

Minutes of the Meeting of Subject Expert Committee (SEC) - Vaccine to review proposals and advice Drugs controller General (India) {DCG (I)} in matters for Biological & PAC proposals held on 18.12.2018

Recommendation:

The SEC (Vaccine) deliberated the proposals on 18.12.2018 and recommended the following:

S. No.	File No. & name of Drug/Vaccine	Name of firm	Recommendations
1	BIO/Form44/FF/2018/11312 Rotavirus Vaccine Interchangeable study (CT)	M/s NICED, ICMR, Kolkata	M/s NICED, ICMR presented their request for the design to be non-inferiority trial. The DG, ICMR has also stated that historically such interchangeable studies are done in non-inferiority design. After detailed deliberation, the committee recommended for grant of approval for the clinical trial as per the submitted protocol.
2	BIO/Form44/FF/2018/11506 Tetanus and adult Diphtheria (Td) vaccine (Adsorbed) (MA)	M/s Central Research Institute, Kasauli	M/s Central Research Institute, Kasauli presented their proposal of market authorization of Tetanus and adult Diphtheria (Td) vaccine (Adsorbed) without non-clinical studies and clinical trial in detail. As per letter from the DC, Immunization, MoHFW, the government wants to replace TT vaccine with Td vaccine in Universal Immunization Programme (UIP). After detailed deliberation, the committee recommended for grant of permission to manufacture Td vaccine with waiver of clinical and toxicity data. However, the package insert should delete the words "every 5 to 10 years".
3	BIO/Form44/FF/2018/11214 Tetanus toxoid (Adsorbed) I.P. (MA)	M/s Bio Vaccine (India) Pvt. Ltd., Indore, MP	M/s Bio Vaccine (India) Pvt., Ltd., Indore, MP presented the proposal along with the data from Phase II/III clinical trial. After detailed deliberation, the committee recommended for grant of market authorization of Tetanus toxoid (Adsorbed) I.P. for the indication of "for active immunization against tetanus between 10 to 60 years age group".
4	BIO/Form44/FF/2018/11597 Typhoid Vi Conjugate Vaccine I.P. (CT Phase-IV)	M/s Cadila Healthcare Limited, Ahmedabad	The firm presented their proposal for conduct of Phase IV clinical trial. After detailed deliberation, the committee recommended grant of permission for the conduct of the study subject to the following conditions:

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			<p>1. All the sites from the previous study to be included.</p> <p>2. Approximately, the drop out should not be more than 30%.</p> <p>3. The firm should submit the study results at the end of the study.</p>
5	<p>BIO/Form44/FF/2018/11089</p> <p>Live, Attenuated Bacillus Calmette-Guerin Vaccine (MA)</p>	<p>M/s Serum Institute Of India Pvt. Ltd, Pune</p>	<p>The firm presented their proposal for grant of marketing authorization for Live, Attenuated Bacillus Calmette-Guerin Vaccine along with clinical trial data in Indian population. After detailed deliberation, the committee recommended for grant of marketing authorization for Live, Attenuated Bacillus Calmette-Guerin Vaccine.</p>
6	<p>BIO/Form44/FF/2018/11170</p> <p>Poliomyelitis Vaccine (Inactivated) I.P. (MA)</p>	<p>M/ Serum Institute of India Pvt., Ltd., Pune</p>	<p>The firm was asked to conduct phase IV clinical trial in the country for the vaccine. The firm presented data of phase IV clinical trial of the said vaccine conducted in Indian population (published in 2017). After detailed deliberation, the committee recommended for grant of waiver of the condition to conduct phase IV clinical trial and recommended for market authorization for Poliomyelitis Vaccine (Inactivated) I.P.</p>
7	<p>BIO/Form44/FF/2017/5521</p> <p>Pneumococcal Conjugate Vaccine (2+1 Schedule) (CT Phase-III)</p>	<p>M/ Serum Institute of India Pvt., Ltd., Pune</p>	<p>The firm presented their proposal for conduct of phase III clinical trial with 2+1 schedule. After detailed deliberation the committee recommended that the firm should first conduct phase III clinical trial with 3+0 schedule and after submitting the results of the same they can initiate phase III clinical trial with 2+1 schedule.</p>
8	<p>BIO/Form44/FF/2018/11751</p> <p>Pneumococcal Conjugate Vaccine (3+0 Schedule) (MA)</p>	<p>M/ Serum Institute of India Pvt., Ltd., Pune</p>	<p>The firm had submitted proposal for grant of marketing authorization for the proposed vaccine. The firm presented phase III clinical trial data generated in Gambia. After detailed deliberation the committee recommended that the firm should conduct a bridging study with the proposed vaccine in the country with</p>

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			DCGI approved comparator with 3+0 schedule. Accordingly, the firm should submit phase III clinical trial protocol etc. for approval.
9	BIO/Form44/FF/2018/11143 JE Vaccine (CT Phase-IV)	M/s Bharat Biotech Limited, Hyderabad	The firm presented their proposal for conduct of Phase IV clinical trial. After detailed deliberation, the committee recommended for grant of permission for conduct of Phase IV trial subject to following conditions: 1. The age group for enrollment will be 15 to 50 years instead of 18 to 50 years. 2. The title should be amended accordingly. 3. Firm will include sites equally from endemic and non-endemic areas. Accordingly, firm should submit revised clinical trial protocol to DCGI.
10	BIO/Form44/FF/2018/11143 Quadrivalent Influenza vaccine (MA)	M/s Abbott India Limited, Mumbai	The firm presented the proposal along with phase III clinical trial data. After detailed deliberation, the committee recommended for grant of market authorization for Quadrivalent Influenza vaccine for adults.
11	12-170/GSK/PAC-Varicella/16-BD Varicella vaccine (PAC)	M/s GlaxoSmithKline Pharmaceuticals Limited, Mumbai	The firm presented the proposal in detail. After detailed deliberation, the committee recommended for grant of approval for proposed changes in package insert. The data generated outside India should be specified accordingly.
12	12-30/GSK/PAC-MMR/14-BD MMR Vaccine (PAC)	M/s GlaxoSmithKline Asia Private Limited, Nabha (Punjab).	The firm presented the proposal in detail. After detailed deliberation, the committee recommended for grant of approval for proposed changes in package insert.