

COVID-19: Are We Being Misled Again by Big Pharma?

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In March 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic.

This is not the first time. The WHO, in the recent past, had announced H1N1 – also known as swine flu – in June 2009, a pandemic as well.

Between the two pandemics, many facts have been overlooked and do need to be re-visited and re-examined.

After the outbreak of H5N1 (bird flu), and at the beginning of the H1N1 outbreak, transnational pharmaceutical corporations went into a fierce competition to provide treatment, in the absence of vaccines.

Between the years 2005 and 2009, the antiviral medicine oseltamivir, marketed under the trade name Tamiflu by Roche, succeeded in becoming the drug of choice for prevention and treatment by several international agencies such as the WHO, the Centers for Disease Control and Prevention (CDC) of the United States of America, and the European Medicines Agency (EMA).

At the time, and to prepare for a “possible rapid-containment operation”, the WHO received from Roche a donation of three million courses of oseltamivir to use as a stockpile, according to the Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009, issued by the WHO.

The WHO encouraged countries to integrate rapid containment planning into their national pandemic influenza preparedness plans, according to the same report. In addition to that, the WHO developed a “rapid containment protocol” for the same purpose, primarily depending on oseltamivir.

As expected, because of widespread global panic, purchase orders were placed with Roche from countries around the world, including Egypt. Subsequent research and literature indicate that purchase decisions were based on clinical trials mostly funded by Roche, whose results, according to experts, were limited and incomplete, particularly in relation to Tamiflu’s efficacy and side effects, some of which were later revealed to be dangerous.

Besides, there was supporting false information that suggested an uncontrollable outbreak of the infection. A Cochrane review revealed that the benefits of oseltamivir were little in terms of reducing symptoms, since the drug reduced the duration of symptoms by an

average of half a day only.

Cochrane researchers, who managed to obtain the complete reports of the original clinical studies, could also more clearly report on the side effects of oseltamivir. In the end, the Cochrane research raises the question of whether stockpiling of oseltamivir was justified.

There is another angle to the above.

Pharmaceutical companies usually put pressure on governments during such crises. During the H1N1 pandemic, the methodology adopted by Roche was based on persuading governments to sign purchase agreements for Tamiflu because, at the time, the drug was delivered on a first-come, first-served basis.

It should be noted here that these negotiations were taking place against a background of global tension and unspoken competition among countries to procure treatment the soonest from a same single source.

Such a situation demonstrates the gravity of monopolistic practices in the global pharmaceutical market. The likelihood of this scenario being repeated is playing out as countries continue to negotiate access to medicines supplied in a monopolistic market, as seen from the USA purchase of the existing supply of remdesivir from Gilead Sciences and the advance purchase agreements for potential vaccines by several European countries.

Oseltamivir sales at the time exceeded USD 18 billion, half of which were by governments. For instance, the USA had spent more than USD 1.5 billion on stockpiling oseltamivir, based on CDC recommendations, while the United Kingdom spent USD 770 million on the same drug between 2006 and 2014.

No official data is available on the total amount Egypt spent on oseltamivir. There were, however, a few news reports about the Ministry of Health's agreement with Roche to supply 2,500 kilograms of the raw active pharmaceutical ingredient (API) of the drug, to be manufactured by a subsidiary of the Holding Company for Pharmaceuticals, whose chairman estimated the API value to have been approximately 100 million Egyptian pounds.

The WHO is an intergovernmental organisation and is, accordingly, held accountable by its Member States. In 2010, Member States evaluated the performance of the WHO during the H1N1 outbreak in declaring a pandemic. Even the H1N1 declaration of a pandemic was a decision that international scientific and political circles had reservations about, being perceived to have been taken hastily, causing a state of global confusion and costing countries' budgets millions of dollars.

There is an important fact that should not be overlooked amidst the response to COVID-19: there are no "new" medicines that are being tested against the virus. The medicines under investigation are known or have been on the market; they are being tested to prove they are specifically effective against SARS-CoV-2 virus which causes COVID-19.

This re-purposing or re-positioning of existing medicines is a common research practice in the case of a sudden disease outbreak. Besides, and more importantly, pharmaceutical research and development (R&D) no longer produces absolutely "new" pharmaceutical compounds, and therefore, a substantive part of pharmaceutical R&D involves developing

existing products or expanding their scope of indications.

Clinical trials led by the WHO have started with four treatment options, most of which are of cost. Three months after the pandemic had been declared, the global competition narrowed down to two products: remdesivir, produced by Gilead Sciences, and favipiravir, produced by FUJIFILM Toyama Chemical, under the trade name Avigan, later reported to have failed to show clear efficacy in some coronavirus trials, delaying its approval until the trials are completed.

Last March, with the outbreak of COVID-19, the United States Food and Drug Administration (FDA) had approved to assign remdesivir “orphan drug status”, which normally grants the producing company a wider range of exclusive rights in addition to intellectual property rights.

This decision was met with surprise and skepticism by specialised circles all over the world because of its content and timing.

According to the definitions of both the WHO and the USA Law, orphan diseases are those which affect such a small number of individuals in a way that does not adequately incentivise the development of drugs for their treatment, and also justifying the potentially high prices of their treatment.

COVID-19, declared as a pandemic, is but the contrary to orphan diseases, and the “orphan drug” designation revealed the intentions of the company to maximise its sales and profits of remdesivir once FDA approved it.

With the increasing numbers diagnosed with COVID-19 in the USA, rising pressures led Gilead Sciences to withdraw their orphan drug designation. A few weeks later, remdesivir was approved by the FDA for emergency use in COVID-19 patients, following which the company donated 1.5 million courses of treatment to the USA government.

In mid-April, media reported that the Egyptian government had agreed with FUJIFILM Toyama Chemical to use favipiravir (Avigan) for COVID-19 treatment in Egypt. This agreement never materialised, because a few weeks later, the Ministry of Health announced that Egypt would participate in the remdesivir clinical trial, coordinated by the WHO.

In the meantime, the Egyptian company Eva Pharma signed a non-exclusive voluntary licence agreement with Gilead to manufacture remdesivir for distribution in 127 countries. Supply in Egypt is currently restricted to support patients in quarantine hospitals.

There have been rising global concerns about the haste to rely on remdesivir before its efficacy is proven, particularly that the results of published trials show that it has no therapeutic benefits of statistical significance.

Remdesivir has patent applications in many countries, and some have already granted it patent protection. The Egyptian Patent Office rejected the remdesivir patent application in 2017 on technical grounds; however, the final decision remains pending because it has been appealed by the applicant.

Gilead recently priced one treatment course of remdesivir (6 vials) at \$3,120 for private use and \$2,340 for government insurance schemes in the USA. The medicine is

exorbitantly priced; this cannot be justified by research and development expenditure because the medicine is not a novel compound, hence, did not stand patent examination in several countries.

Besides, research demonstrated that the production cost of remdesivir could be as low as \$5.58 per treatment course. In fact, the Indian pharmaceutical company Cipla announced that it will produce a generic version of remdesivir at approximately \$400.

In light of the high incidence and mortality rates of COVID-19, and pressures on governments to take protective measurements for their people, we are faced with competition among pharmaceutical companies to protect their shares in a lucrative global market.

This competition is manifested in seeking to enroll large numbers of patients in hastily conducted clinical trials to demonstrate results in favour of, or against, a particular drug; signing advance purchase agreements with governments, which is the case now between Gilead and the US government; and filing for patent protection in as many countries as possible in order to obtain exclusive rights, including the possibility of selling the medicine at the highest price possible.

In the midst of this crisis, which has had unprecedented economic and social repercussions worldwide, it is concerning to witness a recurrence of the H1N1 scenario. Governments are again undergoing “panic buying” and irrational stockpiling of medicines, none of which has been yet proven to be an effective treatment against COVID-19. Are there not lessons learnt from the recent past?

Translated from Arabic by TWN

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