AGE
BETWEEN 26 TO 50
YEARS OLD

Guiding Principles

World Health Organisation's (WHO) Global Health Sector Strategy on Viral Hepatitis 2016-2021
- to eliminate viral hepatitis as a major public health threat by 2030

World Health Assembly (WHA) resolution 63.18:
“recognized viral hepatitis as a global public health problem and the need for governments and populations to take action to prevent, diagnose and treat viral hepatitis”



WHA resolution 67.6:
“to consider, as necessary, national legislative mechanisms for the use of the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in order to promote access to specific pharmaceutical products”

Key Challenges In Access

- Patent barriers
- Affordability

“Hepatitis C drugs like sofosbuvir are compounds that are relatively simple and cheap to make,” said Dr. Andrew Hill, a pharmacologist at Liverpool University who has published a study showing that sofosbuvir could be produced for as little as \$101 for a 12-week treatment course. “Gilead has already sold over \$32 billion of two hepatitis C treatments in just over two years, with profit last year of \$18 billion. The continued profit projections for the oral hepatitis C drugs are staggering, and stand in no relation to what it costs to make these drugs.”

 **MSF Access Campaign** 
@MSF_access Follow

Gram for gram @GileadSciences #hepC drug #sofosbuvir is 67 times more expensive than gold! [twitter.com/RonWyden/statu ...](https://twitter.com/RonWyden/status/674074074074074074)



MEDICINES SHOULDN'T BE A LUXURY

Sofosbuvir
US\$ 1 000 per pill

Gram for gram, this hepatitis C drug is 67 times more expensive than gold

8:05 AM - 4 Dec 2015

107 Retweets 45 Likes



Government Use License

- “Public non-commercial use”
- **Government right** (government agency, department or contractor) to use patent in the public interest **without the consent of the patent holder.**
- Fast-tracker approach
- No need prior negotiation with patent holder
- Payment of “Adequate Remuneration” to patent holder

Malaysian Journey

NOVEMBER 2016 – AUGUST 2017:

Series of engagements between MOH , patent office, Ministry of Domestic, Trade, Cooperatives and Consumerism (MDTCA) , Ministry of International Trade and Industry (MITI) and legal advisors.

Dec 2015
Start of discussion
with Patent office
Malaysia

May 2016 - May 2017
A total of 8
engagements/correspondence
with the patent holder



Feb 2017
Cabinet
paper for
CL was
submitted

Aug 2017
CL approved
by the
Malaysian
Cabinet

Sep 2017
Approval for CL by
the Minister of
MDTCC and Press
Conference on CL
by the Minister of
Health

Oct 2017
Voluntary
license (VL)
inclusion



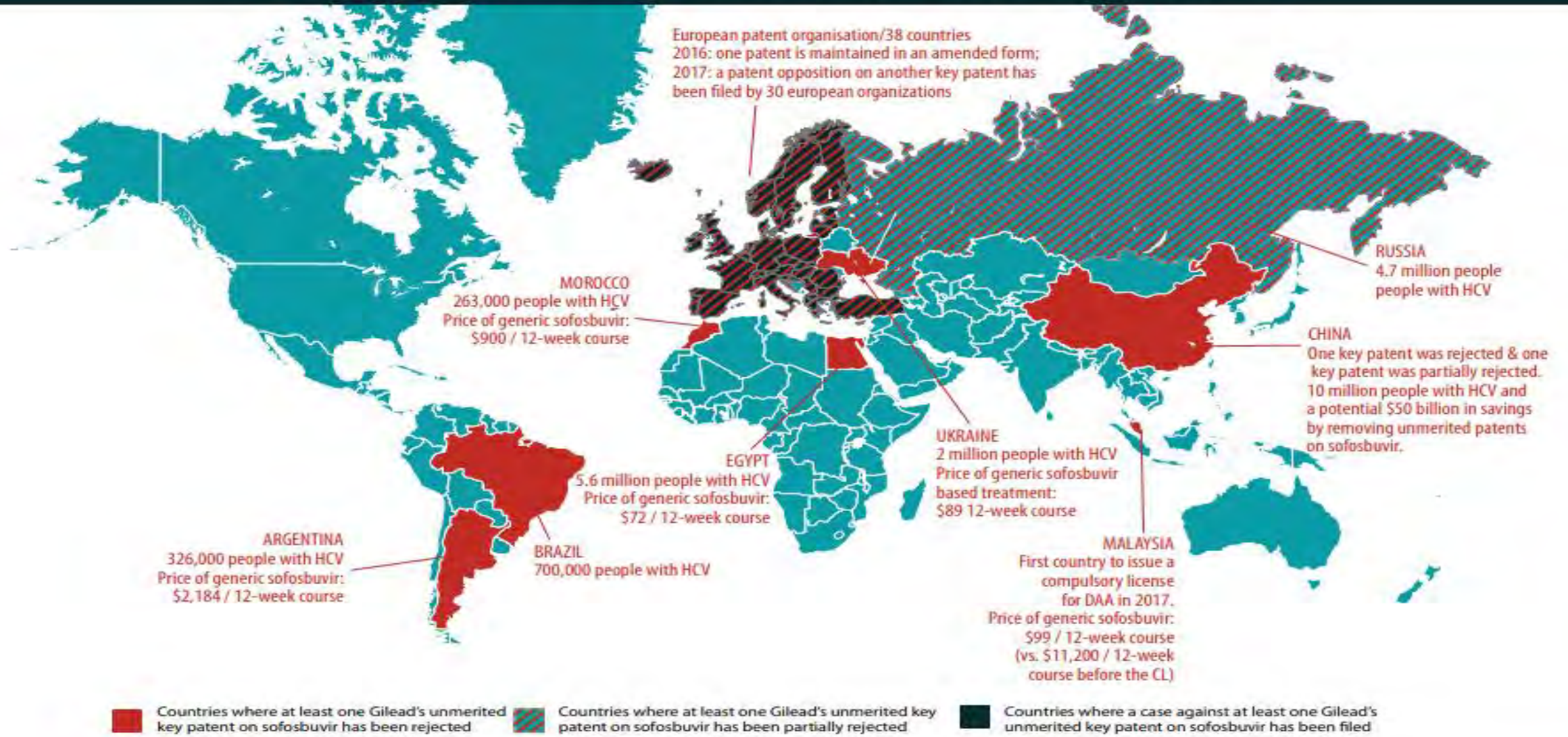
Oct 2016
Declare Hep C
as public health
problem

Nov 2016
Agreement
between MOH
and MDTCA to
exercise CL

*Aug 22: Gilead Sciences (GS) letter to Minister of Health to propose adding Malaysia into the VL program

*Oct 2: GS letter to Prime Minister of Malaysia informing the inclusion of Malaysia in VL program

GLOBAL SOFOSBUVIR INTERVENTION STATUS



The Implementation Process

Procurement of Sofosbuvir in accordance to requirements:

- a. TRIPS & Doha declaration
- b. Malaysia Patents Act 1983
- c. Government procurement procedures



Availability of generic Sofosbuvir

By March 2018, generic Sofosbuvir was available at 21 Public Specialist Hospitals.



Access To Treatment of Hep C



Challenges:

- **Meetings with Patent holder / Representatives of the U.S government / Chamber of Commerce [2 Oct 2017 – 18 July 2019]**

10

Patent Holder

Hon. Prime Minister
Hon. Minister of Health
Hon. Deputy Minister of Health
Hon. Minister DTCA
Hon. Deputy Minister MEA

7

US Embassy

Hon. Minister of Health
Hon. Minister MITI
DG of Health

American-Malaysia Chamber of Commerce (AMCHAM)
US Chamber of Commerce, Global Innovation Policy Center

White House Coordinator for Intellectual Property

Office of the US Intellectual Property Enforcement Coordinator

Challenges: Trade-related (301 Report)

Is Malaysia facing a US sanction on generic Hepatitis C drug?

Ahmad Wazir Aiman Mohd Abdul Wahab - February 20, 2019 8:30 AM

186
Shares



153



21



7



2



- The Trade associations Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Innovation Organization have called for Malaysia to be placed on the US Trade Representative's **Priority Foreign Countries watch list** in its "**2018 Special 301 Report**".
 - **The Government of Malaysia submitted our response through MITI U.S. In April 2018, the final report did not include Malaysia in the Priority Foreign Countries watch list . However, USTR announced that it will initiate Out of Cycle review for Malaysia to promote engagement and progress on specific IP opportunities and challenges.**
- **Again in 2019, PhRMA and BIO have called for Malaysia to be placed on the US Trade Representative's Priority Foreign Countries watch list in its "2019 Special 301 Report".**
- **Due for Out of Cycle Review 2019 in October**

NGOs Support letter to Malaysia

10th December 2018

YAB TUN DR. MAHATHIR BIN MOHAMMAD
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 Director General of Health Services,
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 Precinct Perdana,
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seri@kkesihatan.gov.my

Her Excellency

The Minister,
 Department of Health,
 to procure Sofosbuvir at affordable prices.

Sofosbuvir is the backbone treatment for Hepatitis C virus (HCV) infection. Globally it is estimated that around 71 million individuals around the world are currently living with the hepatitis C virus (HCV), with an additional 1.75 million becoming infected every year and 599,000 deaths annually. In Malaysia, it is estimated that at least 2.5% of the adult population is affected by hepatitis C. Many Malaysians infected with hepatitis C may not even be aware of their status. Sofosbuvir combined with daclatasvir, another direct acting anti-viral, is able to cure HCV infections at high rates of success with little side effect. Access to direct acting antivirals (DAAs), such as sofosbuvir and daclatasvir, which

¹ McCombell SA, Dhillon SK, Mahamad R, Young H, Gishorenblin PH, Ramnarayanan A. (2017) Prevalence of the Current and Past Disease Burden of Hepatitis C Virus Infection in Malaysia. *PLoS ONE* 12(8): e0178951. doi:10.1371/journal.pone.0178951

has set a landmark precedent for other governments to follow, as it is the first such license in the world for accessing affordable HCV treatment.

We would like to confirm that the Malaysian GU license is consistent with Article 11 of the WTO TRIPS Agreement. We also recall paragraph 4 of the 2001 WTO Ministerial Declaration on TRIPS and Public Health which states, "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health". The paragraph also affirms that "the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".

Further consensus expert reports and international instruments such as the World Health Assembly Resolution 63.4 on Essential and TRIPS, World Health Organization, Geneva, 2008, and the

is committed to promoting access to HCV treatment and meeting WHO targets, in addition to

18. Third World Network (TWN), Malaysia

19. Access International para la Salud, Peru
20. Act Up, Brazil, Switzerland
21. AIDS and Rights Alliance for Southern Africa (ARASA)
22. All India Drug Action Network (AIDAN), India
23. ARIE Foundation, India
24. Asia Pacific Network of People Living with HIV (APN+)
25. ARIE C Kazakhstan
26. Ashar Ale Society, Bangladesh
27. Access, France
28. (TWN) Access Foundation, Thailand
29. LAC - Global para el Acceso a Medicamentos (Regional Organization) of People who Use Drugs (ASOPUD)

30. Network of People Living with HIV (APN+),
31. Interdisciplinary AIDS Association (AIIA)
32. Network for Integration of Peoples (Kalay)
33. PLUS
34. La Voz de la Vida y Cooperación en Salud, Colombia
35. Access, France
36. Access, France
37. Access, France
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74. Access, France

10 Dec 2018 : 74 NGOs

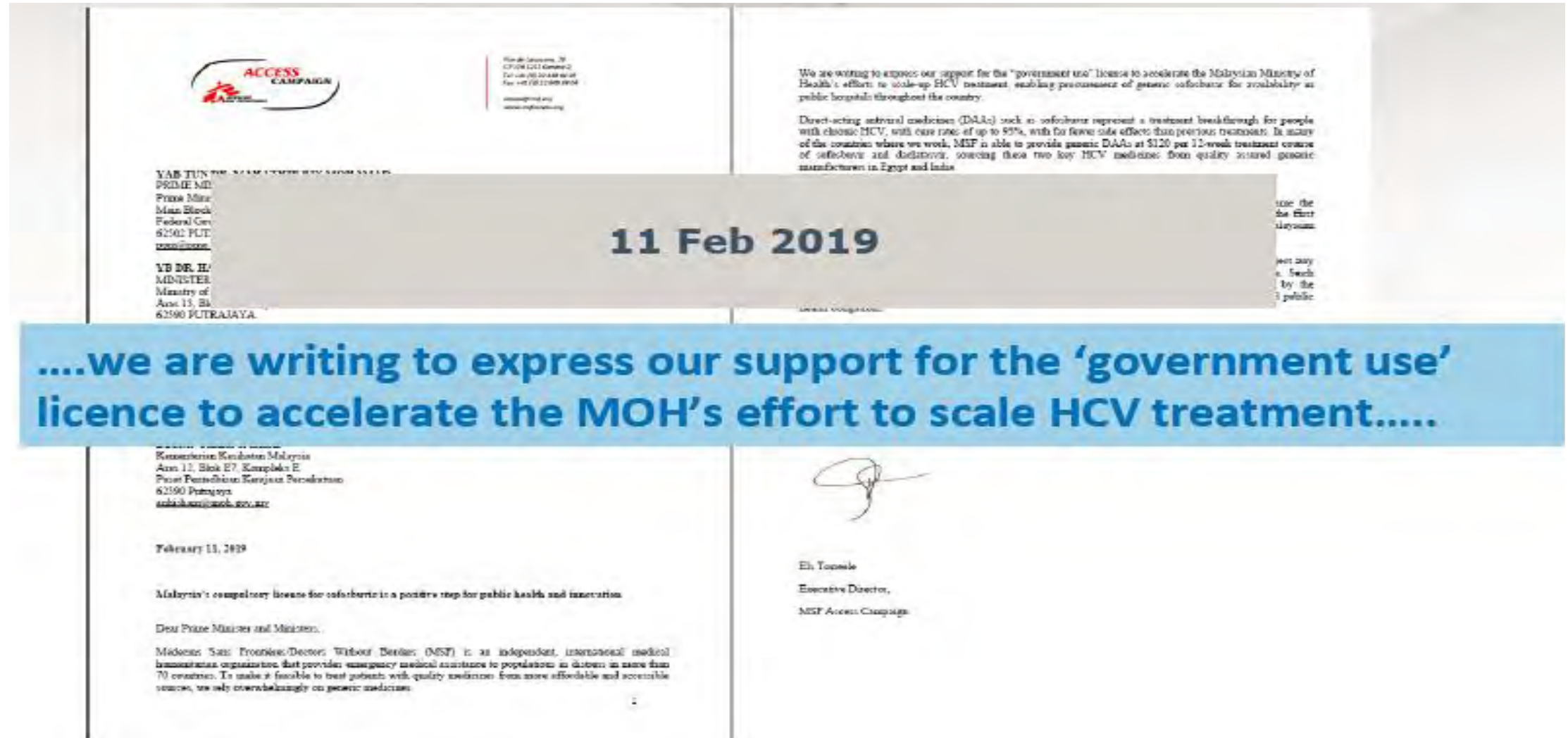
....we strongly support the GU that offers the Government the best option for urgently procuring HCV treatment at a price that MOH to sustainably scale up and make treatment available.....

14. Paralympik Islam Movement, Malaysia
15. Persatuan Kebajikan Komuniti Islam Malaysia
16. Puk Triangle Foundation, Malaysia
17. Positive Malaysia Treatment Access & Advocacy Group, Malaysia

58. Myanmar Positive Group (National PLHIV network)
59. NGO Menophasia Society Mumbai Chapter
61. PLHIV Network of Bangladesh

62. Red Latinoamericana para el Acceso a Medicamentos (RedLAM)
63. Sanjiv Rehabilitation Trust, Mumbai, India
64. Social Awareness Service Organization, India
65. STOPAIDS, UK
66. Thai Network of People Living with HIV/AIDS (TN+), Thailand
67. The Delhi Network of Positive People (DN+), India
68. The 100% Life (Roman AIDS-Ukrainian Network PLHIV), Ukraine
69. The Alliance LAC - Global para el Acceso a Medicamentos (Regional Organization)
70. Treatment Action Group
71. Working Group on Intellectual Property (GIP), Brazil
72. Universities Allied for Essential Medicines - Brazil (UAEM Brazil)
73. Usha Multipurpose Co-operative Society Limited, India
74. Yolo Public Health & Innovation

MSF Support letter to Malaysia



HCV and DNDI: Malaysian experience

TUESDAY 20 MARCH 2018 PP1641/03/2013 (031549) (No. 21383) RM1.30

THE Star

the people's paper

Nation
Redelineation up for debate soon
 Govt may table motion before lawmakers this week and fix next week to debate and pass it. >10

Nation
Proud parents to a baby girl
 Siti Nurhaliza and Datuk K welcome first child after 11 years of marriage. >3



World
Regional support
 EU ministers back Britain in spy poisoning case against Russia. >21



Star2
Creating art with nature
 Gardening enthusiast Kevin Teoh uses rocks, wood and plants instead of paint, to produce art. And the canvas is the aquarium. >2

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Hep C aid for free

Treatment of Hepatitis C with the drug sofosbuvir is now free for patients at 18 government hospitals. This comes after Malaysia initially brought down the cost of a full course from RM300,000 to just RM1,000 after its bold step of invoking the compulsory licence to import or make a generic version of the antiviral. The move will benefit 23,000 Hepatitis C patients currently registered with the Health Ministry, and ultimately the 400,000 nationwide who have the infection. > See Page 4 for reports by LOH FOON FONG and CLARISSA CHUNG

2,000 patients to get free Hep C treatment this year	18 government hospitals nationwide to provide treatment	23,000 Hep C patients registered with the ministry	400,000 patients estimated to benefit nationwide
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MALAY MAIL Friday April 13, 2018

M'sian trials lead to vastly cheaper hepatitis C drugs

PETALING JAYA — Treatment for hepatitis C used to cost nearly RM120,000 for a 12-week course, but now can be done for less than RM2,000 — a drop of more than 98 per cent — thanks to trials of an experimental drug in Malaysia.

Non-profit research and development organisation Drugs for Neglected Diseases initiative (DNDI) presented the result of its combination treatment, which yields cure rates as high as 97 per cent and would benefit millions of people, at the International Liver Conference in Paris.

"The results indicate that the sofosbuvir/ledipasvir combination is comparable to the very best hepatitis C therapies available today, but it is priced affordably and could allow an alternative option in countries excluded from pharmaceutical company access programmes," said its executive director Dr Bernard Pecoul in a statement on its website yesterday.

4 Nation

Patient who watched his friends die finally has hope

PETALING JAYA It has been a long 10-year wait for Hepatitis C patient Khairulnizam before finally being told he could be cured.

The 46-year-old, who works with a NGO, hopes to raise awareness of Hepatitis C among the public.

"There is a lack of awareness about this illness and we have to work to ensure there is early prevention," he said.

Khairulnizam added that his family was happy with the announcement and were holding out hope that he would finally be cured.

The 46-year-old, who works with a NGO, hopes to raise awareness of Hepatitis C among the public.

"There is a lack of awareness about this illness and we have to work to ensure there is early prevention," he said.

Khairulnizam added that his family was happy with the announcement and were holding out hope that he would finally be cured.

Free Hepatitis C treatment for all

PETALING JAYA NGOs are happy that patients can now be cured of Hepatitis C after the Government issued a compulsory licence to gain access to the effective drug.

The World Network (WN) programme director Chee Yee Ling said it welcomes this long-awaited day when Malaysia's treatment could finally be cured.

"We call on the Government to provide early diagnosis and early treatment so that everyone who needs it will get it," she said.

WN also urged the authorities to expand the availability of treatment to university hospitals under the Government initiative.

Drugs for Neglected Diseases Initiative (DNDI) South-East Asia regional office head Jean-Michel Peltre said he is not surprised at the world's move as far in providing life-saving Hepatitis C treatment to all.

"It shows that public political leadership is essential in promoting access to healthcare for the most vulnerable," he said.

Dr Peltre said the international non-profit drug research and development organisation, of which the Health Ministry is a member, has been working with Malaysia's Medical Association president Dr Davidson R. Naidu to provide the free Hepatitis C treatment as a step in the right direction.

"We hope this treatment programme is able to expand to the primary healthcare centres like district clinics because the oral medicines are easy to manage by trained physicians," said LOH when contacted.

2,000 patients need not pay at government hospitals this year

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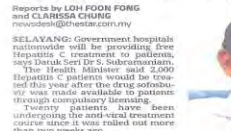
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REPORTS BY LOH FOON FONG AND CLARISSA CHUNG
 newsdesk@thestar.com.my

SELAVANG: Government hospitals nationwide will be providing free Hepatitis C treatment to patients, says Datuk Seri Dr S. Subramaniam.

The Health Minister said 2,000 Hepatitis C patients would be treated this year after the drug sofosbuvir was made available to patients through compulsory licensing.

Twenty patients have been undergoing the anti-viral treatment course since it was rolled out more than two weeks ago.

"This is a long-awaited moment for patients," he said during his visit to Hospital Selangor yesterday.

"We did not have an effective Hepatitis C treatment before and the new available drug is effective, and will save lives," he said, adding that the treatment had a cure rate of 99%.

The generic version of sofosbuvir is currently imported from Egypt, he said.

Dr Subramaniam said the 23,000 patients in the ministry's Hepatitis C registry would be treated in stages.

It has been estimated that 400,000 Malaysians are infected with Hepatitis C.

"We are starting treatment with a small number and will increase it," he said.

Dr Subramaniam said the ministry was also looking at more cost-effective testing so that it could carry out mass screening and provide treatment to more patients.

The access to the affordable medication came after the Government issued a compulsory licence (CL) to import sofosbuvir, one of the drug combinations used for Hepatitis C treatment.

The combination of sofosbuvir and ledipasvir is now being made available in stages at all 18 government hospitals nationwide.

(While sofosbuvir requires a CL, ledipasvir does not because the manufacturer did not apply for patent rights in Malaysia and the Government did not grant data exclusivity to it on public health grounds. Without the patent barrier, the Government is able to buy generic equivalents.)

This is a long-awaited moment for patients. Now, we are able to use a generic drug which can provide a cure and kill the virus.

Datuk Seri Dr S. Subramaniam

Last July, The Star carried a front-page report highlighting the plight of about 400,000 Malaysians who have Hepatitis C.

However, only a fraction could afford the medication, which may cost up to RM300,000 for the full course of treatment.

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

NGOs lobbied the Government to issue a CL so patients could gain access to the medication.

In September, the Domestic Trade, Co-operatives and Consumer Ministry notified that the Cabinet had issued a government-use CL to enable the import of generic versions of sofosbuvir.

Dr Subramaniam said that in registration with the drug compa-

ny offering sofosbuvir, the lowest price paid covered was RM50,000.

After the failed negotiations, the Government initiated the CL and managed to get the cost down to RM1,000 a patient, which it will now bear.

Malaysia is the first country in the world to invoke the CL for importing or producing the generic version of sofosbuvir.

A CL is an authorisation that does not require the permission of the patent holder.

Under the World Trade Organisation's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, countries have the right to issue such licences.

Asked why the Government decided to invoke the CL, Dr Subramaniam said the law allowed it for the greatest of public health.

"It is done purely for the interest of public health," he said.

"We respect the need for patients but we are also looking to those who used them," he said.

He added that Hepatitis C was a big public health issue and if it was left untreated, patients would suffer scarring and even cancer of the liver, and it was an infectious disease that could spread to others.

"We respect the need for patients but we are also looking to those who used them," he said.

He added that Hepatitis C was a big public health issue and if it was left untreated, patients would suffer scarring and even cancer of the liver, and it was an infectious disease that could spread to others.

Watch the video thestar.com



Non-profit's \$300 hepatitis C cure as effective as \$84,000 alternative

Exclusive: 71 million people stand to benefit from reduced price treatment for virus which can lead to liver cirrhosis, cancer and death

Julia Kollewe

Thu 12 Apr 2016 06:00 RST

An affordable hepatitis C treatment has been shown to be safe and effective, with very high cure rates for patients including hard-to-treat cases, in interim clinical trial results that offer hope to the 71 million people living with the disease worldwide.

The treatment is expected to cost \$300 for 12 weeks, or \$3.50 per day, in Malaysia, where trials were conducted along with Thailand – a fraction of the cost of other hepatitis C medicines produced by major drugmakers, which often run to tens of thousands of dollars.

The Drugs for Neglected Diseases initiative (DNDI), a not-for-profit organisation, is working with the Egyptian drugmaker Pharco Pharmaceuticals to bring a combination treatment of two hepatitis C tablets, sofosbuvir (a new drug) and sofosbuvir, to countries that cannot afford to pay the high prices charged by US companies Gilead and AbbVie. This is taking longer than expected but has moved a big step closer with the latest results.

The interim results of the phase II/III trial of 301 people will be presented in Paris on Thursday. It has been funded by Médecins Sans Frontières, one of DNDI's founding partners which also

NGOs laud ministry's efforts as a win for public health

NATION

Tuesday, 20 Mar 2018

PETALING JAYA: NGOs are happy that patients can now be cured of Hepatitis C after the Government issued a compulsory licence to gain access to the effective drug.

Third World Network (TWN) programmes director Chee Yoke Ling said it welcomed this long-awaited day when Malaysians who needed affordable Hepatitis C treatment could finally be cured.

She said the great efforts of the Health Ministry over several years had achieved a victory for public health.

"Malaysia is now able to buy generic sofosbuvir at one of the lowest prices in the world.

"We call on the Government to provide sufficient budget to scale up treatment so that everyone who needs it will get it" said Chee yesterday.

Big pharma against CL move but WHO agrees

KUALA LUMPUR: Malaysia's bid to impose compulsory licence (CL) on the drug sofosbuvir has been heavily criticised by big pharmaceutical companies, but has the support of the World Health Organisation (WHO).

WHO advocates universal health coverage, and that means access to lifesaving treatment, said the head of mission and representative to Malaysia, Brunei and Singapore Dr Lu Yong-Pei.

She said Malaysia, by wanting to provide universal health coverage with limited funding, had decided to make sofosbuvir available for its healthcare system.

Asked how WHO views the pressure Malaysia is facing after issuing a CL for the generic version of sofosbuvir, Dr Lu said: "I understand the Malaysian Government is adhering to the World Trade Organisation's TRIPS Trade-Related Aspects of Intellectual Property Rights agreement.

"It is a global agreement which all should respect."

Last July, The Star carried a front page report highlighting the plight of about 400,000 Malaysians who have Hepatitis C. However, only a fraction could afford the medication which may cost up to RM300,000 for the full course of treatment.

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

NGOs had lobbied the Government to issue a CL so patients could gain access to the medication.

In September, the Domestic Trade, Cooperatives and Consumerism Ministry confirmed the Cabinet had issued power-

ment-use licences to enable the import of generic versions of sofosbuvir.

Since then, big pharmaceutical companies had been pressuring Malaysia to retract its position, as it discourages innovation.

They claimed Malaysia risked being put on the US Watch List on IP-related trade barriers.

Recently, the Pharmaceutical Research and Manufacturers of America (PhRMA) urged the US Trade Representative (USSTR) to take action "to address serious market access and intellectual property barriers" in 19 overseas markets.

It urged the Office of the USSTR

and other federal agencies to pressure the CL in Malaysia and end "discriminatory pricing policies" in Canada, Japan and South Korea.

US-based NGO Public Citizen defended the measures using CL, saying that issuing the licence does not override a patent right.

"Rather, the right reserved by the Government to make use of an invention is embedded in the initial grant of every patent," it said.

Public Citizen also pointed out the patent owner could nullify the medicine and retain the exclusive right to sell to private providers and hospitals.

"We go by the book," he said in reply to The Star, adding that it was a government's right to do so.

Malaysia for its TRIPS-compliant public health policy," it said.

It defended Malaysia's stand as the hepatitis C disease burden was high and projected to rise steadily owing to limited antiviral treatment and the high cost of sofosbuvir.

The treatment price of around RM300,000 is beyond the reach of many Malaysians.

Health director general Haniffa Saif Dr Noor Hisham Abdullah said the Government did not violate any laws or agreements when issuing the CL.

"We go by the book," he said in reply to The Star, adding that it was a government's right to do so.

Malaysia

MOH to propose importing generic Hepatitis C meds

BY YISWAREE PALANSAMY
MARCH 14, 2017

UPDATED: MAR 14, 2017 06:50 PM



Datuk Seri Dr S. Subramaniam says the Health Ministry will propose importing generic drugs to treat Hepatitis C. — Bernama pic

KUALA LUMPUR, March 14 — The Health Ministry will table a working paper to the Cabinet committee for approval to import of generic drugs to treat Hepatitis C.

In a parliamentary written reply to DAP's Klang MP Charles Santiago, Health Minister Datuk Seri Dr S. Subramaniam said this was due to the high price of nearly RM300,000 to treat each patient using Sofosbuvir in conjunction with other medication.

"One way to get cheaper Sofosbuvir, is to use 'hak kerajaan' (government roll), whereby the Malaysian government will be able to import generic Sofosbuvir, which is way cheaper compared to innovator Sofosbuvir, with certain conditions.

Thank you