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)

2,000 newly diagnosed patients per year.

1:10 patients are female.

73% patients were those in the productive age between 26 to 50 years old.

Ministry of Health Malaysia, March 2018
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**

<table>
<thead>
<tr>
<th>CURRENT TREATMENT</th>
<th>NEW TREATMENT</th>
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<tbody>
<tr>
<td><strong>Treatment</strong></td>
<td>Oral Direct Acting Antivirals (DAAs) Sofosbuvir + other DAAs</td>
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<tr>
<td><strong>Administration</strong></td>
<td>Oral</td>
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<tr>
<td><strong>Duration of treatment</strong></td>
<td>12 weeks</td>
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<tr>
<td><strong>Efficacy</strong></td>
<td>Cure rates of over 90%</td>
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<tr>
<td><strong>Side Effect</strong></td>
<td>Less side effects</td>
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<tr>
<td><strong>Cost of treatment per patient</strong></td>
<td><strong>SOFOSBUVIR</strong></td>
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<tr>
<td></td>
<td>&gt;USD 36,000</td>
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<td>&gt; RM150,000</td>
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<tr>
<td></td>
<td><strong>OTHER DAAs</strong></td>
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<td></td>
<td>Variable</td>
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<td>prices</td>
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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
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

**May 2016**
1st price negotiation

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

**Nov 2016**
Agreement between MOH and MDTCA to exercise CL

**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

*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
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 Sofosvubir 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.
Procurement of Sofosbuvir in accordance to requirements:

- TRIPS & Doha declaration
- Malaysia Patents Act 1983
- Government procurement procedures

Availability of generic Sofosbuvir

By March 2018, generic Sofosbuvir was available at 21 Public Specialist Hospitals.
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
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......
we are writing to express our support for the ‘government use’ licence to accelerate the MOH’s effort to scale HCV treatment.....
TOWARDS UNIVERSAL COVERAGE – WHAT IS NEEDED?

- 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

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

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.

Report: Cabinet approves compulsory licence for Hepatitis C generics

Action at last on Hepatitis C?

The Malaysian Government has received the Leadership Award in Intellectual Property for its effort to make affordable generic Hepatitis C treatments available.

US firm expands Hepatitis C generic licensing agreement to Malaysia

Hope for Hepatitis C patients

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 hospitals.

Big pharma against CL move but WHO agrees

PETALING JAYA: Malaysia has received the Leadership Award in Intellectual Property 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 in London the day before the biannual event opens.

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**KEY SUCCESS FACTORS**

**OPEN PLATFORM**
- Continuous discussions with patent holder to reach for an agreement
- Engagements with PhAMA, MOPI etc

**ENGAGEMENT BETWEEN GOVERNMENT AND PHARMACEUTICAL INDUSTRIES**

**STRONG LEADERSHIP & POLITICAL WILL**
- ADVOCATORS AND DRIVERS
  - Minister of Health
  - Director General of Health
  - Secretary Generals of MOH & MDTCA
  - Senior Director of Pharmaceutical Services MOH

**STRONG COLLABORATION WITH OTHER MINISTRIES, MULTI-AGENCIES, NGOs**
- STRONG SUPPORT NETWORK
  - Ministry of International Trade and Industry (MITI)
  - Ministry of Domestic Trade and Consumer Affairs (MDTCA)
  - Malaysia Patent Office (MyIPO)
  - Local and Global NGOs

Ministry of Health Malaysia, March 2018
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