

The Journey of Government Use Licences on Hepatitis C: The Experience of Malaysia



MALAYSIA: HEPATITIS C INFECTION AS A PUBLIC HEALTH ISSUE



453,700 PATIENTS
WERE INFECTED WITH
VIRAL HEPATITIS C

Genotype 1 (39%)

Genotype 3 (56%)

(2010)

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

OUR GUIDING PRINCIPLES TO ELIMINATE VIRAL HEPATITIS

To achieve United Nation Sustainable Development Goals (SDG) Goal 3

- by 2030, i) to end preventable death of newborns and children under 5 and
- ii) to **end epidemics such as AIDS**, tuberculosis, malaria and water-borne diseases



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”

DIRECT ACTING ANTIVIRALS (DAAs) AS A NOVEL TREATMENT TO HEPATITIS C

Treatment
Administration
Duration of treatment
Efficacy
Side Effect
Cost of treatment per patient

CURRENT TREATMENT

Interferon/ Peginterferon + Ribavirin

Injection

48 weeks

Suboptimal (cured half of treated patient)

Severe, intolerable (53.7% did not get treatment due to contraindication)

USD 3,052-10,729
RM12,813 - 45,036

VS

NEW TREATMENT

Oral Direct Acting Antivirals (DAAs) Sofosbuvir + other DAAs

Oral

12 weeks

Cure rates of over 90%

Less side effects

SOFOBUVIR	OTHER DAAs
>USD 36,000	Variable
> RM150,000	prices

LOOKING AT CURRENT PROVISIONS

➤ TRIPS Agreement 1995 set the standards for international property protection and is binding to WTO members.

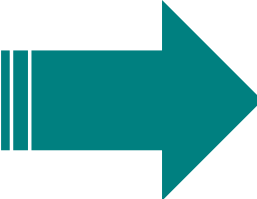
TRIPS Agreement ARTICLE 31

Compulsory License

- The use of a patented invention by a third party e.g. a generic manufacturer without the authorization of the patent holder.
- Terms and conditions apply
- Malaysia's adoption : Malaysian Patents Act 1983 (Act 291) – Sect. 48-54

Government Use

- Authorization for public non-commercial purpose.
- Terms and conditions apply
- Malaysia's adoption : Malaysian Patents Act 1983 (Act 291) Section 84



The adoption of the **Doha Declaration on TRIPS and Public Health by the 2001 Ministerial Conference of the World Trade Organisation (WTO)**, had accordingly affirmed the right of national governments to take measures to protect public health, and confirmed the legitimacy of the broad use of the flexibilities available in TRIPS to promote access to medicines

CONTINUATION OF OUR 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

Aug 2016
2nd price
negotiation



Feb 2017
Cabinet
paper for
CL was
submitted

Aug 2017
CL approved
by Malaysian
Cabinet, 3yrs
Procurement
2+1

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

Oct 2017
Voluntary
license (VL)
inclusion

May 2016
1st price
negotiation

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

OUR JOURNEY (short version)

May 2016 - May 2017
**8 sessions of
engagements with the
patent holder**

Aug 2017
**Use of RoG
approved by the
Cabinet
(3 years for CL)
(Procurement 2+1)**

Oct 2017
**Voluntary license
(VL) inclusion
(Fastrack from
120 to 90 days)**

Dec 2015
**Discussion
with MyIPO**

Oct 2016
**Declare Hep C
as public
health problem**

Sep 2017
**Approval for
RoG by the
Minister of
MDTCA**

*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

Announcement: Availability of generic Sofosbuvir in Malaysia – 19th March 2018



The Ministry of Health is pleased to announce that the Hepatitis C treatment program will commence in beginning of March 2018 at **21 designated government hospitals**. Patients will be able to receive treatment from the relevant specialists based on a set of criteria.

The generic Sofosbuvir 400mg tablet was procured at an **affordable price** through the implementation of the Rights of Government for public non commercial use.

All the steps and efforts taken thus far reflects the government's concern over the Malaysian public's health and to preserve the best interest of the Rakyat in the nation.



THE IMPLEMENTATION PROCESS

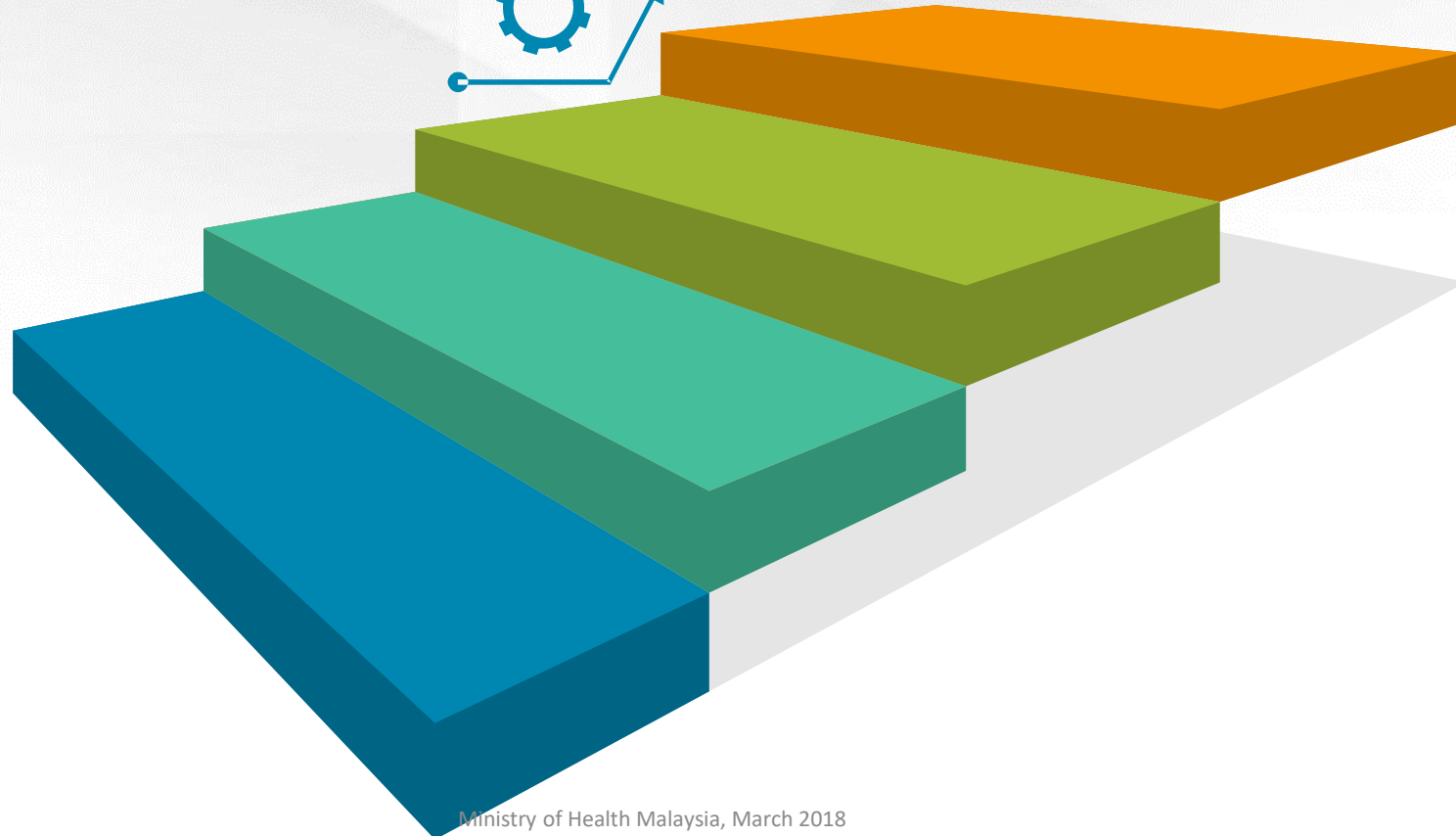
Procurement of Sofosbuvir in accordance to requirements:

- 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 : 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

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- 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

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Re: Government of Malaysia

The undersigned support for the Government of Malaysia's decision to procure generic 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 399,000 deaths annually. In Malaysia, it is estimated that at least 2.5% of the adult population is affected by hepatitis C.¹ 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 McDonald SA, Dabhi M, Mohamed R, Nasing H, Shabaruddin FH, Kamaruluzman A (2015) Projections of the Current and Future Disease Burden of Hepatitis C Virus Infection in Malaysia. PLOS ONE 10(6): e0128091. doi:10.1371/journal.pone.0128091

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 31 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 numerous expert reports and international instruments such as the World Health Assembly Resolution 67.6 on Medicines and WHO's Universal Health Coverage Global Strategy encourage governments to

10 Dec 2018 : 74 NGOs

is committed to promoting access to HCV treatment and meeting WHO targets, its decision to

...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. Pertubuhan Islam Movement, Malaysia
15. Persatuan Kebajikan Komuniti Bhd/Malaysia
16. Pink Triangle Foundation, Malaysia
17. Positive Malaysian Treatment Access & Advocacy Group, Malaysia

18. Third World Network(TWN), Malaysia

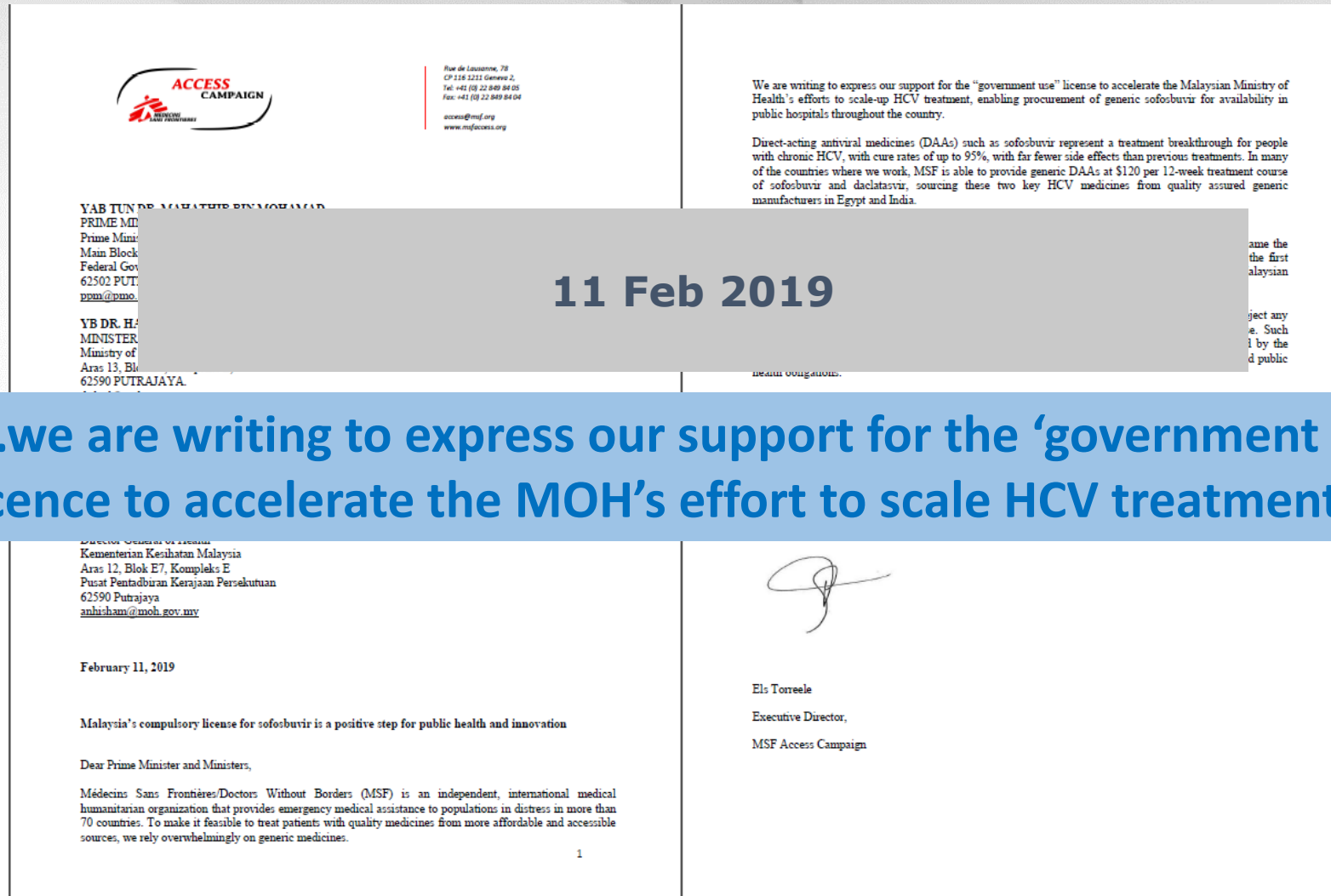
19. Accion Internacional para la Salud, Peru
20. Act Up-Basel, Switzerland
21. AIDS and Rights Alliance for Southern Africa (ARASA)
22. All India Drug Action Network (AIDAN), India
23. ARK Foundation, India
24. Asia pacific network of people living with HIV (APN+)
25. AGEP' C Kazakhstan
26. Ashar Alo Society, Bangladesh
27. Access, France

28. Access Foundation, Thailand
29. LAC - Global por el Acceso a Medicamentos (Regional Organization)
30. Network of People who Use Drug (ANPUD)
31. Network of People Living with HIV (APN+)
32. Interdisciplinary AIDS Association (ABIA)
33. Network for Integration of Peoples (Rebrip)
34. PLUS
35. de Veeduría y Cooperación en Salud, Colombia
36. cion Innovarte Chile
37. India
38. dy Group, Thailand
39. stem Monitoring & Development Center (DMDC), Thailand
40. Luroor Mahila Samanwaya Committee, India
41. Eurasian Community for Access to Treatment (ECAT)

58. Medecins Sans Frontières Access Campaign
59. Myanmar Positive Group (National PLHIV network)
60. NGO Hemophilia Society Mumbai Chapter
61. PLHIV Network of Bangladesh

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

MSF Support letter to Malaysia



TOWARDS UNIVERSAL COVERAGE – WHAT IS NEEDED?



PROGRESS REPORT ON ACCESS TO HEPATITIS C TREATMENT

FOCUS ON OVERCOMING BARRIERS IN LOW- AND MIDDLE-INCOME COUNTRIES

MARCH 2018



- Strong national responses are needed
- Market competition will lead to reduced prices
- Greater market transparency would facilitate price cuts
- Increased financing options should be sought
- Quality assurance and registration of medicines and diagnostics are needed

EXPANDING ACCESS



Increase coverage of screening and diagnostic services

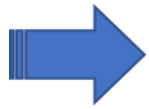
- 43 hospitals from 21 hospitals
- Decentralise treatment to 24 health clinics
- Partnership with FIND diagnostics
- Free screening campaign at 105 health facilities nationwide.

Increase competition to drive down treatment prices

- Competitive market pricing for VL products for new tender.

Increase budgetary allocation for Hep C Treatment

- Budget allocation increased 38% from last year



“We must not tolerate systems that put the protection of intellectual property ahead of the protection of health. Patients must always come before patents.’

*Director General of Health World Health Organization
WHO-WIPO-WTO Technical Symposium on Sustainable Development Goals:
Innovative technologies to promote healthy lives and well-being
26th February 2018*



“ I hope all of us here today, will live to see the day when viral hepatitis will be eliminated by 2030 and by then hepatitis will be a rare cause of morbidity and mortality in Malaysia.’

*Director General of Health Malaysia
National Hepatitis Symposium
1st March 2018*



“I understand the Malaysian Government is adhering to the WTO TRIPS agreement. It is a global agreement which all should respect.

*WHO representative to Malaysia, Brunei and Singapore
National Hepatitis Symposium
1st March 2018*

MEDIA HIGHLIGHTS

Urgent action needed on Hepatitis C

GLOBAL TRENDS

Monday, 31 Jul 2017

It's not acceptable that 500,000 M'sians are infected with the disease but cannot afford treatment, when a total cure is available.

Hepatitis C cure too expensive in Malaysia

Posted on 20 October 2015 - 02:38pm

Last updated on 20 October 2015 - 02:47pm

Timothy Asarian



Report: Cabinet approves compulsory licence for Hepatitis C generics

Action at last on Hepatitis C?

GLOBAL TRENDS

The decision to issue a government-use licence to make a generic drug available is a breakthrough in the fight to cure 500,000 Hepatitis C patients in Malaysia.

US firm expands Hepatitis C generic licensing agreement to Malaysia

Malaysia wins award for access to affordable hepatitis C medicine

NATION

Thursday, 18 Jan 2018

12:18 PM MYT

PETALING JAYA: Malaysia has received the Leadership Award in Intellectual Property and Access to Medicines for invoking the Sofosbuvir compulsory licence to gain access to hepatitis C medicine at an affordable price.

The Malaysian Government received the award at the Global Summit of Intellectual Property and Access to Medicines on Monday (Jan 15) in Morocco, said Health director.



Hope for Hepatitis C patients

NATION

Tuesday

NATION

Friday, 2 Mar 2018

KUALA LUMPUR: Two months after Malaysia received world recognition for taking steps to provide affordable medicine for Hepatitis C sufferers, it is learnt that 18 state hospitals are ready to roll out the treatment, with up to 400,000 patients likely to benefit.

This access to the affordable medicine comes after the Government issued a compulsory licence (CL) to import or produce the generic versions of sofosbuvir - one of the drug combinations used for Hepatitis C treatment.

The combination of sofosbuvir and daclatasvir is now available in all government state



Big pharma against CL move but WHO agrees

NATION

Friday, 2 Mar 2018



KEY SUCCESS FACTORS



KEY MESSAGES MOVING FORWARD

MOH needs to be at the forefront to push for accessibility of medicines that of public health's concern as a **national agenda**

Understanding the flexibilities in TRIPS Agreement to meet public health needs

A strong joint commitment from key stakeholders local and global to protect the public's health

THANK YOU

Kuala Lumpur, Malaysia

