Modern COVID vaccine secured emergency approval from USFDA on 19.12.2020

Editorial:
I am penning down the last editorial of this bulletin for this year with a heavy heart as we lost millions of people round the globe due to the devastating COVID-19 Pandemic. This covid-19 virus affected people in almost all countries round the globe irrespective of race or religion, rich or poor. Health authorities are trying their best to manage the situation and at present the situation has improved marginally. Though a few medicines have been repurposed and approved for emergency use, incidentally, new medicines for the treatment COVID-19 are yet to be developed, and a few COVID vaccines are being developed in different countries. Countries like UK, Bahrain, Canada, Mexico, US, Singapore, Oman, Saudi Arabia, Kuwait, Russia and China have already started vaccination but a section of scientists are apprehensive about its safety and efficacy. Another issue is manufacturing of sufficient quantity of vaccines to make it available to each and every human being. To make this possible, we also need sufficient numbers of vaccinators, but presently such number of vaccinators is meagre. Considering this fact, different global agencies and governments are engaging more cadres as vaccinators like Pharmacists. Indian government has also planned to engage pharmacists as vaccinator along with MBBS Doctors, Staff Nurses, BDS Doctors etc. Therefore this is a challenge for the pharmacists to deliver the responsibility bestowed on them. Wishing all a safe, happy and “normal” New Year 2021!

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CONTENTS
- Editorial
- New Drug approved by DCGI for COVID-19 since 01.01.2020
- New Drugs approved by DCGI as disinfectant since 01.01.2020
- COVID-19 Vaccines approved abroad
- US healthcare worker suffers allergic reaction to Pfizer vaccine
- Affordable treatment part of right to health: Supreme Court observation
- Use Ayush Docs for Clinical Work and You Could Lose Accreditation: NABH to Hospitals
- Readers Column
- 90 year old Margaret Keenan, the first patient in the UK to receive the Pfizer-BioNTech COVID-19 vaccine
### New Drug approved by DCGI for COVID-19 since 01.01.2020

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Name of the Drug</th>
<th>Indication</th>
<th>Date of approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Remdesivir Injection 5 mg/mL and Remdesivir lyophilised powder for Injection 100 mg</td>
<td>For treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalised with severe disease, in light of Covid 19 outbreak, for restricted emergency use in the country.</td>
<td>01.06.2020</td>
</tr>
<tr>
<td>2.</td>
<td>Favipiravir bulk and Favipiravir film coated tablet 200mg</td>
<td>For the treatment of patients with mild to moderate Covid-19 disease, in light of Covid 19 outbreak, for restricted emergency use in the country.</td>
<td>19.06.2020</td>
</tr>
<tr>
<td>3.</td>
<td>Remdesivir bulk drug</td>
<td></td>
<td>20.06.2020</td>
</tr>
<tr>
<td>4.</td>
<td>Favipiravir film coated tablet 400mg</td>
<td>For the treatment of patients with mild to moderate Covid-19 disease, in light of Covid 19 outbreak for restricted emergency use in the country</td>
<td>22.07.2020</td>
</tr>
</tbody>
</table>

### New Drugs approved by DCGI as disinfectant since 01.01.2020

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Name of the Drug</th>
<th>Indication</th>
<th>Date of approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Hydrogen peroxide 0.5% w/w wipes</td>
<td>Cleans, disinfects and deodorizes hard nonporous inanimate environmental surfaces</td>
<td>29.04.2020</td>
</tr>
<tr>
<td>2.</td>
<td>Hydrogen peroxide 0.5% w/w spray</td>
<td>Cleans, disinfects and deodorizes hard nonporous inanimate environmental surfaces</td>
<td>28.05.2020</td>
</tr>
<tr>
<td>3.</td>
<td>n-alkyl dimethyl benzyl ammonium chloride 0.105% w/w spray</td>
<td>Cleans, disinfects, deodorizes hard, nonporous inanimate environmental surfaces</td>
<td>31.07.2020</td>
</tr>
<tr>
<td>4.</td>
<td>Octyl decyl dimethyl ammonium chloride 6.670% spray</td>
<td>Cleans, disinfects, deodorizes hard, nonporous inanimate environmental surfaces</td>
<td>07.08.2020</td>
</tr>
</tbody>
</table>

### COVID-19 Vaccines approved abroad

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Name</th>
<th>Vaccine Type</th>
<th>Primary Developers</th>
<th>Country of Origin</th>
<th>Authorization/ Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>BNT162b2</td>
<td>mRNA-based vaccine</td>
<td>Pfizer, BioNTech; Fosun Pharma</td>
<td>Multinational</td>
<td>UK, Bahrain, Canada, Mexico, US, Singapore, Oman, Saudi Arabia, Kuwait</td>
</tr>
<tr>
<td>2.</td>
<td>mRNA-1273</td>
<td>mRNA-based vaccine</td>
<td>Moderna</td>
<td>USA</td>
<td>USA</td>
</tr>
<tr>
<td>3.</td>
<td>CoronaVac</td>
<td>Inactivated vaccine (formalin with alum adjuvant)</td>
<td>Sinovac</td>
<td>China</td>
<td>China</td>
</tr>
<tr>
<td>4.</td>
<td>Sputnik V</td>
<td>Non-replicating viral vector</td>
<td>Gamaleya Research Institute, Acellena Contract Drug</td>
<td>Russia</td>
<td>Russia</td>
</tr>
</tbody>
</table>
US healthcare worker suffers allergic reaction to Pfizer vaccine

A healthcare worker in the US suffered an allergic reaction after receiving Pfizer's Covid-19 vaccine, the only vaccine that has been authorised for emergency use in the country so far. The worker was among the healthcare workers being vaccinated at Bartlett Regional Hospital in Juneau in the US state of Alaska on Tuesday. According to a report in CNN on Wednesday, the healthcare worker who suffered the allergic reaction felt flushed within 10 minutes of receiving the vaccine. Other symptoms included shortness of breath and an elevated heart rate. She was taken to the emergency room when she reported shortness of breath. She also reportedly developed rashes on her face and torso.

Alaska's Chief Medical Officer Dr Anne Zink on Thursday said that the patient is doing well. "Thanks to the team and Bartlett who did a great job managing an adverse reaction to the Pfizer vaccine. While we think this is incredibly rare, and the CDC and FDA told us this is the only known case in the US to date, reporting problems is as important as reporting successes," she said in a tweet.

"But most importantly -- thank you to the patient, who is doing well, glad she got her first dose and disappointed it means she won't get her second. She encouraged us all to get ours."

As the vaccine is in limited supply at the moment, it is being given mainly to healthcare workers. The UK's medical regulator last week advised that anyone who has a history of significant allergic reactions to medicines, food or vaccines should not receive the Pfizer-BioNTech vaccine currently in use in the country.

The precautionary advice by the country's Medicines and Healthcare Products Regulatory Agency (MHRA) came a day after two National Health Service staff members experienced allergic reactions after being vaccinated, Xinhua news agency quoted a Sky News report as saying.

Source: The Economic Times

Affordable treatment part of right to health: Supreme Court observation

The Supreme Court on Friday termed the worldwide fight against Covid-19 as “world war” and asked states to act vigilantly and harmoniously with the Centre while directing them to increase policing of crowded places to strictly enforce the ‘mask must’ rule and other preventive norms. It noted that right to health is a fundamental right and it included affordable treatment, reports Dhananjay Mahapatra. It also directed setting up of district-level committees for carrying out fire audits of each Covid hospital at least once a month.
Devise plan for intermittent rest to doctors, SC tells Centre

Every state must act vigilantly. Safety and health of citizens must be the first priority, rather than any other considerations,” a bench of Justices Ashok Bhushan, RS Reddy and MR Shah said.

It said treatment of Covid patients had become very costly and was going beyond the reach of the common man. “Even if one survives from Covid-19, many times financially and economically he is finished. Therefore, either more or more provisions are to be made by the state government and the local administration or there shall be a cap on the fees charged by private hospitals,” it said. Expressing dismay over the attitude of people towards Covid-19, the bench said police should be deployed in more numbers in crowded places to monitor and enforce ‘mask must’ rule.

“In a micro containment zone or in an area where the number of cases are on the higher side, to cut the chain, they should be sealed and there should be complete lockdown so far as such areas are concerned. Such containment areas need to be sealed for a few days except essential services,” it said. The bench also factored in the fatigue of doctors and health workers who have been working continuously for the last eight months and asked the Centre to devise a mechanism to give them intermittent rest.

Source: ET Health

Use Ayush Docs for Clinical Work and You Could Lose Accreditation: NABH to Hospitals

The National Accreditation Board for Hospitals and Healthcare providers (NABH) has warned allopathic hospitals accredited with it that they could face withdrawal of accreditation if they were found employing Ayush doctors for performing clinical duties in ICUs and other patient care areas in place of MBBS resident medical officers (RMOs) and emergency doctors.

A “cautionary notice” the board issued on Thursday said, “This is a blatant violation of NABH standards for healthcare accreditation and very much against patient safety norms and compromise quality of modern medicine clinical care outcomes.” TOI had, in October, reported on the use of Ayush doctors in ICUs for night duty being a fairly common practice in many private hospitals, particularly in Maharashtra and Gujarat.

For Details: DrugsControl.org

Readers Column

Dear Editor,

I liked this issue very much. This is very much informative issue and filled with recent developments in Covid vaccine.

Thank you.

N Sivaprasad

90 year old Margaret Keenan, the first patient in the UK to receive the Pfizer-BioNTech COVID-19 vaccine

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