Drug Information Bulletin

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Regulatory Affairs Division (RAD), IPA

Favipiravir 200mg oral tablets approved by CDSCO for the treatment of mild to moderate Covid-19 patients

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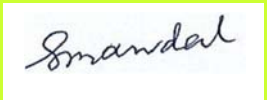
Editorial

CDSCO has approved under the provision "accelerated approval" the Favipiravir 200 mg. tablets for the treatment of mild to moderate Covid-19 patients in India on 20th June 2020 and it has been marketed under the trade name FaviFlu. It has been reported that each strip containing 34 tablets will come at an approximate a MRP of Rs. 3,500. As per the sources most patients exhibiting mild to moderate symptoms can benefit from FaviFlu use. The drug will be available as a prescription medicine for INR 1103/tablet, with recommended dose being 1800 mg. twice daily on day 1, followed by 800 mg twice daily up to day 14.

Favipiravir is approved in Japan since 2014 for the treatment of novel or re-emerging influenza virus infections. It has a unique mechanism of action: it is converted into an active phosphoribosylated from (favipiravir-RTP) in cells and recognized as a substrate by viral RNA polymerase, thereby inhibiting RNA polymerase activity.

On the same day the CDSCO has given emergency approval to Remdesivir injection for hospitalized patients suffering from Covid-19 to an Indian company. Earlier Gelad Science-a multinational company has got emergency approval for Remdesivir injection for hospitalized patients suffering from Covid-19. CDSCO also approved use of Hydrroxychloroquine for prophylactic use against Covid-19.

Now we are having three medicines to fight against Covid-19 though there are so many questions about scientific evidence of all three medicines.



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Favipiravir 200 mg tablets approved by the CDSCO for get approval for treatment of mild to moderate Covid-19 patients in India

The Drug Controller General of India (DCGI) has granted permission to manufacture and sell Glenmark pharmaceuticals' Favipiravir for Covid-19 on 19.06.2020. The approval for Favipiravir 200 mg tablet has been given following the recommendation of special subject expert committee (SEC) on Covid-19.

"Under an accelerated approval process at the Central Drugs Standard Control Organization (CDSCO), the SEC has recommended the grant of permission to manufacture and market Glenmark's Favipiravir, 200 mg tablet," sources added.

"Glenmark Pharmaceuticals has received the manufacturing and marketing approval from India's drug regulator to launch the oral antiviral drug Favipiravir (FabiFlu®) for the treatment of mild to moderate Covid-19 patients in India," said the company in a statement. Reportedly, each strip containing 34 tablets will come at an approximate MRP of Rs 3,500. For the treatment 122 tablets will be required for 14 days. The approval comes with a caveat that the company will have to submit a copy of the informed consent and report of the ongoing clinical trials within three months. The SEC has also recommended that the drug should be used with caution in patients with a history of abnormalities in metabolism of uric acid. It also asked the company that post marketing surveillance should be conducted on the first 1,000 patients to assess safety and efficacy of the drug.

Ref. Economic Times

Dexamethasone cuts risk of death by 35% in COVID-19 patients on ventilation

Preliminary results from the RECOVERY trial suggest that low-dose Dexamethasone can reduce the risk of death by up to one third in hospitalised patients with severe respiratory complications of COVID-19. When compared to usual care alone, Dexamethasone reduced deaths by 35% among intubated patients and by 20% in those receiving oxygen only, although there was no survival benefit among patients who did not require respiratory support. Peter Horby, one of the study's chief investigators, said "it is a major breakthrough...Dexamethasone is the first drug to be shown to improve survival," adding the "benefit is clear and large in those patients who are sick enough to require oxygen treatment, so Dexamethasone should now become standard of care in these patients."

According to the findings, one death would be prevented by treatment of around eight ventilated patients with Dexamethasone, or around 25 patients requiring oxygen alone. Martin Landray, another of RECOVERY's chief investigators, noted that Dexamethasone "costs about £5 ($6.32) per patient (on the NHS), so essentially it costs £35 ($44) to save a life." He also pointed out that the drug is globally available and costs "substantially less, probably less than $1, in other parts of the world, for example in India... It's going to be very hard for any drug really to replace this."

Ref. Irish times, The Gurdian

WHO cuts Hydroxychloroquine from COVID-19 trial again, citing lack of efficacy

The World Health Organization (WHO) stopped investigating Hydroxychloroquine in the ongoing **Solidarity Trial** after determining that the malaria drug does not result in the reduction of mortality, compared with standard care, in hospitalised COVID-19 patients. The move comes after the WHO temporarily paused enrolling patients in that arm of Solidarity in late May after findings from a now-retracted study in The Lancet suggested that there was a higher risk of ventricular arrhythmia and death in COVID-19 patients who took Chloroquine and Hydroxychloroquine. That arm of the study was resumed about two weeks ago following a safety review by the agency. Henao Restrepo noted that the latest decision to cut Hydroxychloroquine from the Solidarity Trial does not "constitute WHO policy, that this is not a WHO policy recommendation," or a reflection on if or how Hydroxychloroquine may work as a possible prophylaxis...

Ref. Bloomberg

FDA pulls emergency-use status for Chloroquine, Hydroxychloroquine in COVID-19

The WHO's decision came shortly after the FDA revoked the emergency-use authorisation (EUA) for Chloroquine and Hydroxychloroquine, citing data suggesting that the malaria drugs "may not be effective to treat COVID-19" and their "potential benefits for such use do not outweigh...known and potential risks." The EUA, issued in late March, permitted the medicines to be used for hospitalised adults and adolescents with COVID-19, when a clinical trial was not available or feasible. The FDA said it revoked the EUA after reassessing publications that were relied upon at the time the approval was granted. The agency indicated that new analyses suggest "it is unlikely that the dosing regimens in the EUA would be able to have an antiviral effect," and that "the substantial increase in dosing that would be needed to increase the likelihood of an antiviral effect would not be acceptable due to toxicity concerns."...
Ref.NIH

CDSCO to replace words 'Chemists & Druggists' with 'Pharmacists'

The Central Drugs and Standards Control Organisation (CDSCO) has prepared a draft notification replacing the words 'chemists and druggists' with 'pharmacists'. The move comes in following several requests to this effect from Karnataka State Registered Pharmacists Association (KSRPA). The draft notification is currently pending with the ministry of health and family welfare. The replacement of the words chemists and druggists with pharmacist will be in Rule 65 (15)(b) of the Drugs and Cosmetics Rules, 1945.

In a communication to KSRPA president Ashok Swamy Heroor, CDSCO said that after examining the matter with the concerned division, the regulatory authority is directed to replace the words chemists and druggists with pharmacists. This would give better professional recognition to the chemists and druggists.

According to Heroor, there is considerable delay as the amendment is not considered for approval from concerned authority in a period of 11 months. We now urge the concerned department to amend the same immediately without delay.

The Rule 65 (15)(b) of the Drugs and Cosmetics Rules refers to the retail pharmacists as druggists and chemists. The change is mandated by the Association as the word 'Pharmacists' gives an instant acknowledgment to the dedicated retail outlets vending medicines, Herror told Pharmabiz.

The name druggists and chemists was coined in 1945 and this has lost relevance over a span of 74 years in 2019. The present situation is quite different from what prevailed in 1945. The evolution of English language too has provided different meanings of these words. At present the word 'drug' is looked upon as more clandestine and as addiction for chemicals. Hence the expression just does not suit to refer a professional pharmacist, said Heroor in his communication to the Union minister for health and family welfare.

On the other hand, these days medical shops are popularly referred to as pharmacies. This word also conveys respect to the profession. Since retail medical business is more of a profession than a mere trade it should be rightly called as Pharmacy, he added.

Unfortunately, Rule 65 (15)(e) restricts the name only to a place where compounding of medicines are carried out. Moreover in the current scenario, the compounding of medicines by registered medical practitioners ceases to exist with a capable pharma industry in place in the country. There are also slew of regulations calling to prove the quality and efficacy of the drug. Therefore it would be more practical to rename the service of druggists and chemists as pharmacy, said Heroor.
Source: Pharmabiz

Govt. lifts Export Ban on Hydroxychloroquine API and Its Formulations

The Centre has removed the ban on export of Hydroxychloroquine (HCQ) — the anti-malaria drug being used as a possible cure for Covid-19 in many countries — and has made it freely exportable vide Notification No.13/2015-2020 dtd. 18.06.2020.

The earlier notification prohibiting exports has been amended to change the export policy of HCQ Active Pharmaceutical Ingredients (API) and its formulations from 'prohibited' to 'free' with immediate effect, according to the latest notification issued by the Directorate General of Foreign Trade on Thursday.

This means that HCQ can now be exported without special nod from the government on a purely commercial basis based on demand.

The government had banned export of the medicine on March 25 as it had feared a shortfall in supplies with the rapid spread of the Covid-19 across the country.

However, following a request for HCQ supplies made by the US and some other countries, India decided the following month to export the drug on a case-to-case basis.

On April 30, the MEA said that as there was adequate supply of HCQ in the country, India was exporting it to 87 countries to help them meet their Covid-19 related health needs.

"Amphan" Relief camp at Sundarban organized by IPA, Bengal Branch jointly with IPA Bengal Pharma & Health Care trust and TOA

Dr. T.V.Narayana, National President, Indian Pharmaceutical Association speaking in a webinar recently