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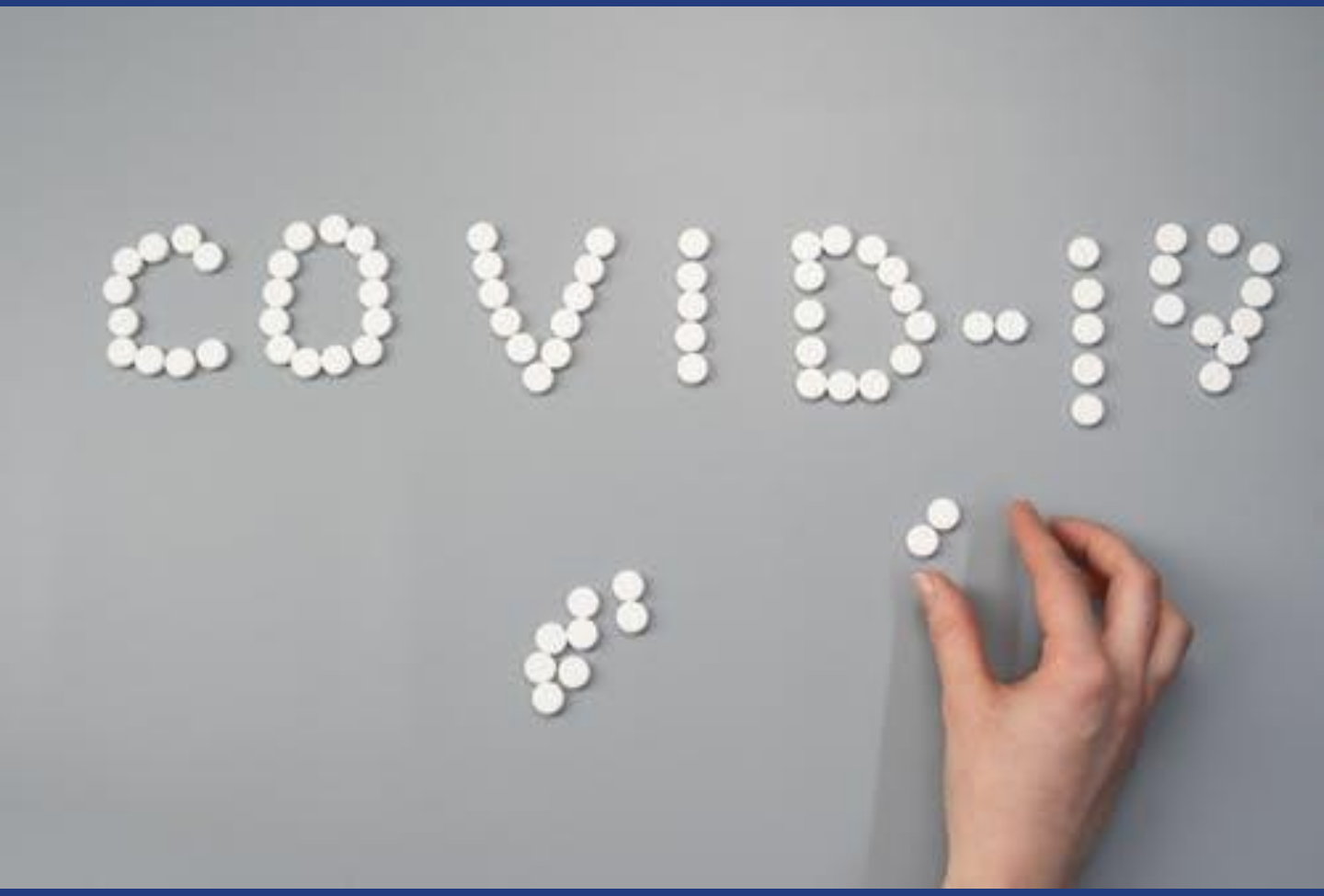
NEWSLETTER

COVID-19: EXTENSION OF MARKET ACCESS TO LIFE-SAVING AND LIFE-EXTENDING DRUGS

June 2020



Industry Report: Issues impacting the Life Sciences

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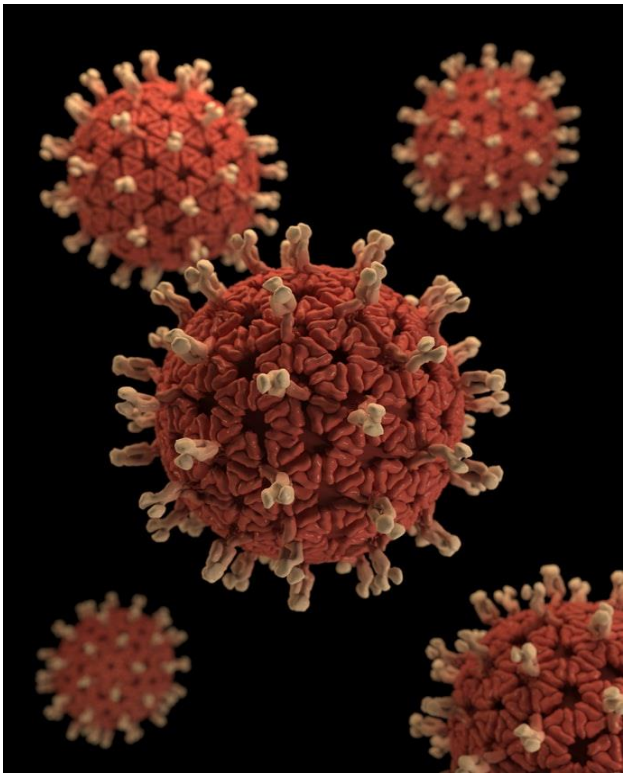
Vietnam, a country of 97 million people, has been widely recognized for its successful handling of the novel coronavirus outbreak. On January 27, as the country celebrated the Lunar New Year holiday, Prime Minister Nguyen Xuan Phuc declared war on the coronavirus, having said "fighting this epidemic is like fighting the enemy". The Prime Minister and his cabinet acted expediently in controlling the spread of the virus. After implementing early preventative methods such as contact tracing and quarantining by area and apartment buildings, culminating in a three-week nationwide lockdown, Vietnam lifted various social distancing and restrictive rules in late April. Businesses and schools have reopened, and life is gradually returning to normal.

However, after defeating this "enemy", Vietnamese people are facing another challenge, which will place the lives of thousands of Vietnamese in great danger. Currently, Marketing Authorizations ("**MAs**")—that permit foreign manufactured drugs access to the Vietnamese market and to the Vietnamese patient—for a large number of medicines, which are for the treatment of acute, chronic illnesses will expire on July 1, 2020. If the MAs of medicines are not re-certified, the medicines cannot, as a matter of law, be imported into Vietnam.

In this Newsletter, we provide a broad picture of the situation and make certain recommendations. including: (i) the background; (ii) the reasons for this problem; (iii) what happened in the past; (iv) available legislative options for current situation; (v) recommendations; and (vi) conclusion.



1. The Background: A Backlog in Approving the MAs of Life-Saving and Life-Extending Drugs

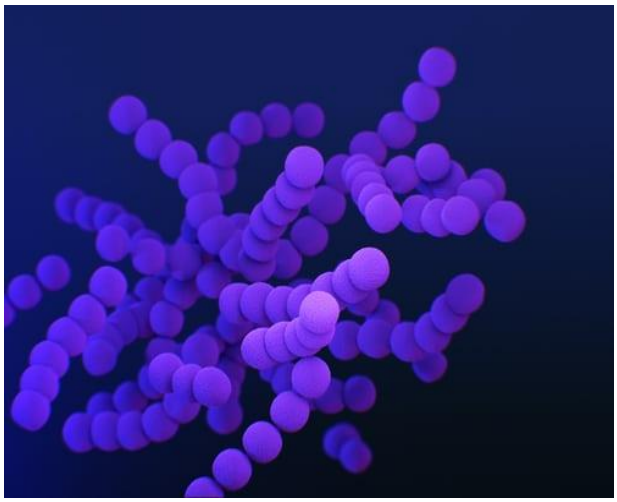
By way of background, Circular No. 32/2018/TT-BYT ("**Circular 32**"), permitted extension of MAs for medicines that have been previously approved. Within 12 months prior to the expiration date of an MA, its holder may apply for renewal. If the MAs of medicines are not re-certified, the medicines cannot continue to be imported into Vietnam. Without an MA extension, medicines can no longer access to the market and these crucial medicines will not be available to patients.

Currently, it is estimated that there are thousands of MA extension applications submitted to the Drug Administration of Vietnam ("**DAV**") between June 2019 and June 2020. Some of them only have one registration number on the market and there is no alternative for patients' continued treatment. It is anticipated that, additionally, more than seven hundred (700) MAs of medicines, which belong to multinational companies, will expire from July 1, 2020, and hundreds more soon to follow. Unfortunately, this delay—as discussed below—and its related problems were compounded by Covid-19 and the shutdown of the government's offices for an entire month.

Simply put, without the renewed MAs, the medicines will not be allowed to continue to be imported to Vietnam. Families may be forced to buy these drugs on the black market at excessive prices and without appropriate regulation in place to ensure efficacy, putting many Vietnamese lives at risk. This may also cause severe resource constraints at hospitals, as well as unnecessary suffering of both patients and hospital staff because they will be forced to watch patients suffer in a situation that was completely preventable.

2. The Reasons this Problem Exists: Vietnam's Incredible Response to Covid-19; Heavy Workload of the Government Authorities during the Global Pandemic

When the world has nearly 8 million confirmed cases and nearly 435,681 confirmed deaths due to the novel coronavirus, Vietnam bucked the global trend and largely escaped the scourge of the coronavirus with a mere 260 cases arising from community transmission.



However, this success has come at the price of extensive resource allocation by the Vietnamese Government to these efforts. A strong network of 63 provincial centers for disease control ("**CDC**"), more than 700 district-level CDCs, and more than 11,000 commune health centers were devoted to meticulous contact-tracing, direct and in-direct. As of May 1, 2020, about 70,000 people had been quarantined in Vietnam's government facilities, while about 140,000 others had undergone isolation at home or in hotels.

These large efforts meant that the Ministry of Health ("**MOH**") in general and the DAV, among other parts of the Vietnamese Government, have had to focus on Covid-19 as a priority, resulting in resources being stretched when it comes to other "ordinary" functions. It is, therefore, not surprising that there is a massive backlog of re-certification of MA requests, and with more and more dossiers being submitted adding to this backlog every day of the week. Consequently, there does not appear to be a clear resolution to this problem. However, our practice has thought thoroughly through this problem to develop the ability to offer a few practical solutions for the Government to consider.

3. What Happened in the Past?

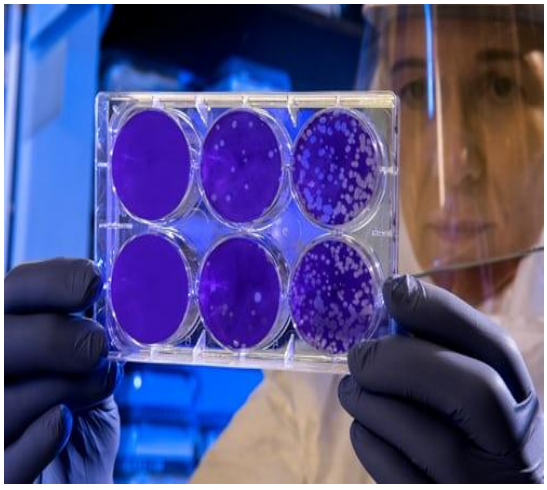
This is not the first time Vietnamese patients encountered a problem of lack of specialized drugs for chronic illnesses. In recent years, there are two notable events as follows:

(i) Lack of cancer treatment drugs under support programs due to complicated procedures for importation of aid-related drugs according to a new decree (at the time)

Glivec or Tasigna are special drugs for treatment of chronic myeloid leukemia. Currently, in Vietnam, there are 3,000 patients depending on these drugs. From January 1, 2015, Novartis started a drug support program. According to which, for patients participating in health insurance continuously for less than 36 months, Novartis would sponsor 100% of the cost of treatment with Glivec or Tasigna. For patients participating in health insurance continuously for more than 36 months, the health insurance fund would pay 40% of, and Novartis will pay 60% of, the cost of treatment with Glivec or Tasigna.

However, with the promulgation Decree No. 54/2017/ND-CP guidelines for implementation of the law on pharmacy ("**Decree 54**"), which was effective on July 1, 2017, the dossier for granting importation of aid or humanitarian materials must be completed similar to a dossier of application for MAs of other medicines, and the dossier evaluation process must also comply with the prescribed order and time. As a result, lives of many patients contributing the health insurance, getting chronic myeloid leukemia and receiving treatment with Glivec or Tasigna were in great danger.

In order to solve the difficulty described above, the Government agreed to allow establishments receiving aid-related drugs to continue to import such drugs by using the importation dossiers according to the old regulations. In addition, the DAV also asked the Hanoi and Ho Chi Minh City Health Departments, together with the relevant medical facilities, to urgently compile dossiers requesting importation of Glivec aid medicine to send to the competent agencies.



(ii) Lack of drugs for cancer treatment because of the expiration of drug support programs

From December 31, 2019, the drug support program for Glivec and Tasigna for chronic myeloid leukemia sponsored by Novartis expired.

The expiration would have resulted in patients needing to pay for life-saving medication at high prices. The VSS sent a written request to the MOH to extend the implementation of the drug support program for Glivec and Tasigna. As a result, VSS and the MOH agreed to extend the implementation of the program to support Glivec and Tasigna drugs for patients for two more months, January and February 2020. This extension was sufficient time for the revision of Circular No. 30/2018/TT-BYT on payment conditions for pharmaceutical drugs, biologicals, radiopharmaceuticals and tracers under the scope of entitlement of participants covered by national health insurance. According to which, manufacturers will reduce drug prices to 65% of the current price and the health insurance fund will increase the payment rate to 80% - 100% of drug costs, and the patients will be responsible for the remaining amount, which all concluded was a reasonable share and possible for even poor patients to assume.

4. Legislative Options Available to Regulators and the Vietnamese Government for Immediate Relief

(i) Quick and shortened evaluation process applying to new MAs application

According to Circular 32 there is a fast track option available for new MA applications for certain special drugs, among others, specialized drugs and drugs with special dosage forms, to which there are no more than two similar drugs (the same active ingredient, the same dosage form, the same content and concentration) with a valid MA at the time of filing. An example would be in the case of cancer drugs. Or, in our view, drugs to treat Covid-19, for example (if they existed).

Drugs will be appraised in accordance with the shortened evaluation process and must meet the following conditions: (i) drugs manufactured at GMP-qualified establishments subject to periodical evaluation by the DAV, (ii) drugs must be on the list of over-the-counter medicines, (iii) the drugs are non-modified release dosage forms, and (iv) drugs cannot be those directly applied to the eyes.

Given policy considerations applicable to the fast track evaluation process available to new MA applications so that critical medicines can reach patients, there is a strong argument that this fast track process should be applied to re-certification of MAs, since the medicines have been tested and used for years and the lives of many Vietnamese patients depended on these drugs.

(ii) Procedures for special MA allocation for two invitro diagnostic bio-products testing for coronavirus (sars-cov-2)

On March 4, 2020, the Minister of the MOH issued Decision No. 774/QD-BYT ("**Decision 774**") announcing the MAs for two invitro diagnostic biologicals testing for coronavirus. Accordingly, the biologicals were granted temporary MAs for 6 months for screening and testing purposes. Notably, this procedure is not mentioned in any applicable decree on registration and circulation of medical equipment or circulars on drug circulation.

Decision 774 proves that the MOH, in general, and the Minister of the MOH, in particular, are willing to, within their authority, provide a special procedure, which has not yet been prescribed under available legal documents in exceptional circumstances, such as the coronavirus global pandemic presented.

In our view, based on the foregoing precedents, it is clear that when it comes to matters effecting the health and safety of the Vietnamese, the Vietnamese Government, the Ministries, and the Prime Minister, in particular, are working together tirelessly to make decisions in the best interests of Vietnamese people.

We believe that either the Prime Minister, the MOH or DAV, and even the VSS, has the regulatory authority to issue an official letter/decision replying to recently submitted letter(s), one of which was co-submitted by several Chambers of Commerce in Ho Chi Minh and Hanoi to the Prime Minister and the Government Office ("**GO**") (or, myriad other letters submitted by individual companies in the pharmaceutical sector with life-saving drugs with MA Numbers set to expire), which gives a temporary, one (1) year, approval for a specific list of life-saving or life-extending drugs that will have their MA Numbers expire as the result of delays caused by the Covid-19 Global Epidemic.

5. Recommendations

Given that nearly all novel coronavirus related Decisions have been issued by the GO, we recommend that the GO should be the body that issues the official letter/decision that:

- temporarily grant a one-year extension to the MA Numbers of the Life-Saving and Life-Extending Drugs or until the MAs are re-certified, whichever is earlier.

- allowing the same regulatory body to issue most, if not all, critical decisions related to Covid-19 creates a regulatory precedent and contributes to future issues of government continuity, to the extent they ever come into question.

6. Conclusion

During the nation's history, and the recent Covid-19 global pandemic, the Vietnamese Government has solemnly announced to the world, how a new member of the list of middle-income countries with a much less-advanced healthcare system than others in the region could fight against the global pandemic, which other developed nations have struggled to contain with very grim and serious consequences for patients, families and nations. Once again, the Vietnamese Government has done an outstanding job and showed the people of Vietnam how far the Vietnamese Government is willing to go to protect the wealth, health, and safety of the Vietnamese and any fortunate foreigners that happened to be in Vietnam during this global pandemic. We believe that this tradition will be continued, and the Government will work with pharmaceutical manufactures to find a solution to the backlog of MA renewal application dossiers and develop a novel process to ensure the continued well-being of patients and the Vietnamese.

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