



Persatuan Pengguna Pulau Pinang Consumers Association of Penang

檳城消費人協會 பினாங்கு பயனீட்டாளர் சங்கம்

10 Jalan Masjid Negeri, 11600 Pulau Pinang, Malaysia
Tel: 604-8299511 Fax: 604-8298109
email: consumerofpenang@gmail.com

Websites:
www.consumer.org.my

Press Statement

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CAP Applauds Government Decision to Issue Government Use License for Hepatitis C Drug, which can save hundreds of thousands of lives

The Consumers Association of Penang welcomes and applauds the Malaysian government's decision to issue a government use license that will enable the government to import medicines for Hepatitis C treatment at the lowest possible prices and cure the hundreds of thousands of Malaysians infected with Hepatitis C virus (HCV).

According to various reports and reliable sources, this decision was taken by the Cabinet on 4 August 2017.

The government's action to issue the government use license is perfectly legal under Section 84 of the Malaysian Patents Act to address barriers imposed by patents that lead to prohibitive drug prices, and is in line with the rules of the World Trade Organisation (WTO), specifically its TRIPs Agreement (Trade-related Intellectual Property Rights Agreement).

HCV is a major national and international concern. It is highly infectious and a major cause of mortality, with 400,000 deaths a year worldwide.

In Malaysia, it is estimated that about 2.5% of the adult population (i.e. about 500,000) is infected with Hepatitis C. Many more are likely to be affected, as most people infected with HCV are unaware of their status until it has progressed to advanced liver disease, liver failure or cancer.

In recognition of its public health importance, the United Nations General Assembly, as part of the 2030 Agenda for Sustainable Development, called for specific action to combat viral hepatitis.

In May 2016, the World Health Assembly adopted the first "Global Health Sector Strategy on Viral Hepatitis, 2016-2021", which set out a vision of eliminating viral hepatitis as a public health problem by 2030.

Until recently, Hepatitis C treatment was based on therapy with *pegylated* interferon and *ribavirin* which required weekly injections of 24 to 48 weeks. The therapy has poor treatment outcomes and life-threatening side-effects.

The availability of oral direct acting antivirals (DAAs) has revolutionized treatment with cure rates exceeding 90% and shorter treatment duration with good safety profiles. In short, Hepatitis C can now be cured with a simplified and relatively safe oral regimen.

However prohibitive prices has hindered access and use of these anti-virals in Malaysia. Very few Malaysian patients have been able to use the new drugs.

In July 2017, news reports cited Hepatitis C experts at the Universiti Malaya as stating that the cost of full treatment per patient may be up to RM300,000.

The exorbitant prices are due to patent monopolies held by multinational pharmaceutical companies existing over the anti-virals, in particular sofosbuvir, which is the backbone anti-viral for any HCV treatment regimen. The monopoly and unsustainable prices charged has been at the expense of the lives and health of hundreds of thousands of patients and this is simply unacceptable.

Thus, we strongly welcome Malaysian government's decision to issue a government license that will enable the government to urgently source and secure the supply of Hepatitis C treatment from generic drug companies. A government use license, similar to a compulsory license, allows for the sale of generic versions of a patented drug. Without this license, only the patented version is allowed to be sold.

The Ministry of Health is conducting clinical trials in Malaysia of relevant Hepatitis C drugs in cooperation with the Geneva-based Drugs for Neglected Diseases initiative. This is part of a project where it is envisaged that the government will be able to obtain a combination of two DAAs from the Egyptian generic drug industry for a targeted price of RM 1,000 per patient. However, for this project to succeed, the government needs to issue a government use license (similar to a compulsory license), which is why it is so important that a decision has been taken to do so.

According to recent media reports, the originator US company Gilead is now offering to include Malaysia in the list of countries eligible to take part in its licensing scheme that allows for some generic versions of sofosbuvir to be sold locally.

The government's move to issue a government use license is one reason why the company has after so many years agreed to include Malaysia in the scheme.

However it is imperative that the government sticks to its decision to issue a government use license for sofosbuvir. This is because there are strict limits to what Malaysia can do or cannot import or produce under the Gilead license, and other factors that restrict the freedom to choose the generic companies that it can work with.

By issuing a government use license, the government will have maximum degree of policy choices to determine the combination drugs, the prices, and the companies and institutions to cooperate with, and be able to secure the lowest possible prices for Hepatitis C treatment.

Therefore, it is best for Malaysian consumers and patients that the government have both the government use license as well as the license scheme that Gilead will extend to Malaysia. Both can co-exist, providing Malaysia with maximum policy choice.

In other countries where a compulsory license or government use license is planned or is issued, there are reports of pressures exerted by the companies holding the patent or by the governments of these companies not to issue or not to implement the measures. CAP sincerely hopes that such pressures will not be placed on Malaysia. Indeed, Malaysia should be praised worldwide for taking these pro-public health measures.

The Malaysian government measure of issuing a government use license is not only legal national and internationally but in line with the landmark 2001 WTO Ministerial Declaration on TRIPS and Public Health, that urged developing countries "to affirm their rights to use to the full the provisions of the TRIPS agreement to protect public health and in particular provide access to medicines for all."

A breakthrough long awaited for by millions of Malaysians, especially those with a family member suffering from Hepatitis C, is now within sight.

For this to happen, the government must act swiftly and courageously.

1. We urge the government to immediately implement the issuing of a government use license on sofosbuvir and to then take urgent action to import the much needed drugs and act quickly so that they are available in hospitals and clinics in Malaysia.
2. The Health Ministry should also explore other Hepatitis C drugs that are required for use in combination with sofosbuvir, and take measures to remove restrictions to their sale at affordable prices in Malaysia.
3. The Health Ministry should also complete its clinical trials undertaken in cooperation with Drugs for Neglected Diseases initiative (DNDi), and continue its collaboration thereafter with the aim of making an appropriate combination drug available in Malaysia at the initial targeted price of RM1,000 per treatment per patient.

S. M. Mohamed Idris
President
Consumers Association of Penang