



Persatuan Pengguna Pulau Pinang Consumers Association of Penang

檳城消費人協會 பிளாங்கு 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 / Letter to the Editor

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Proper Monitoring and Investigation of Adverse Drug Reactions Needed in Malaysia

There is an urgent need for a proper system for public reporting and access to adverse drug reactions records in light of the recent incident of adverse reactions to vaccines reported in the Kajang Prison.

In October 2021, the Kajang Prison authorities wrote to the Hulu Langat District Health Office, highlighting 18 cases of adverse reactions to Covid-19 vaccines, including 2 deaths, among inmates vaccinated.

The prison director had written to the district health office to get its view on the need to give prisoners booster doses.

A letter by the Hulu Langat district health officer Dr Zailiza Suli which went viral, revealed the adverse effects suffered by the affected inmates as follows: 3 cases of cardiovascular-related issues, 4 involving temporary paralysis, 3 of distant abscesses (sores with pus far from the inoculation point), and 6 inmates who suffered lung infections after receiving their jabs.

The viral letter says 15 inmates were given Pfizer shots, and 3 inmates CanSino.

Dr Zailiza noted in the letter that the death rate from AEFI ("adverse effects following immunisation") – one fatality per 1,391 inmates – is a worrying ratio. She recommended further studies be carried out before mandating additional or booster vaccine shots to these inmates.

On 4 January 2022, the Malaysian Muslim Consumer Association (PPIM) urged the MOH for answers about the reported AEFIs and the general safety of vaccines in view of Dr Zailiza's leaked letter.

On the same date, the Ministry of Health (MOH) said it was investigating the matter. National Pharmaceutical Regulatory Agency (NPRA)'s director Dr Roshayati Mohamad Sani said in a statement: "The Health Ministry is continuously monitoring the safe usage of all vaccines including Covid-19 vaccines through the NPRA by monitoring the AEFI reports."

Dr Roshayati in her statement said all reports stated in the letter that went viral have been received by the NPRA and are being investigated.

Till today we have not heard of the results of the investigations.

It took a viral letter to shake the complacency of the health authorities to take note of the deaths and adverse events. This should not be the case.

This is not the only reported incident of adverse events. On 19 January 2022, Perlis Mufti Datuk Dr Mohd Asri Zainul Abidin was reported in Berita Harian as saying that his father had a stroke after getting the third booster jab.

He called on the MOH to postpone the 3rd booster dose drive which is feared to have serious adverse health events. The authorities, he said, needs to reassess the safety and necessity of the 3rd vaccine dose for certain groups of people.

According to him, many people have approached him to relate the side effects they, their friends or family have experienced. “Some have claimed that deaths have occurred after the 3rd dose but these are villagers with no means of channeling official complaints to the authorities,” he said.

Reconsider Frequent Booster Jabs

Repeated Covid-19 booster jabs are unsustainable, WHO experts recently said.

On 12 January a WHO expert group, created to assess the performance of Covid-19 vaccines, said that a vaccination strategy of repeated booster doses of existing vaccines against new coronavirus variants is not an effective way to deal with the pandemic. The current vaccines need to be reworked to ensure they are effective against infection and disease by VOCs (variants of concern), including Omicron and future variants, they said.

In Malaysia, a public health expert also doesn’t support the frequent administration of Covid-19 vaccine booster shots without strong evidence that initial vaccination is ineffective against infection or severe disease.

“In my opinion, the decision for further booster doses because of waning immunological parameters – from a small fraction of the population – must be corroborated with epidemiological evidence that the vaccine and other public health measures are no longer working. We cannot be boosted after every few months,” says Prof Dr Lokman Hakim Sulaiman, pro vice chancellor of research at the International Medical University. (Code Blue, 20 January 2022)

CAP’s recommendations

1. Malaysia should set up a more transparent reporting system like VAERS in the US and the Yellow Card scheme in the UK where the public can report the adverse events and also see the report of the adverse events. Currently Malaysians can report adverse events to the authorities but there is no public access to such reports.

In the US, anyone can submit a report to VAERS (Vaccine Adverse Event Reporting System) including parents, patients, health care professionals and vaccine manufacturers. VAERS reports are monitored carefully by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). All adverse events reported to VAERS are made available to the public online.

In the UK, there is a specific website set up under the Yellow Card scheme where the public can report suspected side effects from medicines, vaccines or medical devices relating to COVID-19 treatment.

The scheme relies on voluntary reporting of suspected adverse incidents by healthcare professionals and members of the public (patients, users, or carers). The purpose of the scheme is to provide an early warning that the safety of a product may require further investigation.

In the European Union, the European Medicines Agency (EMA) monitors the safety of COVID-19 vaccines authorised for use “extremely carefully”. This enables the detection of any rare side effects that may emerge once many millions of people are vaccinated. The latest information on the safety of each vaccine, including the number of cases of suspected side effects, is given in the vaccine's monthly safety update, which is easily accessible to the public online.

2. Our health authorities must take adverse events seriously, investigate them and perform autopsies on people who have died from suspected adverse events, to find out the real cause of deaths.

According to a famous German pathologist Peter Schirmacher of the University of Heidelberg, his group has studied 40 people who have died within 2 weeks of vaccination; he concluded that around 30% to 40% of the total did indeed die from the vaccine. He believes that the overall deaths following vaccination are underreported.

We are using these experimental vaccines which are approved by emergency regulations, thus the need for investigations into adverse events and deaths due to these experimental vaccines are even more

crucial than ever to protect Malaysians.

3. Instead of using experimental vaccines only, we should also be looking at the available alternative treatments which are safe, cheap and efficacious. These treatments have been used in many countries and showed positive results.

High-vaccine-rate countries (eg: USA, UK and Israel) are suffering from high infection rates. COVID-19 infections in the US have reached 1 million daily. Vaccination has not lowered infection rates although they are effective in reducing hospitalisations and deaths.

4. The long-term effects of these experimental vaccines may take many years to unravel. Therefore, we have to take a serious view of adverse events and act on them now to protect ourselves now and in the future.

Mohideen Abdul Kader
President
Consumers Association of Penang (CAP)