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Need for more caution and transparency over Pfizer vaccine purchase

The Consumers Association of Penang (CAP) calls on the federal government to exercise greater caution and transparency in proceeding with its purchase of the Pfizer vaccine in an effort to tackle the COVID-19 pandemic, as there is a need to ensure that Malaysians are given safe and effective vaccines.

We refer to the agreement which the government has signed with Pfizer for the supply of COVID-19 vaccine. It is reported that the volume purchased will cover 20% of the Malaysian population with priority for our high-risk population.

We welcome the conditions outlined by the Ministry of Health (MOH) for the procurement and use of the vaccines, including in MOH monitoring the effectiveness of the vaccines on the high-risk groups; assessing its effectiveness and side effects and to assess whether they are effective for herd immunity.

However, CAP views with grave concern the safety and efficacy issues that have been raised worldwide concerning the first generation of these vaccines, more so as they will be administered to the high-risk members of the population.

In the US the marketing approval process has been truncated due to the urgent need for these vaccines. The scientific community has expressed concern over emergency use authorisations (EUAs), including that these could complicate efforts to study long-term effects.

While the US Food and Drug Administration (FDA) has issued EUAs sparingly for diagnostics and therapies aimed at other infectious diseases, such as H1N1 and Zika, a vaccine has never been used in civilians under an EUA. Vaccines are different from other medical products in that they are deployed broadly and in healthy people, so the bar for approving one is high.

This is why **CAP is doubly concerned with the condition that Pfizer imposes on advance purchase agreements such as the one signed with Malaysia – that the company will be indemnified from liability for its vaccine.**

It must be noted that Pfizer has been involved in many lawsuits both by consumers and the US Justice Department involving healthcare fraud, failure to warn of substantial risks in medicines and illegal marketing.

In any agreement, the integrity of the negotiating parties is of utmost importance, more so in this situation where it can be a matter of life and death. Pfizer's chequered past does not bode well in the circumstances.

It is very disturbing that the US government has assumed liability for vaccine side effects. Reuters has reported that in Europe, drug makers, including Pfizer, have insisted on liability indemnity from the government in the event of side effects.

CAP wishes to know if the situation is the same for Malaysia, i.e. if the government will assume all liability for any adverse effects of the Pfizer vaccine. We would also ask if this indemnity is also required by the other vaccine companies in negotiations with the government.

CAP joins the call of civil society organisations as well as many scientists and health experts worldwide that details of the vaccine purchase agreements between governments and pharmaceutical companies must be disclosed. Billions of Malaysian taxpayers' money is being set aside to buy the vaccines, and if liability is to be on the Government's shoulders then the rakyat will ultimately be the ones to pay again in ringgit and in their lives and health.

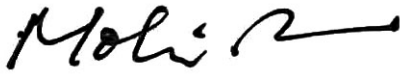
If the government has agreed to exempt Pfizer and others from liability in the event of adverse effects, domestic law will have to be enacted to provide for this, as this is not the norm under both civil and criminal law. Is this the intention of the government?

In addition, in the event that the government has a dispute with Pfizer will such disputes be heard by the Malaysian courts or overseas? It is reported that Argentina had to agree to pharmaceutical companies' demands that disputes are arbitrated abroad. If such a condition is required of Malaysia it would be a gross violation of our national sovereignty.

In addition, CAP also calls for the government to support the proposal initiated by South Africa and India at the World Trade Organisation (WTO) to waive implementation of several provisions of the intellectual property agreement called TRIPS Agreement for COVID-19 medical technologies and products for a specified duration.

With a TRIPS waiver, countries will have the ability suspend intellectual property rights implementation and enforcement until management of COVID-19 is achieved. This would provide countries with the policy space needed to collaborate in research and development and manufacturing, scaling up and supplying COVID-19 tools.

An increase in the production of vaccines, medicines and diagnostics will result in greater competition, bringing prices down, making them available to all.



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