Minutes of the Meeting of Subject Expert Committee (SEC) - Vaccine to review proposals and advice Drugs controller General (India) in matters for Biologicals & PAC proposals held on 01.06.2020 (through web-conferencing)

The Recommendations:
The SEC (Vaccine) deliberated the proposals on 01.06.2020 and recommended the following:

Sl. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	BIO/CT/19/000063 DTwP-HepB-IPV-Hib (Hexavalent) Vaccine [Part I safety data of Phase II/III CT]	M/s Serum Institute of India Pvt. Ltd., Pune	The firm presented Part-I safety data of Phase II/III clinical trial of Hexavalent Vaccine. After detailed deliberation, the committee noted the safety results of part-I of Phase II/III clinical trial of Hexavalent vaccine.
2	BIO/MA/19/000010 Rubella vaccine MA (regularization)	M/s Serum Institute of India Pvt. Ltd., Pune	In continuation to the recommendation of the committee dated 18.03.2019, for the regularization of marketing authorization, the firm further requested for waiver of local clinical data with respect to re-vaccination, for non-pregnant adolescents & adult females and co-administration of Rubella vaccine and made presentation. After detailed deliberation, the committee recommended that firm should submit published literature on the clinical trial data generated either nationally or internationally or WHO guidance document in support of the claims made in package insert to CDSCO, based on which CDSCO can grant approval.
3	BIO/MA/19/000011 MMR vaccine MA (regularization)	M/s Serum Institute of India Pvt. Ltd., Pune	In continuation to the recommendation of the committee dated 18.03.2019, for the regularization of marketing authorization, the firm further requested for waiver of local clinical data with respect to re-vaccination, for non-pregnant adolescents & adult females and co-administration of other vaccines and made its

			presentation. After detailed deliberation, the committee recommended that firm should submit published literature on the clinical trial data generated either nationally or internationally or WHO guidance document in support of the claims made in package insert to CDSCO, based on which CDSCO can grant approval.
4	BIO/MA/19/000004 MR vaccine MA (regularization)	M/s Serum Institute of India Pvt. Ltd., Pune	In continuation to the recommendation of the committee dated 18.03.2019, for the regularization of marketing authorization, the firm further requested for waiver of local clinical data with respect to re-vaccination, for non-pregnant adolescents & adult females and co-administration of other vaccines and made its presentation. After detailed deliberation, the committee recommended that firm should submit published literature on the clinical trial data generated either nationally or internationally or WHO guidance document in support of the claims made in package insert to CDSCO, based on which CDSCO can grant approval.
5	BIO/CT/20/000019 Typhoid Vi Conjugate Vaccine I.P. [Phase IV CT]	M/s Cadila Healthcare Limited, Ahmedabad	The firm presented their proposal of Phase IV clinical trial of Typhoid Vi Conjugate Vaccine I.P. After detailed deliberation, the committee recommended for grant of permission to conduct clinical trial subject to following amendments: 1. In the exclusion criteria point no. 2 should be

			revised and no. 3 should be omitted. 2. Age group in Cohort-4 should be revised to 18 to 45 years age group. 3. Indication of booster dose to be given after 3 years should be removed from package insert. 4. Failure to obtain consent entry in the protocol deviation criteria should be omitted. Accordingly, firm should submit revised protocol for approval from CDSCO
6	BIO/CT/20/000024 Typhoid Vi Conjugate Vaccine I.P., [Phase IV CT]	M/s Cadila Healthcare Limited, Ahmedabad	The firm presented their proposal of Phase IV clinical trial of Typhoid Vi Conjugate Vaccine I.P. After detailed deliberation, the committee recommended for grant of permission to conduct clinical trial subject to following amendments: 1. In the exclusion criteria point no. 2 should be revised and no. 4 should be omitted. 2. Indication of booster dose to be given after 3 years should be removed from package insert. 3. Failure to obtain consent entry in the protocol deviation criteria should be omitted. Accordingly firm should submit revised protocol for approval from CDSCO
7	BIO/IMP/20/000016 23-valent Pneumococcal Polysaccharide Vaccine [MA]	M/s G. C. Chemie, Mumbai	The firm presented their proposal for grant of market authorisation for import of 23-valent Pneumococcal

			polysaccharide Vaccine without conducting Phase III clinical trial in the Country. After detailed deliberation, the committee opined that the waiver of local clinical trial is not justified and therefore, not recommended for grant of import & marketing.

Additional Agenda:

Addition of clinical trial sub-sites in Phase II/III clinical trial of Hexavalent vaccine of M/s Serum Institute of India Pvt. Ltd., Pune: The firm requested for approval of sub-site under one main site with separate study physicians at each sub-site.

After detailed deliberation, the committee recommended that, the firm should enrol the sub-sites as main sites fulfilling all the criteria of the main site.