Editorial:

It is my proud privilege to pen the editorial at a historical moment—the completion of 14 years of publication of this Drug Information Bulletin. The weekly bulletin started its journey in April 2007, brought out by the Drug Information Centre (DIC), IPA, Bengal Branch and is now a fortnightly bulletin jointly published by DIC, IPA-Bengal Branch and Regulatory Affairs Division (RAD), IPA. As far as my information goes, this is the first of its kind of bulletin serving its readers from all spheres of the society like- Pharmacists, Doctors, Nurses, health workers, NGOs, and general public worldwide. It has received accolades and great appreciation from most of the readers due to its content and its regular publication. Initially it was started to serve IPA members then receiving request from other professional stake holders, as well as request from other countries the bulletin marched ahead. Presently we have readers from different countries all over the world and different strata of society. Some hospitals and educational institutes are forwarding this Bulletin among their faculty members and keeping hard copies in their libraries with our prior permission so that students can read this. A number of Drug Information Centers are reproducing this with our permission both in Government and private sector. A few international agencies have extended recognition. This is a free service to anybody and everybody, and any person / institute interested in drug information, and we have never accepted any donation or advertisement from anybody for this publication to keep our voice unbiased. This has been possible due to help and co-operation from all of our readers and mentors. Hope this bulletin will continue its service to the society with help from all of you in future too. Greetings to all!

Dr. Subhash C. Mandal, Editor
Email: Subhash.mandaldr@gmail.com
Mobile: 9830136291
<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Name</th>
<th>Vaccine Type</th>
<th>Primary Developer</th>
<th>Country of origin</th>
<th>Authorization/Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BBIBP-CorV</td>
<td>Inactivated Vaccine</td>
<td>Beijing Institute of Biological Products (Sinopharm)</td>
<td>China</td>
<td>33 countries</td>
</tr>
<tr>
<td>2</td>
<td>Comirnaty (BNT 162b2)</td>
<td>mRNA-based vaccine</td>
<td>Pfizer, BioNTech, Forsun Pharma</td>
<td>Multinational</td>
<td>48 Countries, European Union and WHO</td>
</tr>
<tr>
<td>3</td>
<td>Convidicea (Ad5-nCoV)</td>
<td>Recombinant vaccine (adenovirus type 5 vector)</td>
<td>CanSino Biologics</td>
<td>China</td>
<td>4 countries</td>
</tr>
<tr>
<td>4</td>
<td>CoronaVac</td>
<td>Inactivated vaccine (formalin with alum adjuvant)</td>
<td>Sinivac</td>
<td>China</td>
<td>23 Countries</td>
</tr>
<tr>
<td>5</td>
<td>Covaxin</td>
<td>Inactivated vaccine</td>
<td>Bharat Biotech, ICMR</td>
<td>India</td>
<td>4 Countries</td>
</tr>
<tr>
<td>6</td>
<td>Covid-19 vaccine AstraZeneca (AZD1222) Covishield</td>
<td>Adenovirus vaccine</td>
<td>BARDA, OWS</td>
<td>UK</td>
<td>53 countries (including UK, US), EU and WHO</td>
</tr>
<tr>
<td>7</td>
<td>COVID-19 Vaccine, Janssen (JNJ-78436735:Ad COV2 S)</td>
<td>Non-replicating viral vector</td>
<td>Janssen Vaccines (Johnson &amp; Johnson)</td>
<td>The Netherlands, US</td>
<td>11 countries (including EU,US), and WHO</td>
</tr>
<tr>
<td>8</td>
<td>CoviVac</td>
<td>Inactivated Vaccine</td>
<td>Chumakov Federal Scientific Center for Research and Immune and Biological Products</td>
<td>Russia</td>
<td>Russia</td>
</tr>
<tr>
<td>9</td>
<td>EpiVac Corona</td>
<td>Peptide Vaccine</td>
<td>Federal Budgetary Research Institution State Research Center of Virology and Biotechnology</td>
<td>Russia</td>
<td>Russia, Turkmenistan</td>
</tr>
<tr>
<td>10</td>
<td>Moderna COVID-19 Vaccine (mRNA-1273)</td>
<td>mRNA based vaccine</td>
<td>Moderna, BARDA, NIAID</td>
<td>US</td>
<td>15 Countries (including UK, US) and EU</td>
</tr>
<tr>
<td>11</td>
<td>No name announced</td>
<td>Inactivated virus</td>
<td>Wuhan Institute of Biological Products; China National Pharmaceutical Group (Sinopharma)</td>
<td>China</td>
<td>China</td>
</tr>
<tr>
<td>12</td>
<td>Sputnik V</td>
<td>Recombinant adenovirus vaccine (rAD26 and rAD5)</td>
<td>Gamaleya Research Institute, Acellena Contract Drug Research and Development</td>
<td>Russia</td>
<td>53 countries</td>
</tr>
<tr>
<td>13</td>
<td>ZF2001</td>
<td>Recombinant vaccine</td>
<td>Anhui Zhifei Longcom Biopharmaceuticals, Institute of Microbiology of the Chinese Academy of Sciences</td>
<td>Russia, Uzbekistan</td>
<td>Russia, Uzbekistan</td>
</tr>
</tbody>
</table>

For details: [https://www.raps.org/](https://www.raps.org/)
Govt revises dose interval for Oxford-AstraZeneca’s Covishield vaccine up to 8 weeks

DCGI Issues Notice to Sub-Committee On Irrational FDCs To Hear Manufacturers

The Drugs Controller General of India (DCGI) has issued notice on 23rd March 2021 to sub-committee on irrational fixed dose combinations (FDCs) to hear manufacturers from April 19, 2021 to May 7, 2021.

As per the DCGI notice, it is requested that the concerned applicants for hearing through WebEx (video conference) with effect from April 19, 2021 to May 7, 2021 with reference to FDCs may kindly confirm participation through email at fdc@cdsco.nic.in by April 9, 2021 and also submit power point (PPT) presentation along with presenter details, mobile number, email, FDC identification number and also highlight any additional new information which has been included in the PPT and was not submitted earlier.

A sub-committee of Drug Technical Advisory Board (DTAB) has been constituted under the chairpersonship of Dr Nilima Kshirsagar, Emeritus Scientist, former Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR) to examine FDCs considered irrational by the Kokate Committee.

“Accordingly, the subcommittee has invited the concerned stakeholders for a hearing from April
19, 2021 to May 7, 2021. As regards to hearing for
the particular FDC, the schedule of hearing will be
published from time to time on CDSCO website
www.cdsco.nic.in. Accordingly companies may
regularly visit CDSCO website and avail the
opportunity of hearing on the given date,” the
DCGI notice stated.

Union health ministry had on September 16, 2014
constituted a committee under the chairmanship
of Prof C K Kokate, former vice-chancellor, KLE
University, Belgaum, Karnataka for examining the
safety and efficacy of unapproved FDCs which
were licensed by the SLAs without due approval
of DCGI.

After holding a series of meetings the Kokate
Committee had submitted its second assessment
report to the Union health ministry on May 27,
2016 categorizing FDCs into “irrational (category
‘a’)”, “requiring further deliberation (category
‘b’)”, “rational (category ‘c’)” and “FDCs requiring
generation of data (category ‘d’)”. The DCGI had
earlier directed the drug manufacturers to submit
data with reference to 66 fixed dose
combinations by May 30, 2020 in view of the
Supreme Court (SC) directive on 294 irrational
FDCs.

DCGI had also earlier directed manufacturers to
submit data of 66 FDCs which required further
generation of data based on the Kokate
Committee report latest by September 30, 2019.

DCGI has further informed in the notice served to
the manufacturers that in case of failure to
submit the data by May 30, 2020, the decision
will be made on the basis of information available
before the DCGI office in light of the judgement of
the Supreme Court in cases related to 294 FDCs.

DCGI in a notice stated, “This is in continuation to
the DCGI letters and notices dated December 12,
2018, April 12, 2019 and August 27, 2019.” The
deadline on the same was further extended in
view of representations received in the matter for
extension of time for submission. Central Drugs
Standard Control Organisation (CDSCO) had
extended the deadline for submission of the FDC
data till August 16, 2019 from the earlier deadline
of June 30, 2019 based on representations from
manufacturers to give sufficient time.

The Union health ministry had earlier directed the
manufacturers to submit specific information on
irrational FDCs in the prescribed format along
with supporting documents by June 30, 2019.
Besides other things, it was also asked to submit a
one-page summary with the highest level of
evidence, supporting the claim of postulated
advantage or rationale of the FDCs.

A copy of the DCGI letter has also been sent to all
state drugs controllers, CDSCO Zonal and Sub-
Zonal offices and Indian Drug or Pharmaceuticals
Association Forum.

Source: Pharmabiz

DISCLAIMER:
The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt
to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they
are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the
organization shall be responsible for any liability for any damage incurred as a result of use of contents of this publication.
The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.