1. **Recommendations of New Drugs Advisory Committee of Vaccine held on 30.03.2012 at FDA Bhawan, 1st Floor, New Delhi.**

AGENDA NO.	NAME OF DRUG/VACCINE	RECOMMENDATIONS
Global Clinical Trials Biological		
1	**V212**	All the experts agreed that the toxicity studies done with heat treated varicella zoster vaccine were sufficient. Committee recommended for approval of the study subject to the following conditions :- i) The trial batch should be tested at CDL, Kasauli before initiating the study. ii) Subjects aged 18 to 65 years should be enrolled in the study. iii) At least one member in the DSMB should be an Indian representative. iv) One medical oncologist should be present at every study site.
Bacterial Vaccine Proposals		
2	**Meningococcal (ACW 135 Y) Polysaccharides Diphtheria toxoids conjugate vaccines**	Committee recommended for marketing approval of the vaccine subject to the following conditions :- i. It should be used in individuals aged 2 to 55 years. ii. India specific package insert should be submitted to this office before launching the product in India.
3	**13 Valent Pneumococcal saccharide conjugate vaccine (Prevenar)**	Committee recommended for marketing approval of the vaccine subject to the following conditions :- i. Phase IV study on 1000 adult subjects aged ≥ 50 years should be conducted. ii. Protocol should be submitted to the office of DCG(I) within 3 months of marketing approval and study should be initiated within 2 months after protocol approval. iii. Study should be completed within 2 years of grant of marketing approval.
4	**Typbar (Typhoid Vi Capsular Polysaccharide)**	Committee recommended for approval of the study subject to condition that inclusion criteria should be revised to clearly define the inclusion of immunocompromised patients as per immunisation guideline.
5	**Hib conjugate and Pneumococcal conjugate vaccines**	The applicant presented the protocol which was different from the protocol submitted to the experts. Committee recommended for revision of the protocol to include the following points:- i) Age group of subjects should be defined. ii) Blood withdrawal in control group should be clearly mentioned. iii) Name of the laboratories to be used should be mentioned. iv) Investigator should be paediatrician/radiologist/ microbiologist. The committee recommended that the revised

		protocol will be reviewed by Dr. A. P. Dubey and based on his recommendation the DCG (I) will take the appropriate decision.
Miscellaneous		
6	**Seasonal trivalent influenza vaccine**	Recommended for approval.

2. Recommendation of New Drugs Advisory Committee of Vaccine held on 12.05.2012 at FDA Bhawan, 1st Floor, New Delhi.

AGENDA NO.	NAME OF DRUG/VACCINE	RECOMMENDATIONS
1	**Measles, Mumps, Rubella Vaccine (Live), Multidose**	Committee Recommended Phase I trial. Issue of Hoshino strain of Mumps was discussed & experts wanted to know the countries where the said strain is approved, marketed and the clinical data in this regards. The firm explained that the said strain is marketed in Japan & Iran only, and is a WHO qualified strain. The firm also presented the published clinical data on the Hoshino strain. The expert's panel also discussed the issue of toxicity studies conducted on MMR vaccine conducted by the firm in this group. Reconstitution studies for Multidose to be done.
2	**Rubella vaccine, Single Dose**	Committee Recommended Phase I trial based on Toxicity data generated on MMR Vaccine.
3	**Measles, Mumps, Rubella Vaccine (Live) Single Dose**	Committee Recommended Phase I trial. Issue of Hoshino strain of Mumps was discussed & experts wanted to know the countries where the said strain is approved, marketed and the clinical data in this regards. The firm explained that the said strain is marketed in Japan & Iran only, and is a WHO qualified strain. The firm also presented the published clinical data on the Hoshino strain. The expert's panel also discussed the issue of toxicity studies conducted on MMR vaccine conducted by the firm in this group.
4	**Measles, Rubella (Live) vaccine, Multidose**	Committee Recommended Phase I trial based on Toxicity data generated on MMR Vaccine. Stability study data after reconstitution need to be submitted.
5	**Measles Vaccine (Live) Single dose**	Committee Recommended Phase I trial based on Toxicity data generated on MMR Vaccine.
6	**Measles-Rubella (Live) Single dose vaccine**	Committee Recommended Phase I trial based on Toxicity data generated on MMR Vaccine.
7	**Rubella Vaccine (Live) Multi Dose**	Committee Recommended Phase I trial based on Toxicity data generated on MMR Vaccine. Stability study data after reconstitution need to be submitted.
8	**Mumps Vaccine (Live) Single dose**	Committee Recommended Phase I trial based on Toxicity data generated on MMR Vaccine.
9	**Measles Vaccine (Live)**	Committee Recommended Phase I trial based on Toxicity data generated on MMR Vaccine. Stability

	Multi dose	study data after reconstitution need to be submitted.
10	**Live attenuated Tetravalent Bovine Human Ressortant Rotavirus vaccine**	Committee Recommended to conduct the Phase I/II trial with the condition 1. To submit and take approval of the DCG(I) office based on the safety data generated on cohort on adults before starting the study in infants. 2. ICF should be amended to accommodate three sample of blood sample should be taken from each subject and fourth blood sample should be taken after the concerned from the parents/guardians. 3. The error in the animal toxicity data with respect to route of administration should be rectified.
11	**Inactivated Japanese Encephalitis Vaccine**	Committee Recommended grant of Marketing Authorization subject to condition 1. To follow up the patients of clinical Trial up to 2 years for safety and Immunogenicity. 2. Dosage Regimen should be 2 doses.
12	**Freeze dried Live Attenuated Hepatitis A (Biovac A) vaccine**	Committee Recommended conduct of Phase III trial on the said vaccine based on the PSUR Data on 50 million doses from China. Trial permission will be subject to 1. Submission of revised protocol terming the trial as Phase III should revised. 2. The Hindi Version of ICF should be revised.
13	**Varicella vaccine (VR 795 vericella Oka strain)**	Committee Recommended the trial Subject to conditions: 1. Protocol amendment should be done in respect of Inclusion criteria to include that the study Should be done in age group from 12 months to 12 years of age. 2. Name of all study centers should be notified to this office. 3. ICF should be revised.
14	**bOPV vaccine**	The committee observed that the composition of the bivalent OPV vaccine of M/s Sanofi is different from already permitted Vaccine of M/s Panacea Biotech with M/s Sanofi Pasteur bulk and also there is no data on clinical trial on the said vaccine world over. Committee Recommended to conduct Phase III study in India. The firm needs to submit Protocol for Phase III study in statistically significant subjects.
15	**Zostavax vaccine**	Committee Recommended the trial. The batches of clinical trial should be tested at CDL Kasauli.
16	**Rotavirus Vaccine**	Committee Recommended the amendment in indication to include G9 with the condition that the firm should generate PMS study data on at least 100 subjects and submit the protocol within three month of approval and the study report should be submitted wihin 2 years of approval.

3. Recommendation of New Drugs Advisory Committee of Vaccine held on 08.08.2012 at FDA Bhawan, 1st Floor, New Delhi.

AGENDA NO.	NAME OF DRUG/VACCINE	RECOMMENDATIONS
1	**lactobacillus brevis CD2 nasal drops**	No safety and efficacy data was provided by applicant on the trial drug in animals. The committee recommended that the safety and efficacy data on animals needs to be generated before the permission is granted to carry out the study in humans.
2	**INDIRAB(Chromatogarphically Purified, Inactivated, LyophilizedRabies Vaccine, Prepared on Vero Cells)**	The data was reviewed by the committee and it was noted that in the text of report there was some discrepancy in the dose of the drug (either 3 or 4 dose given to subjects), which was explained by the firm to be typographical error so the Committee Recommended to again submit the report with the corrected data and table which will be reviewed in the next NDAC (Vaccine) meeting.
3	**Rabies vaccine(Rabipur)**	Firm has requested to defer the proposal and was not present for their proposal.
4	**Varicella Vaccine, Live, I.P. (BIOPOXTM) manufactured by Bio-Med (P) Ltd**	Committee Recommended to give the permission to conduct Phase I clinical trial subject to the condition of submission of revised Informed Consent Form and to submit the revised undertaking of Principal investigator.
5	**Cervarix(HPV)**	Committee Recommended to give the permission of Market Authorization with the condition to generate the PMS data in 100 trial subjects with age group of 9 years.
6	**bOPV (type 1 & 3)**	Committee Recommended for the Market Authorization subject to conduct and the submission of Phase IV protocol on 1000 subjects and with the direction to submit the interim report on 500 subjects to this office for evaluation.
7	**Rabies vaccine**	Committee Recommended to give permission to conduct Phase II/III Clinical trial subject to condition to

		submit the interim data of category 2 subjects on 45 subjects before going in category 3.
8	**VGX-3100**	Committee Recommended to give the permission to conduct Phase II clinical trial subject to the following conditions: 1. The blood samples of trial subjects should be collected according to ICMR guidelines. 2. The trial batch of vaccine should be tested from CDL, Kasauli before initiation of study.
9	**Epidermal growth factor (EGF) cancer vaccine**	Committee Recommended Phase III trial with the condition 1. Standard of care should be given free of cost to the trial subjects. 2. The trial batch of vaccine should be tested from CDL, Kasauli before initiation of study. 3. The firm is required to obtain clearance from GEAC before permission to conduct the trial is granted.
10	**DTaP Vaccine**	Committee Recommended to give the permission to conduct the Phase I clinical trial with the condition to submit the data on the age group of 4-6 years of age for satisfactory evaluation by this office, before conducting the study in lower age group.
11	**Typhoid (Vi Capsular Polysaccharide) - Tetanus Toxoid Conjugate vaccine**	Committee Recommended to grant the Market Authorization with the condition to follow up the subjects included in the clinical trial for up to Three years for evaluation of safety and efficacy as part of PMS study and submit the report to this office.

4. Recommendation of New Drugs Advisory Committee of Vaccine held on 28.08.2012 at FDA Bhawan, 1st Floor, New Delhi.

AGENDA NO.	NAME OF DRUG/VACCINE	RECOMMENDATIONS
Vaccine Proposals		
1	**Human Diploid Cell Rabies Vaccine (Rabivax)**	The committee did not recommend the study on the ethical grounds and asked to provide the rationale for the conducting additional Phase IV study. The reason for evaluating the immunogenicity and safety of the said vaccine when there is adequate safety & efficacy data available. Any issues observed by the firm on the safety and immunogenicity of the said vaccine. Whether any detection of safety being signed in the post licensure since licensing. If so, the details?
2	**PMS to assess the safety of Gardasil in females of age 9 to 45 years in routine clinical care**	The committee recommended the study with the following conditions 1) Out of the 500 doses proposed to be administered to the subjects at least 100 subjects should be covered who have received all three doses of the vaccines. 2) All the trial centres should have emergency services and preferably should be multispecialty hospitals. 3) The applicant should explore the possibility of study to be conducted in major Government hospitals like AIIMS, Army hospital and Railway Hospitals etc.
3	**Vaccine (Rabipur)**	The committee opined the applicant should explain in writing the reason for not appearing in the committee two times.
4	**Rabies Vaccine Human**	The committee recommended the use of 1 ml diluents for reconstitution of vaccine by intramuscular route with the condition to conduct Post Marketing Surveillance study on more than 500 doses.
5	**tOPV (type 1, 2 & 3)**	The committee recommended the approval of Form 46 with the waive off the requirement for evaluation of CMC, non clinical data and clinical data.

5. Recommendation of New Drugs Advisory Committee of Vaccine held on 26.10.2012 at FDA Bhawan, 1st Floor, New Delhi.

AGENDA NO.	NAME OF DRUG/VACCINE	RECOMMENDATIONS
1	**Rabies Vaccine (Rabipur)**	The committee recommended to submit the following data for further review by NDAC committee:- 1. Comparability data of indigenously and imported Vaccine with respect to safety and efficacy of the products. 2. Justification for importing of the Rabies vaccine in respect of shortage of Vaccine in India.
2	**MMR (Tresivac) Vaccine**	Committee recommended for permission of the said study subject to the submission of following data:- 1. The immunogenicity study data using the proposed new device. 2. The compatibility data of container & closures system as per the requirement of guidance for Industry.
3	**Rabies Vaccine, Human (Cell Culture)**	Committee recommended the study protocol subject to submission of the revised protocol in respect to the following changes: 1. Proper dosage regimen of TRC as (2, 2, 2 & 0, 2) at day 0, 3, 7 and 28. 2. Revised Ethics Committee approval. 3. Informed Consent form in the local language. 4. LLR, Meerut site for REFFIT Analysis test.
4	**Optimizing Intradermal Delivery of Rabies Vaccine in India**	Committee does not recommend the study for post-exposure cases as the said device is not approved anywhere in the world and only safety data on 20 healthy Adults in US has been submitted by the firm therefore the firm is advised to submit the protocol to conduct the study of pre-exposure in 50 subjects.
5	**CERVARIXTM (Human Papillomavirus Vaccine rDNA Ph Eur)**	Earlier proposal was discussed in NDAC meeting dated 08.08.2012 wherein the committee recommended the firm to conduct the PMS study in age group of 09 years is stand withdrawn by the committee, as the current proposal for conducting PMS study in approved age group 10-45 years has been forwarded to ICMR. Now Committee recommended to conduct the PMS study in approved age group i.e., 10 to 45 years only subject to the approval of protocol from ICMR.
6	**Hepatitis A**	Dr. A. P. Dubey did not participate during the presentation of this study. Committee recommended to submit 1. Revised Phase III protocol to first conduct the study in Adult age group before in the paediatrics group. 2. Amendment in the inclusion criteria with respect of age group and sample size which is to be certified by biostatistician.

		3. The study centres should be geographically distributed across the country. 4. Regulatory approval along with clinical trial data from China, Magnolia and Nepal.
7	**pentavac (DTwP-HB-Hib)**	Committee recommended for permission of the said study subject to the submission of following data:- 1. The immunogenicity study data using the proposed new device. 2. The compatibility data of container & closures system as per the requirement of guidance for Industry.
8	**10-valent Pneumococcal Polysaccharide Conjugate**	Committee recommended to give the permission subject to following conditions: 1. The upper age group should be 65 years 2. The bio-data of all Investigators and co-investigators should be submitted. 3. Submit the details of unbound protein present in the final vaccine with the acceptable limit as per the validation data. 4. The copy of certificates of GCP training provided to the Principle Investigators and other trial related team members.
9	**TT**	Committee recommended to give the permission to conduct the subject study.
10	**DT vaccine**	Committee recommended to give the permission to conduct the subject study.
11	**DTaP vaccine**	Committee recommended to give the permission to conduct the subject study.
12	**DTaPHib vaccine**	Committee recommended to give the permission to conduct the subject study.
13	**quadrivalent seasonal influenza vaccine GSK2321138A (FLU D-QIV)**	Committee recommended for the permission of study. The clinical trial batches should be certified from CDL, Kasauli before initiating of study.
14	**Verorab®**	Committee recommended for the permission of study subject to submission of regulatory approval from other participating countries for protocol version 4.0. In India subjects between age groups of 18-50 years should be enrolled.

6. Recommendations of New Drugs Advisory Committee of Vaccine held on 05.03.2013 at FDA Bhawan, 1st Floor, New Delhi.

AGENDA NO.	NAME OF DRUG/VACCINE	RECOMMENDATIONS
1	**Live Attenuated Bovine-Human Rotavirus Reassortant Pentavalent Vaccine (BRV-PV)**	The Committee recommended the trial and suggested • To include study site from north, south and east region in India. • Immunogenicity data will be compared with already licenced vaccine in India and it shall be reviewed by DCG(I) office prior to market authorization.
2	**Live Influenza Vaccine (NASOVAC-S)**	The committee recommended market authorization with subject to condition- • Phase IV trial protocol will be submitted within one month after the grant of market authorization permission in order to systematically evaluate formulation A in larger population.
3	**Recombinant Hepatitis B Vaccine**	The committee recommended the market authorization with subject to condition- • Phase IV trial protocol to be submitted by the firm within one month of approval with approximately 200 subjects and trial to be started within four months of receipt of manufacturing Licence. Phase IV protocol may be approved without further referral to NDAC
4	**Inactivated Polio Vaccine Human**	The committee recommended the proposal.
5	**Freeze-dried Live Attenuated Hepatitis A Vaccine(H2 Strain)**	The committee recommended the proposal in principle subject to submission of • Strain prevalence data in India • Post Marketing Surveillance data of China • □ CMC data
6	**DTaP-IPV-Hib-HepB-PRP-T combined Vaccine(Hexaxim)**	The committee recommended the trial.
7	**Liquid Penta Valent Vaccine**	The committee recommended • Animal Toxicity data in test animals shows relative weight gain in many organs and simultaneously reduction in the loss of the weight in the other organ. Therefore the pre-clinical data will be sent to Toxicologist from CDRI, Lucknow or other Government Institute for expert opinion and if the data is adequate the protocol will be approved

		without considering the comparator in phase I and II. The Committee recommended that phase I/II shall be carried out sequentially in descending age group of 2 to 5 years and 16 to 24 months at least in 40 to 60 subjects. The company shall provide revised protocol which shall be approved if the toxicologist give clear favourable opinion and shall be again put to the committee if opinion is not clear.
8	**Bivalent oral poliovirus vaccine (bOPV) and trivalent oral poliovirus vaccine (tOPV) in the standard EPI schedule, with or without inactivated polio vaccine (IPV)**	The committee has recommended for the study other than intra-dermal route i.e. five arms subject to the submission of the revised protocol. The committee has not recommended for the intra-dermal route due to the lack of following data • Preclinical data is to be submitted. • Efficacy data in small population in phase II trial to be generated for ID route for which company shall submit another protocol. • If above is submitted and found satisfactory then the trial arm for intra-dermal evaluation may be approved
9	**Bivalent Poliomyelitis Vaccine Type 1 & 3, Live (Oral)**	The proposals are verified & manufacturing authorization based on data available is considered acceptable. It is recommended that PSUR data of these vaccines shall be reviewed regularly by CDSCO. Polio bulk/ formulation was imported from the already approved source, so committee agreed for the regularization of market authorization for all the five additional proposals.
10	**Bivalent Poliomyelitis Vaccine Type 1 & 3, Live (Oral)**	
11	**OPV type 1**	
12	**Trivalent OPV**	
13	**Oral Polio mylitis Type 1 Vaccine (Monovalent)**	

7. Recommendations of New Drugs Advisory Committee of Vaccine held on 15.04.2013 at FDA Bhawan, 1st Floor, New Delhi.

Agenda no.	Name of drug/vaccine	*Recommendations*
1	**Japanese Encephalitis Inactivated Vaccine (JE)**	The committee recommended the said trial subject to submission of revised protocol with the following : • Term the study as phase IV • To include 100 subjects • Equal distribution of all age groups • To include one more centre preferably from North/East India.
2	**Tetanus, Diphtheria vaccine**	The committee noted that vaccine has already been licensed by the office of DCGI and in order to regularize the product the firm may be advised to submit the form 44 along with TR challan in order to ensure that the regulatory documents are in compliance as per Drugs & Cosmetics Act & Rules, before the phase IV is conducted in the country. The protocol was well accepted by the committee.
3	**Oral Rotavirus Vaccine, 116E attenuated**	The committee recommended the conduct of the study subject to submission of a revised protocol with one year of follow-up for intussusceptions after the last dose of vaccine. The committee felt it was necessary to follow up the subjects upto one year. The committee also recommended that 6ml of blood be drawn from all groups to ensure blinding. The objection if any by the ethics committee on this issue be intimated to this office as mentioned by the investigator. The lot selection should be random.
4	**JENVAC (Purified, Inactivated Japanese Encephalitis Vaccine**	The committee recommended to conduct study using the licensed mouse brain derived inactivated vaccine as the comparator since the comparator suggested by the firm is a newly licensed vaccine
5	**INDIRAB® (Chromatographically Purified, Inactivated, Lyophilized Rabies Vaccine, Prepared on Vero Cells)**	The committee recommended the proposal without conducting the trial as there is no change in label claims.
6	**Measles, Mumps and Rubella Vaccine (Live) Single**	The committee recommended the trial subject to following condition, • To revise the no. of subjects as 50. • To specify the amount of blood sample to be withdrawn.

	dose	
7	**Measles, Mumps and Rubella Vaccine (Live) Multi dose**	The committee recommended the trial subject to following conditions, • To revise the no. of subjects as 50 • To specify the amount of blood sample to be withdrawn.
8	**Measles Vaccine (Live) single dose**	The committee recommended the trial subject to following conditions, • To revise the no. of subjects as 50. • To specify the amount of blood sample to be withdrawn.
9	**Measles Vaccine (Live) Multi dose**	The committee recommended the trial subject to following conditions, • To revise the no. of subjects .as 50 • To specify the amount of blood sample to be withdrawn.
10	**Mycobacterium W.**	The committee recommended the trial. However the PMS data need to be submitted.
11	**Conivaptan**	The committee recommended that the study should be conducted on higher age group (11-15 yrs) before going to lower age group and no. of centres should be reduced.
12	**Herpes zoster gE/AS01B candidate vaccine**	The committee recommended the approval of the proposal.
13	**Lactobacillus rhamnosus+Saccharomyces Boulardii+Zinc**	The committee recommended that firm should make a detail presentation before the committee.
14	**USL#3 Probiotic**	The committee noted that VSL#3 formulation is approved for IBS, rotavirus diarrhoea in children by office of DCGI however for management of sepsis the drug is not yet approved. The committee recommended for the submission of report of VSL#3 in sepsis conducted by ICMR, Sponsor Undertaking for providing compensation in case of clinical trial related injury/death to trial subjects, registration of Ethics committee of the institutes at DCGI office.
15	**Probiotic USL#3**	The committee noted that VSL#3 formulation is approved for IBS, rotavirus diarrhoea in children by office of DCGI. however the applicant has proposed to

		assess the effect of VSL#3 administered during initial 4 weeks of life on bone strength in preterm (>34 weeks of gestation age) newborns. The committee requested for clarifying in respect of following for further review 1. Whether the drug is to procured from ICMR or directly from the manufacturer 2. Rationale for not inclusion of L.Salivarius, L.helventicus and B.infantis in the proposed drug formulation Sponsor Undertaking for providing compensation in case of clinical trial related injury/death to trial subjects, registration of Ethics committee of the institutes at DCGI office may also be submitted.
16	**tOPV vaccine**	The committee opined that the tOPV may be granted since the product is used since 1996 and being programme vaccine. Dr. Y.K. Gupta did not participate in this proposal.

8. Recommendations of New Drugs Advisory Committee of Vaccine held on 03.05.2013 at FDA Bhawan, 1st Floor, New Delhi.

Agenda no.	Name of drug/vaccine	Recommendations
1	**Monovalent oral poliovirus vaccine type 3, Nitazoxanide and Azithromycin**	• After discussion the committee recommended that both the drugs (Nitazoxanide and Azithromycin) should be approved for use in less than one year of age (6 to 11 months age group) before it is considered by NDAC for approval.
2	**Gardasil-Human Papilloma virus Quadrivalent (type 6, 11, 16 and 18) recombinant vaccine**	• Firm not presented the proposal.
3	**Quinvaxem (DTwP-Hib-HepB) Pentavalent vaccine**	• The committee recommended to approve market authorization subject to condition that PMS data in toddler population will be generated. • Firm will also submit the application in CTD format.
4	**Meningococcal A C W Y conjugate vaccine**	• The committee noted the safety data in the adult age group and found to be satisfactory. The protocol for conducting in the lower age group has been approved with the condition that the safety data of 11 to 18 years will be submitted to the Office of DCGI for the satisfactory evaluation before going to the lower age group population (2 to 10 years). • The lower age group should also be stratified into two age groups i.e. 2 to 5 years (30 numbers) and 6 to 10 years (30 numbers).
5	**Agrippal (seasonal influenza vaccine)**	• The committee noted that there is no change in the composition, indication and dosage form of already marketed product and there is only change of the Indian Authorized agent which is approved.
6	**13-valent pneumococcal vaccine**	• The committee recommended to conduct the safety and immunogenicity study between 50 to 65 years old adults in 1000 subjects and submit the revised protocol to DCGI for approval.
7	**13-valent pneumococcal vaccine**	• The committee approved the proposal with the inclusion of age group of 6, 10 and 14 weeks as primary immunization in the package insert.
8	**13-valent pneumococcal vaccine**	• The committee recommended the proposal to conduct the safety and immunogenicity study between 6 to 17 years age group in 200 subjects and submit the protocol to DCGI for approval.

9	**10-valent Pneumococcal conjugate vaccine**	• The committee recommended to do Phase I study only in adult population in 18 to 40 years age group. • The matter regarding the use of 10-valent serotype vaccine using recombinant CRM197 conjugate material was discussed in detail and it was decided that the approval of RCGM in this regard has been obtained by the firm and RCGM has recommended for conduct of appropriate Phase I trial.
10	**Measles, mumps, rubella and varicella vaccine (live, attenuated) (VaMMRix)**	• The committee recommended to use the vaccine from 1 year to 12 years of age.
11	**Boostrix (DTaP) vaccine adsorbed**	• The committee recommended for submission of Indian PSUR data to the DCGI for evaluation and recommend appropriate action.
12	**Typhoid Vi Polysaccharides- Diphtheria Toxoid Conjugate vaccine**	• The committee recommended the conduct of Phase I/II study subject to the submission of revised protocol with two cohorts with the age group of 18 to 45 years and 2 to 17 years and the firm will proceed to the lower age group only after submission and satisfactory evaluation data from the adult age group.

9. Recommendations of New Drugs Advisory Committee of Vaccine held on 28.06.2013 at FDA Bhawan, 1st Floor, New Delhi.

Agenda no.	Name of drug/vaccine	Recommendations
1	**Haemophilus Type B-Tetanus Toxoid conjugate vaccine (adsorbed) I.P.**	Recommended for conducting Phase I study with the condition to submit COA of 3 batches and only CDL certified batches shall be used for the study. Additionally firm has to submit the insurance coverage also.
2	**Hepatitis A vaccine inactivated**	The firm has to submit revised protocol specifying that the study shall be conducted only in adults. The study should not be conducted in private clinics and no samples shall be taken for genomic studies.
3	**Gardasil-Human Papilloma virus**	The proposal to be referred to ICMR for further directions.
4	**Synflorix (10 valent Pneumococcal-polysaccharide Non Type able Haemophilus influezae protein D conjugate) vaccine**	Deferred by the firm.
5	**Poliomyelitis Vaccine (Inactivated) IP, Trivalent (POLIORIX®)**	The committee recommended to allow the new drug permissions based on the safety and efficacy data derived from the Indian subjects on the WHO sponsored study. However before granting the permission the firm is advised to produce the letter from WHO that data can be used for MA purpose in India.
6	**Rotavirus liquid vaccine**	Committee recommended the firm to conduct the Phase IV study in Indian population before approving the product in liquid formulation for Indian market. Dr. A.P. Dubey did not participate in discussion.
7	**Tetanus Toxoid bulk and formulation**	Committee recommended the proposal for regularization of new drug permission. The firm was also directed to conduct the PMS study on 500 subjects
8	**Varicella vaccine**	Committee recommended the proposal in-principle with the condition to revise the protocol as Phase II/III and divide the age groups into 2 cohorts >6-12 years and 1-6 years and study should be done in sequential manner. Dr. A.P. Dubey and Dr. Iqbal kaur did not participate in the discussion.
9	**Oral Polio**	Committee recommended the proposal for

	Vaccine, (Trivalent), Live attenuated	regularization of new drug permission. The firm was also directed to conduct the PMS study on 500 subjects
10	**Recombinant Hepatitis B vaccine 10 µg (0.5 ml) & 20 µg (1ml)**	Committee recommended that the firm will submit safety and purification data of 3 batches being a new cell line (CHO cells) and also release certificate from CRI Kasauli. The above data shall be put to NDAC for further recommendations.
11	**tOPV**	Committee recommended the proposal for regularization of new drug permission. The firm was also directed to conduct the PMS study on 500 subjects.

10. Recommendations of New Drugs Advisory Committee of Vaccine held on 02.08.2013 at FDA Bhawan, 1st Floor, New Delhi.

Agenda no.	Name of drug/vaccine	Recommendations
1	**Oral Rotavirus vaccine 116E, Live attenuated (ROTAVAC®)**	After the detailed discussion of quality, safety and efficacy of Live attenuated oral Rotavirus vaccine (116E) manufactured by BBIL, Ltd the committee recommended to allow the new drug permission with the following conditions: 1. The buffer and the vaccine should be supplied as a combi pack in both single and multiple dose vials. 2. The upper age limit for the third dose should be modified to 8 months of age instead of 2 years as per the protocol. 3. A strong pharmacovigillance plan should be developed and submitted within 1 month of permission for further review by the committee. 4. The multidose vial once opened should be kept at 2-8 degree centigrade and used in the same immunization session (within maximum 8 hours). 5. The cases of intussusceptions reported were reviewed in both the group by the committee and it was not found statistically significant.
2	**Inactivated Japanese Encephalitis vaccine**	The committee recommended the Phase IV trial with equal number of subjects in the following age group: 1. 1-5 yrs (120 subjects). 2. >5-10 yrs (120 subjects). 3. >10-15 yrs (120 subjects).
3	**Purified, Inactivated, Lyophilized Rabies Vaccine, prepared on Vero cell (INDIRAB) 0.5 ml ID**	The committee recommended the proposal for the regularisation of new drug permission as per the conditions stipulated in the NOC for Intra dermal route.
4	**Hepatitis B vaccine (rDNA) and (Bulk).**	The committee recommended the proposal for the regularisation of new drug permission with the condition to generate PMS data in 500 subjects.
5	**Japanese Encephalitis vaccine**	The committee recommended the proposal for additional presentation in 0.5 ml (3mcg for paediatric dose) and 0.5 ml (6 mcg for adult dose) to new drug permission with the condition to generate PMS data in

		800 subjects. The protocol to be submitted to this Directorate within one month of grant of permission.
6	**Tetanus Toxoid vaccine (Adsorbed) I.P.**	The committee recommended the proposal for the regularisation of new drug permission with the condition to generate PMS data in 500 subjects.
7	**Diphtheria, Tetanus and Pertussis vaccine (Adsorbed) I.P.**	The committee recommended the proposal for the regularisation of new drug permission with the condition to generate PMS data in 500 subjects.
8	**Fully Liquid Hexavalent DTwP-HepB-Hib-IPV Vaccine (EasySixTM)**	The committee recommended to provide additional toxicity and immunogenicity data in a Rodent species which will be reviewed by the committee along with the study protocol.
9	**EasyfourPol vaccine (DTwP-Hib-IPV) vaccine**	The committee recommended to provide additional toxicity and immunogenicity data in a Rodent species which will be reviewed by the committee along with the study protocol.
10	**Nepadutant**	The committee recommended for submission of following data: 1. Safety and rationale of use of each component of the formulation. 2. Phase I safety data in the target age group. 3. Inclusion of Standard Therapy in the trial.
11	**Fully liquid DTwP-Hib (TTconjugated)-HB vaccine**	The committee recommended the conduct of the said trial subject to getting the comments from the CDRI Lucknow regarding the response submitted by the firm on their queries on the toxicity studies.
12	**Typhoid Vi capsular polysaccharide-Tetanus Toxoid protein conjugate vaccine (Typbar- TCV)**	The committee recommended to use the booster dose after 2 years on the ongoing PMS. However the subjects in the Non Booster Dose group who do not show the protective titre should be given the booster dose.

11. Recommendations of New Drugs Advisory Committee of Vaccine held on 08.11.2013 at FDA Bhawan, 1st Floor, New Delhi.

Agenda no.	Name of drug/vaccine	Recommendations
1	**monovalent Oral Poliovirus Vaccine type 3 and Azithromycin**	The committee deliberated the study in detail (including the inclusion of vulnerable population of six months) and recommended to approve the study. The committee also felt that the study is of scientific and programmatic relevance.
2	**live attenuated rotavirus vaccine**	Firm made a detailed presentation and explained the study design with respect to the use of buffer in the proposed Phase IV study. The committee deliberated the proposal and recommended to approve the study with the inclusion of at least one centre from the northern region.
3	**Pseudomonas aeruginosa Vaccine**	The firm's representative did not attend the presentation, however the committee went through the details of the outcome of the study, and also the amended protocol. After the discussion, the committee noted the following points- 1. There was a high mortality in the treatment as well as in comparison arm possibly due to severity of the underlying burn. 2. The ethics committee of one of the sites (SMS Jaipur) raised concern about high mortality rate leading to suspension of the study at that site. In the light of the facts provided, the committee is of the view that this study be discontinued and the data so far generated be provided to the CDSCO. The committee suggests that a fresh study protocol that is properly designed and powered with inclusion of subjects with less severe burns, be submitted for further consideration/ discussion at the NDAC. The amendment as sought by the firm presently is not allowed.
4	**Cholera vaccine**	The committee deliberated the post licensure study of indigenously developed oral Cholera vaccine

	(shancol)	(Shancol) and recommended the product for target age group 01-47 years.
5	**Solco UroVac vaccine**	After the detailed deliberations, the committee recommended that this product is not approved for marketing and therefore it was recommended to conduct safety and efficacy study in recurrent urinary tract infection in Indian subjects.
6	**Pneumococcal Polysaccharide and Non-Typeable Haemophilus influenza (NTH) Protein D Conjugate Vaccine, adsorbed (Synflorix)**	The committee recommended the following changes in the prescribing information : 1. Schedule for preterm infants (between 27-36 weeks of gestation)-three primary and one dose 2. Full term infants >36 weeks-2 primary plus one doses. 3. Catch up (for unvaccinated older children)-2 doses, recommendation will be reviewed after examining the study report.
7	**Inactivated Hepatitis A vaccine**	The committee approved permission for addition of manufacturing site for syringe filling and packaging operations of hepatitis A vaccine. However, firm will submit a protocol for PMS Study.
8	**Menactra**	The committee recommended the study with the following stipulations: Two more sites from western and southern region of the country shall be submitted to CDSCO for approval. The vaccine will be beneficial in preventing Meningococcal infection in children of the age group 9-23 months in the country. It was noted that the vaccine is already approved in many countries in this age group including USA, Canada. For market authorization in India, data on a optimum number of subjects should be submitted separately to CDSCO for further review by NDAC.
9	**Chlorhexidine**	The committee recommended approval of the study. Dr. V.K. Paul was not present during the discussion and approval.
10		The committee was satisfied with the clarification

	Probiotic VSL #3	provided by the applicant on issues raised by NDAC in the previous meeting. The committee approved the study. However approval letter will be issued after receipt of the undertaking for compensation.
11	**Live Varicella Vaccine**	The representative of the firm did not attend the presentation .However, the committee discussed the study in detail and reviewed the report of Phase-I study data as satisfactory and therefore recommended to approve the Phase –III study in sequential age group 6-12 years followed by 1-6 years as proposed in last NDAC meeting. Dr. A. P. Dubey and Dr. Iqbal Kaur did not participate in the deliberations.
12	**Oral Rotavirus vaccine 116E, Live attenuated**	The firm has submitted the response to the queries raised by the committee during the approval of the oral Rotavirus vaccine in the last NDAC meeting. Committee was satisfied with the responses to conditions no. 1 and 4. The committee reiterated condition no. 2 for the upper age limit for the third dose upto 8 months. Committee/CDSCO awaits the firm's response for pharmacovigilance plan (Condition no. 3).
13	**Typhbar TCV-Measles interface**	Firm made a detailed presentation and explained the study design. The committee deliberated the proposal and recommended to approve the study.
14	**Bivalent (O1 & O139) Oral Cholera Bulk Vaccine**	The committee approved the manufacturing of bulk drug.

12. Recommendations of New Drugs Advisory Committee of Vaccine held on 30.01.2014 at FDA Bhawan, 1st Floor, New Delhi.

Agenda no.	Name of drug/vaccine	Recommendations
1	**bivalent Oral Polio Vaccine (bOPV)**	The committee recommended the proposal for conducting Phase IV study as per the protocol submitted by the firm. Dr. A. P. Dubey did not participate in the discussion.
2	**oral live attenuated human rotavirus (HRV) vaccine**	The committee approved the proposal as Phase IV study. Dr. A. P. Dubey did not participate in the discussion.
3	**Varicella virus vaccine Live**	The proposal was discussed. The company was asked to submit the details of age groups for Indian study and to provide information with respect to vaccine batches used in the clinical trial were commercial scale or not. Comments from CDL, Kasauli are awaited.
4	**Hepatitis A vaccine Inactivated**	The proposal has been recommended based on the compliance of the earlier observations of NDAC.
5	**Live Attenuated Bovine-Human Rotavirus Reassortant Pentavalent Vaccine (BRV-PV)**	The amended protocol was reviewed by the experts and there is no objection for the amended protocol however, the company was directed to furnish the details of tOPV vaccine being used in the trial.
6	**live attenuated Varicella vaccine**	The committee recommended the approval of the vaccine with respect to safety and efficacy in the concerned age group. Comments from CDL, Kasauli are awaited.
7	**10 valent Pneumococcal Polysaccharide conjugate vaccine (Adsorbed)**	The committee approved the trial for Phase I study only.
8	**EasyFourPol Vaccine (DTwP-Hib-IPV)**	The committee recommended the proposal.
9	**Easysix Vaccine (DTwP-HepB-HibIPV)**	The committee recommended the proposal.
10	**Mycobacterium w (Mw) as an adjunct to Paclitaxel &**	The proposal was approved after discussion.

	platinum based chemotherapy	
11	**Pentavalent vaccine (Shan5-DTwP-HepB-Hib) with imported WcP**	The committee after discussion recommended the proposal. Dr. A. P. Dubey did not participate in the discussion.
12	**Bi-valent Poliomyelitis Vaccine Live Oral (Di-Valent)**	The committee recommended the proposal subject to the condition that, the firm will resubmit the Animal Toxicity data since there are some inconsistencies in the data provided.
13	**Rabies Vaccine, Human I.P.**	Since the firm had already been licensed to manufacture and sale anti rabies vaccine (Vero cell) and hence committee recommended for regularization of new drug permission as per the prevailed Drugs & Cosmetics Rule
14	**Pneumococcal Polysaccharide and Non-Typeable Haemophilus influenza (NTH) Protein D Conjugate Vaccine, adsorbed (Synflorix)**	The proposal was recommended by the committee. The company has been asked to submit list of countries where the vaccine has been approved for the said variation.
15	**Rabies Vaccine**	The committee asked the firm to submit the result of analysis of serum sample for antibody titer to rabies by Pasteur Institute of India, Coonoor by rapid analysis method.

13. Recommendations of New Drugs Advisory Committee of Vaccine held on 17.04.2014 at FDA Bhawan, 1st Floor, New Delhi.

Agenda no.	Name of drug/vaccine	Recommendations
1	**Varicella Vaccine (Live attenuated, Freeze Dried IP)**	The proposal was discussed and recommended for approval.
2	**Inactivated Trivalent Influenza Vaccine (Split Virion) I.P. Single dose**	The proposal was discussed and recommended for approval.
3	**Inactivated Tetravalent**	The proposal was discussed and recommended for approval, however DCGI office has to deliberate

	Influenza Vaccine (Split Virion) I.P. Single dose	whether the proposal needs IND approval.
4	**Japanese Encephalitis vaccine measles vaccine interface**	The proposal was discussed and advised first to generate immunogenicity and safety data in children below 1 year (Current approved age).
5	**Quadrivalent Influenza Vaccine**	The proposal was discussed and advised to submit safety data in subjects 18 year and older. The same safety data will be reviewed by the NDAC before granting permission to proceed to younger age group.
6	**Bivalent oral poliovirus vaccine (bOPV) and trivalent oral poliovirus vaccine (tOPV)**	The request for protocol amendment was discussed and recommended for approval.
7	**DTwP-Hib vaccine (Easyfour-TT, Panacea Biotec Ltd.)**	The proposal was discussed and recommended for approval.
8	**Rabies Vaccine (Pre exposure only)**	The proposal was discussed and recommended for approval, however the Product label should be modified for Booster Injection at 5 Years and Insert the Phrase-in case of exposure use one of the rabies vaccine approved for Post exposure administration".
9	**Vi Polysaccharide Typhoid Vaccine (WHO) and Typhoid Polysaccharide Vaccine (I.P.).**	The proposal was discussed and recommended for approval.
10	**Herpes Zooster Vaccine**	The responses to the queries submitted by the company were reviewed and found satisfactory. Proposal recommended for approval. The Study is to be conducted on 21 subjects in India.
11	**Monetasone Furoate Monohydrate Nasal spray 50 mcg/dose**	The proposal was discussed and recommended for approval.
12	**Monoclonal tetanus Immunoglobuli n**	The proposal was recommended for IND committee.

14. Recommendations of New Drugs Advisory Committee of Vaccine held on 12.06.2014 at FDA Bhawan, 1st Floor, New Delhi.

Agenda no.	Name of drug/vaccine	Recommendations
1	**Zoster vaccine**	The committee deliberated the results of the study and recommended for approval of Marketing Authorisation of Varicella Zoster Vaccine.
2	**Influenza Vaccine (Human Live attenuated)**	The committee recommended for the approval of the study with the recommendation that the subjects should be stratified by age into 3 groups (2-17 years, 18-49 years, 50 and above) in roughly equal proportion.
3	**Japanese Encephalitis Inactivated Vaccine**	The committee recommended for the approval of the study.
4	**Pharmacovlilance Plan of Rotavirus Vaccine**	The committee reviewed the pharmacovigillance plan and found to be adequate. The committee recommended it for approval.
5	**Rotavirus vaccine**	The committee had a detailed discussion on the protocol. It was proposed that the two formulation of rotavirus vaccine namely F1 and F2 will be evaluated for non inferiority with ROTAVAC based on immunogenicity in exploratory phase. The better of the two will be taken for confirmatory phase. The committee noted that the criteria for deciding non inferiority in both the phases is not clear; and the assumption for sample size estimation was ambiguous. Further it was opined that the safety profile of the new formulation should also be considered while selecting the formulation for confirmatory phase. Moreover, 4 to 5 sites should be selected preferably from Government institutions. The protocol needs to be revised and reviewed by the NDAC again.
6	**Varicella Vaccine**	The committee recommended the proposal for approval to update the posology and to submit the Periodic Safety Update Report (PSUR).
7	**Prevenar 13 (Pneumococcal saccharide conjugate vaccine adsorbed, 13-valent) suspension for injection**	The committee reviewed the presentation of the firm in detail and opined that the market authorization in the age group of 6 to 17 years will be considered only after presentation of safety and immunogenicity data in Indian Population this age group.
8	**Hepatitis B**	The committee recommended for approval of the

	Vaccine	study.
9	**Rotavirus Vaccine**	The committee recommended for approval of the study.

15. Recommendations of New Drugs Advisory Committee of Vaccine held on 17.09.2014 at FDA Bhawan, 1st Floor, New Delhi.

Agenda no.	Name of drug/vaccine	Recommendations
1	Live attenuated Monovalent Rotavirus vaccine	The committee discussed the revised proposal. All the queries raised in earlier NDAC meeting have been satisfactorily addressed. The committee advised to constitute DSMB with Paediatric surgeon to specifically look for Intussusception. The committee recommends the proposal for approval.
2	Poliomyelitis Vaccine Live (Oral) I.P. (Trivalent)	The committee discussed the proposal and directed the firm to submit consent form instead of assent form. The proposal is recommended for approval.
3	(Recombinant Hepatitis B vaccine)	The proposal is accepted in principle after reviewing the responses to the queries communicated to the company. However, the company will do the study first in the age group of 18-55 years and submit the result for further permission by SEC.
4	Live Attenuated Varicella Vaccine	The committee discussed the proposal and advised the following modification: 1) There should be yearly follow up starting from 2nd year onwards to include both telephonic and immunogenicity data and submit amended protocol. The proposal is approved in principle.
5	Hepatitis B Vaccine (rDNA)	The committee deliberated the proposal and found that same product of Hepatitis B Vaccine (rDNA) is already licensed for Biological Evans will be used and there is a provision in Drugs & Cosmetics Rules to manufacture under loan license. The committee recommended the grant of New drug permission to M/s HLL Biotech Limited for manufacturing in the already licensed premises of Biological Evans
6	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis-B (rDNA) and Haemophilus Type b Conjugate Vaccine (Adsorbed)	The committee deliberated the proposal and found that same product of Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis-B (rDNA) and Haemophilus Type b Conjugate Vaccine (Adsorbed) is already licensed for Biological Evans will be used and there is a provision in Drugs & Cosmetics Rules to manufacture under loan license. The committee recommended the grant of New drug permission to M/s HLL Biotech Limited for manufacturing in the already licensed premises of Biological Evans.

7	DTwP-HepB-Hib Vaccine (MyFive)	The committee recommended the proposal for approval.
8	DTwP+Hib (Quadrovax®)	The committee reviewed the PMS data and found it acceptable.
9	Pseudovac vaccine	The committee deliberated the proposal and the result submitted by the firm of earlier trial and felt that further opinion may be sought from Burns department of Lok Nayak Hospital, New Delhi and SSKM Hospital, Kolkata.
10	Expansion of additional indication for Human Papilloma virus Vaccine	The committee noted that cervarix vaccine is already approved for prevention of cervical cancer and the present application is to expand the indication to include prevention premalignant genital (cervical, vulvar and vaginal) lesions and cervical cancer causally related to certain oncogenic Human Papillomavirus (HPV) types. The company has also written that this vaccine is approved for said indication in 60 countries however, there is no Indian study to support the indication. Even in the studies done in other countries the premalignant lesions were "Exploratory Objective" and not the primary outcome of the study. The matter has also been referred to ICMR for their opinion on this issue. The matter may again deliberated in the NDAC after receiving opinion from the ICMR.
11	Goat Lung Surfactant	The committee perused the available documents and is of the following opinion: 1) The proposed trial is an investigator driven academic study which addresses an important issue of making surfactant in India at significantly low cost. 2) The CDSCO in its letter F.No. 12-80/09-DC dated 17 may 2010 asked some clarification from the manufacturer based on the ICMR queries. The reply by them is to be submitted for evaluation. 3) The committee considered based on the presentation that both Goat and Calf Lung Surfactant are same. 4) The applicant has made presentation on the toxicology, efficacy and safety data. 5) The committee perused the study protocol and was satisfied. 6) The committee recommends the proposal in principle subject to compliance with Point 2. 7) Prof. V.K Paul opted out from the discussion and decision.
12	VSL#3	The committee discussed the proposal and made the following observations: 1) The PI will submit an undertaking to complete the study as per timeline. 2) The PI will furnish the Institutional Undertaking for compensation. 3) The DSMB should be constituted and shall have subject experts from outside the Institution.

13	Paracetamol Syrup	The study presented will compare Paracetamol with Ibuprofen for PDA closure in preterm neonates in an academic institution i.e, JIPMER, Puducherry and trial is investigator driven. The committee agrees the proposed doses regime of Paracetamol and recommends the proposal for approval.
14	Meningococcal (Group A, C, Y &W135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine	As per the recommendation of the NDAC- 8th Nov. 2013, the firm has included 2 additional sites. The committee now reviewed the presentation made regarding protocol amendment version no. 5 dated 7th Feb 2014. The committee recommended the amended protocol for inclusion of additional subjects in India.
15	JAIVAC-1 Vaccine	The committee accepted the proposal of the sponsor (ICGEB) not to proceed with trial since there was no appreciable change in the GMR of PfMSP-119.
16	Quadrivalent Influenza vaccine	The committee deliberated the proposal and opined that the decision of earlier NDAC may be considered.