



Persatuan Pengguna Pulau Pinang Consumers Association of Penang

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Letter to Editor

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Malaysian Government Needs to Act Now to Import Affordable Hepatitis C Treatment

Hepatitis C is curable. And yet thousands of Malaysian patients do not have access to treatment for this highly infectious disease.

Data available suggests that more than 500,000 Malaysians are living with the Hepatitis C virus (HCV). Most people infected with HCV are unaware of their status until it has progressed to advanced liver disease, liver failure or cancer. According to the World Health Organization (WHO), 150 million people worldwide have chronic Hepatitis C infection and 500,000 die yearly.

Until recently, Hepatitis C treatment was based on therapy with pegylated interferon and ribavirin, which had poor treatment outcomes and was accompanied by life-threatening side-effects. New oral direct-acting antivirals have since revolutionized HCV treatment, with cure rates exceeding 90%, shorter treatment duration and good safety profiles. A simple regime of these new antivirals for a period of 12 or 24 weeks can cure patients.

A critical backbone in the treatment of HCV is the drug sofosbuvir. However, a multinational pharmaceutical corporation, Gilead, sells it at astronomical prices, as the company enjoys market monopoly due to patents and data exclusivity.

Gilead entered into licensing agreements with a number of generic-drug companies allowing such companies to manufacture and sell generic sofosbuvir to 101 developing countries, but this arrangement excludes Malaysia, thus making it extremely difficult for Malaysians to gain access to affordable HCV treatment.

Gilead sells Sovaldi (its brandname for sofosbuvir) in the US for US\$64,680, in France for US\$41,885 and in Brazil for US\$6,875. In 2015 a patient in a Malaysian private hospital, which obtained permission to use the drug, was charged RM385,000 for a 24-week course. According to sources, Sovaldi is presently retailing in Malaysia for RM144,000 for a 12-week course. At these prices, life-saving Hepatitis C treatment is beyond the reach of most Malaysians.

A recent WHO report on access to Hepatitis C treatment reveals how a developing country such as Egypt has managed to treat around 670,000 people with the new antivirals in 2015 and 2016. Due to generic competition, sofosbuvir is available in Egypt for as low as US\$150.

Affordable generic sofosbuvir is also available from countries such as India and Bangladesh. For instance, in India, generic sofosbuvir is available for about US\$300 for a 12-week treatment course.

However, due to inaction on the part of the Malaysian Ministry of Health, patients in this country do not have access to any of these affordable treatments.

Presently the Ministry of Health is undertaking a clinical trial with the Drugs for Neglected Diseases initiative and Pharco Pharmaceuticals for a combination of sofosbuvir and ravidasvir at a price of less than US\$300. While a commendable step, this clinical trial is only for 600 patients, which is inadequate to address the scale of HCV infection in Malaysia.

Malaysians urgently need access to affordable Hepatitis C treatment if we are to treat the hundreds of thousands of patients infected with HCV. The Malaysian government needs to take prompt action to gain access to affordable sofosbuvir.

One clear option available to the government is to utilize the flexibilities available in the Malaysian Patents Act and issue a “government use” licence to import affordable generic sofosbuvir for use in government hospitals.

It is worth recalling that a recent report by the United Nations Secretary-General’s High-Level Panel on Access to Medicines clearly recommended that member states of the World Trade Organization (WTO), such as Malaysia, make full use of flexibilities allowed in the WTO’s intellectual property rules to promote access to health technologies when necessary.

Many lives are at stake and there is simply no reason to wait.

The Consumers Association of Penang calls on the government, in particular the Ministry of Health, to act now to secure access to affordable treatment for this potentially deadly disease.

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