

1. RECOMMENDATIONS OF THE NDAC (DERMATOLOGY AND ALLERGY) HELD ON 23.03.2012:-

The NDAC (Dermatology and Allergy) deliberated the proposals on 23.03.2012 and recommended the following:-

AGENDA NO.	NAME OF DRUG		RECOMMENDATIONS
Global Clinical Trials			
1	Debrase Gel Dressing		<p>The firm has earlier conducted similar study in India. Committee recommended for approval of the study subject to the following conditions:</p> <ul style="list-style-type: none"> i) The study should be conducted in at least 2 countries globally. ii) The trial should be conducted only in patients aged 18 to 65 years. iii) Number of subjects to be enrolled from India should not be more than 50% of total number of subjects to be enrolled globally. iv) Informed Consent Document should be modified to include the following clause:-“In case of study related injury or death, M/s GVK Bio will provide complete medical care as well as compensation for the injury or death”. <p>Before formal approval of the study is granted by DCG(I), the firm should submit their revised protocol as above for consideration by DCG(I).</p>
2	Ozenoxacin 1% cream		<p>The study is to assess the efficacy and safety of Ozenoxacin 1% cream applied twice daily for 5 days versus placebo in the treatment of patients with impetigo. In patients with impetigo, the infection cannot be left untreated by giving placebo for days together. Therefore the committee did not recommend for approval of the study.</p>
3	Esmolol Hydrochloride		<p>Committee recommended for approval of the study subject to the following conditions:</p>

			<ul style="list-style-type: none">i) The study should be termed as Phase I/II trial.ii) Upper age limit of the subjects to be enrolled in the study should be 65 years.iii) There should be culture sensitivity test every 2 weeks.
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2. RECOMMENDATIONS OF THE NDAC (DERMATOLOGY AND ALLERGY) HELD ON 18.05.2012 :-

The NDAC (Dermatology and Allergy) deliberated the proposals on 18.05.2012 and recommended the following:-

AGEND A NO.	NAME OF DRUG	RECOMMENDATIONS
1	Super-Oxidised Solution	<p>Committee recommended that firm should initially conduct Phase II clinical trial with the drug to determine safety and efficacy of the product in wounds of different size on atleast 80 Indian patients with different sizes of wounds at a minimum of 3-4 centres geographically distributed across the country out of which at least 2 centres should be from government hospitals. Accordingly, protocols etc. should be submitted to the Office of DCG(I) for approval. Based on the results of Phase II Clinical trials conduct of further Phase III Clinical trials may be considered.</p>
2	Biomodified Silk Protein wound dressing Film	<p>The product is basically intended for wounds of larger sizes. The Phase II data generated so far is not supportive with respect to the safety and efficacy in wounds of larger size.</p> <p>Committee therefore, recommended that a Phase II multicentric clinical trial should be conducted in at least 40 patients with wounds of minimum size of 10cm x 10cm at 3-4 centres geographically distributed across the country out of which at least 2 centres should be from government hospitals. Accordingly,</p>

			<p>protocols etc. should be submitted to the office of DCG(I) for approval.</p> <p>Based on the results of Phase II clinical trials conduct of further Phase III clinical trials may be considered.</p>
3	Mupirocin+Sucralfate Ointment		<p>Mupirocin is generally used in condition where there is no requirement of cell regeneration. Therefore, use of both Mupirocin & Sucralfate is not rational.</p> <p>Further, mupirocin is not effective in post surgical secondary infections. Hence, the FDC is not rational.</p> <p>Committee did not recommend for the grant of permission for the proposed FDC.</p>
4	Hyaluronic Acid+Lidocaine Prefilled syringe		<p>This new strength is not approved in USA and is approved in EU as a medical device. Also there is risk of sensitivity to lidocaine on its use.</p> <p>At present there is no need for this new strength. The committee therefore, did not recommend for the grant of permission for this new strength of the FDC.</p>

3. RECOMMENDATIONS OF THE NDAC (DERMATOLOGY AND ALLERGY) HELD ON 12.10.2012:-

The NDAC (Dermatology and Allergy) deliberated the proposals on 12.10.2012 and recommended the following:-

AGENDA NO.	NAME OF DRUG		RECOMMENDATIONS
1	Flutrimazole Cream 1% w/w		The firm did not turn up for presentation. Committee decided to defer the proposal.
2	Hyaluronic acid with 0.9% Mannitol Prefilled Syringe Dermal Filler		Beneficial effect of Hyaluronic acid with 0.9% Mannitol Prefilled Syringe Dermal Filler over the existing product is not supported by the evidence. Therefore the committee recommended that a comparative clinical trial of Hyaluronic acid with 0.9% Mannitol Prefilled Syringe Dermal Filler vis a vis the existing product of Hyaluronic acid injection marketed by the firm should be conducted on at least 120 subjects at four sites geographically distributed in the country with 50% sites in Gov. medical colleges/institutions. Accordingly protocol etc. should be submitted to DCG(I) for his approval. The clinical data so generated should be placed before the committee for examination.
3	Adapalene Gel 0.3%w/w		Committee recommended that a clinical trial with the proposed formulation in Indian patients is required to be conducted. Protocol etc should be submitted to the Committee for examination.

4	Benzoyl Peroxide + Microsphere Adapalene		The firm has withdrawn their proposal.
5	Ammonium Lactate + Halobetasol propionate		Committee opined that there is no rationality of the combikit Ammonium Lactate lotion & Halobetasol propionate ointment as there is chance of its misuse which will lead to additional burden to patients where both the drugs may not be required. Hence the committee did not recommend for the combination.
6	Tretinoin + Clindamycin		Committee recommended that a 3 arm statistically powered clinical trial of Tretinoin + clindamycin Vs Tretinoin Vs clindamycin in sites distributed geographically in the country with at least 50% government medical College/ Institution is required to be conducted. Accordingly protocol etc should be submitted to the committee for further examination.
7	Fusidic Acid + Fluticasone Miconazole		Committee opined that there is no rationality of combining Sodium Fusidate with Fluticasone Propionate and Miconazole Nitrate. Therefore the committee did not recommend for approval of the proposed FDC.
8	Clindamycin Phosphate 1.2% / Benzoyl Peroxide 5% gel		The proposed clinical trial is for generation of data for export purpose. So Committee recommended for giving permission of the study with the condition that at least 50% of the study centers should be Government Medical Colleges/ Institutions and other sites should be multispecialty hospitals.
9	Selegiline		Proposed study is planned to be conducted in healthy volunteers to

			assess the safety and tolerability of Selegiline transdermal patch with its multiple dose administration for 21 days. Since Selegiline is an antidepressant drug, the proposed study in healthy volunteers has serious ethical issue involved. Therefore committee did not recommend for approval of the study.
10	Secukinumab		Committee recommended that the firm should make detailed presentation on the core studies in the next meeting so as to take decision on the proposed extension study.
11	Secukinumab		Committee recommended that the firm should make detailed presentation on the core studies in the next meeting so as to take decision on the proposed extension study.

4. RECOMMENDATIONS OF THE NDAC (DERMATOLOGY AND ALLERGY) HELD ON 25.04.2013 -

The NDAC (Dermatology and Allergy) deliberated the proposals on 25.04.2013 and recommended the following:-

AGENDA NO.	NAME OF DRUG	RECOMMENDATIONS
Global Clinical Trials		
1	<p>Special Agenda</p> <p>Daptomycin Powder for concentrate for solution for infusion 350mg/500mg per vial</p>	<p>The Committee was apprised that the Parliamentary Standing Committee (PSC) for the Ministry of Health & Family Welfare had presented its 59th report to the Parliament on 08.05.2012 on the functioning of the CDSCO. The report has made various recommendations and observation on various aspects such as approval of New Drugs, Pharmacovigilance, approval of clinical trials etc. The Ministry of Health & Family Welfare has submitted final action taken report on the observation/recommendations contained in the 59th report of the Hon'ble Parliamentary Standing Committee.</p> <p>As per the action taken report, it has been decided by the Ministry that 73 drugs including Fixed Dose Combinations, on approval of which the Hon'ble PSC has made various observations, would be referred to the NDACs for examination and review related to continued marketing of these drugs and updating of their product monographs in light of recent knowledge and regulatory changes overseas. Out of these 73 drugs, 1 drug is in the category of (Dermatology and Allergy) which is given below:-</p> <p>Daptomycin Powder for concentrate for solution for infusion 350mg/500mg per vial</p> <p>The NDAC (Dermatology and Allergy) discussed the issue and noted that Ministry of Health & Family Welfare has already constituted a Committee to formulate policy guidelines and SOPs for a) approval of new drugs, clinical trials, and banning of drugs under the Chairmanship of Dr. Ranjit Roy Chaudhury and b) for approval of the Fixed Dose Combinations under the Chairmanship Dr. C.K. Kokate. Therefore, the Committee opined that these drugs related to</p>

		<p>continued marketing and updating of the product monograph in the light of recent knowledge and regulatory changes overseas could be examined as per policies, guidelines and SOPs being prepared by the Dr. Ranjit Roy Chaudhury Committee and Dr. C.K. Kokate Committee. However, in the meantime the data/information on safety, efficacy of this drug including published data, PMS/PSUR, PSUR data especially on Indian patient required to be prepared in the Form of Dossier. Such data should be prepared from three different sources viz. i) by CDSCO ii) by Pharmacovigilance Programme of India (PvPI) and iii) the firm concerned.</p> <p>The Dossier shall be circulated to all the experts of the NDAC (Dermatology and Allergy) for their further review. If needed manufacturer may be requested to make their Presentation before the NDAC on safety and efficacy of the drug.</p> <p>The NDAC further recommended the following :-</p> <p>CDSCO may collect the following information on the drug</p> <p>The date of approval of the drug.</p> <p>The date of manufacturing and marketing of the drug by the manufacturer.</p> <p>The mandatory PSUR reports submitted by these companies.</p> <p>Pharmacovigilance data if any from PVPI on the drug.</p> <p>Marketing status of the drug.</p> <p>Global Marketing status of the drug.</p> <p>Clause, condition and opinion under which permission was granted for the drug.</p> <p>As soon as the above information is available, a meeting may be called. In the meeting, the recommendations of the other 2 committees may be placed which would be discussed.</p>
2	MEBO Burn Ointment	<p>The data presented was an open label trial conducted in only one region. Committee opined that a Phase III double blind trial on large number of patients should be conducted in India. 50% of</p>

			the sites should be Govt hospitals and the sites should be geographically distributed across the country. Microbiological culture data before application of the test and reference drug should also be included in the protocol. Accordingly, protocol etc. should be submitted to DCGI for evaluation by the committee.
3	Tazarotene Microsphere Gel 0.1% w/w		Committee recommended that a Phase III clinical trial should be conducted in India on statistically significant number of subjects for evaluating the safety and efficacy at sites geographically distributed across the country. 50% of the sites should be Govt. Hospitals/medical colleges. Accordingly, protocol etc. should be submitted to DCGI for evaluation by the committee.
4	Isotretinoin soft gelatin Capsules 16 mg		The firm did not turn up for presentation, therefore the committee deferred the proposal.
5	Minocycline ER tablet 45/65mg		Committee opined that there is no Indian data on the proposed dosage form. Therefore committee recommended for conducting a Phase 3 clinical trial in India with the proposed formulation to prove its safety and efficacy. Accordingly, protocol etc. should be submitted to DCGI for evaluation by the committee. The firm should also submit adverse event data observed with the 100mg formulation.
6	Finasteride + Minoxidil		Firm could not produce any data with respect to the PK study of Finasteride. Moreover, there is no published data on the use of Finasteride as topical preparation. The proposed FDC is also not approved anywhere in the world. Firm could not justify any rationality for the proposed FDC. Committee opined that the proposed FDC is not rationale, hence not recommended.
7	Tretinoin microsphere 0.04% w/w/0.1% w/w + Clindamycin 1% w/w/1% w/w gel		Committee recommended that a three arm, single blind, Phase III clinical trial should be conducted in India on statistically significant number of subjects for evaluating the safety and efficacy at sites geographically distributed across the country. 50% of the sites should be Govt. Hospitals/medical colleges. Accordingly, protocol etc. should be submitted to DCGI for evaluation by the

			committee.
8	HemaGel		The committee recommended that a double-blind, randomized clinical trial should be conducted in Indian patients in a specific indication. Hence, a new detailed protocol should be submitted for the review by the committee.
9	DFA-02		The committee opined that the protocol for the FDC of Gentamycin and Vancomycin and its rationality for the proposed indication requires the opinion of a surgeon.
10	Etanercept		The committee recommended that the company has to submit the Phase IV and PSUR's data prior to consideration of this study.
11	Invivo preparation of epidermal cells		Out of 6 experts; 4 experts namely Dr. Amrinderjit Kanwar, Dr. D.M. Thappa, Dr. S.N. Bhattacharya and Dr. C. Adithan strongly recommended the protocol. However 2 of the experts namely Dr. Vijay Kumar and Dr. H.S. Rehan opined that the investigator shall submit pre-clinical and clinical safety and PK data.
12	Azathioprine		The committee recommended for approval of the study.
13	Secukinumab For Re-examination		The firm has withdrawn their proposal.
14	Secukinumab For Re-examination		The firm has withdrawn their proposal.
15	Selegiline For Re-examination		The committee opined that the study with Selegiline patches for 21 days is not justified in healthy volunteers due to ethical issues. The committee rejected the proposal for the clinical trial.

5. RECOMMENDATION OF THE NDAC (DERMATOLOGY&ALLERGY) HELD ON 30.07.2013

The NDAC (Dermatology & Allergy) deliberated the proposals on 30.07.2013 and recommended the following:-

Agenda no.	Drug Name		Recommendations
1	Moxifloxacin 400 mg, Rifampicin 600 mg, Minocycline 200 mg		The committee recommended for conducting the clinical trial with the condition the drug response is not observed within the six months for PB patients and 12 months for MB patients should be shifted to standard WHO regime.
2	Terbinafine dusting powder 1% w/w		The proposal has been deferred to the next NDAC meeting on the request of the firm.
3	Terbinafine dusting powder 1% w/w		Committee opined that a Pilot Clinical study is required to be conducted. Accordingly CT protocol etc., may submitted for further review by the committee and to revise manufacturing formula of proposed product without starch as base.
4	Ammonium Lactate lotion 5% w/v and cream 5% w/v		The proposal has been deferred to the next NDAC meeting on the request of the firm.

5	<p>Silver Sulfadiazine + Chlorhexidine Gluconate</p>		<p>The committee recommended that phase III clinical trial with the following conditions</p> <ol style="list-style-type: none"> 1. Sample size of min. 250 patients 2. In inclusion criteria; subjects with partial thickness burns of thermal origin covering 5-10% of total body surface arm. 3. Photography should be taken at the 0, 7, 14, 21 day visits. 4. Quantify the amount of drug administered with respect to the cm²/burn area shall be defined in the protocol. 5. Point nos. 6 and 7 of exclusion criteria should be deleted. 6. Accountability of the drug administered shall be recorded. 7. Swab for Culture sensitive should be performed from affected area at 0 and 7 days visit. 8. The sites should be Multispecialty hospitals/institutes having own Institutional Ethics Committee including 50% of sites being government hospitals across the country. <p>In the pilot study (Phase II) efficacy of silver sulfadiazine was inferior to that reported in the literature. The reason for its lower efficacy may be clarified.</p>
6	<p>Lxekizumab+ Medoxomil</p>		<p>The committee considered the issue of placebo controlled treatment and decided that it is not a denial of standard treatment as per the inclusion criteria. The committee recommended phase III clinical trial with the following conditions</p> <ol style="list-style-type: none"> 1. To include a Co-PI from chest dept 2. Patients shall be screened for TB every 6 months and other intestinal pathogen quarterly.

			<p>3. Interim data shall be submitted annually.</p> <p>4. The sites should be Multispecialty hospitals/institutes having own Institutional Ethics Committee including 50% of sites being government hospitals across the country.</p>
7	Triamcinolone Acetate Injectable Suspension USP 40 mg /ml (1 ml vial)		The committee has recommend for the BE study.

6. RECOMMENDATIONS OF THE NDAC (DERMATOLOGY AND ALLERGY) HELD ON 13.12.2013 -

The NDAC (Dermatology & Allergy) deliberated the proposals on 13.12.2013 and recommended the following:-

Agenda no.	Drug Name		Recommendations
1	Candida Albican		<p>Candida Albican is available as intradermal use for diagnostic purpose. The proposed study is to assess the Intralesional Immunotherapy with Candida Albicans Antigen for multiple cutaneous warts. After deliberation the committee recommended for the study subject to the condition that only new patients should be included in the study. Those patients who fail in the treatment and having induration of less than 5 mm should be advised for standard care of therapy. The applicant should also specify the source of the drug for the proposed study.</p>
2	MomentasoneFu roateIP+Salicylic Acid IP		<p>FDC is already approved for treatment of psoriasis vulgaris/plaque psoriasis. Firm presented various published data in respect of the FDC.</p> <p>Committee opined that FDC is already in clinical practice for the treatment of chronic plaque psoriasis. Therefore the committee recommended for approval of the indication - treatment of chronic plaque psoriasis, in place of moderate to severe plaque psoriasis as proposed by the firm.</p>
3	Calcipotriol+Halobetasol Propionate		<p>Firm didn't turn up hence proposal deferred to next NDAC meeting.</p>
4	Clindamycin+Tetrinoinmicrospha re		<p>The firm presented the detailed protocol before the committee. Committee opined that the protocol is adequate hence permission may be granted for conducting the clinical trial in the country. Treatment emergent as mentioned in</p>

			<p>the protocol shall be replaced by adverse event during the study. Committee opined that the trial shall be conducted in 650 patients in ratio of 250 (FDC):250(treatment):150(clindamycin). Committee also opined that 50% of the patients shall be enrolled in govt. Hospital/medical colleges.</p>
5	Clindamycin+Tetrinoinmicrospha re		<p>The firm presented the detailed protocol before the committee. Committee opined that the protocol is adequate hence permission may be granted for conducting the clinical trial in the country. Trial shall be conducted in 650 patients in ratio of 250(FDC) :250(treatment) :150(clindamycin). Committee also opined that 50% of the patients shall be enrolled in govt. Hospital/medical colleges.</p>
6	Minoxidil 5% + Finasteride 0.1% lipid solution		<p>Firm presented various published literature including report of clinical trial with regard to topical use of finasteride. Firm also presented one published clinical trial report on the FDC. Firm also presented the pharmacokinetic data of Finasteride. The firm has already conducted the clinical trial with the treatment duration of 6 months. After detailed deliberation the committee recommended for the grant of permission to manufacture and market of the said FDC in the country for the treatment of androgenetic alopecia in males. Protocol for Phase IV study may be submitted for review by NDAC</p> <p>Committee also opined that there shall be a warning on the package insert as well as label as below:</p> <p>Not to be used in women of reproductive age group.</p>
7	Adalimumab		<p>The firm has applied for the grant of permission to conduct a phase III to compare safety and immunogenicity of a biosimilar Adalimumab (GP2017) and Humira® in patients with moderate to severe plaque type psoriasis. Adalimumab(GP2017) powder (40 & 80 mg)</p>

			<p>reconstituted with 0.8 ml sterile water for injection (WFI). US FDA & EU has already approved Humira® (adalimumab) for the treatment of psoriasis, rheumatoid arthritis, psoriatic arthritis (PsA), ankylosing spondylitis and Chron's disease. The proposed study planned to be conducted on Globally 448 subjects and from India 100 subjects spread across 12 countries which including Germany, France, Bulgaria, Russia, Spain, USA and India. The Drug substance is manufactured using recombinant CHO cell line at Sandoz (Austria)A number of in vitro bio assays for biological characterization of GP2017 have been performed. Assays for characterization of the antigen-binding part of the antibody: binding of TNF-α and functional neutralization of TNF-α (cell based bioassay), the potential biological effects of Fc part of the antibody and assays evaluating the binding of the Fc part to apanel of Fc receptors including FcyRIa, FcyRIIa, FcyRIIIa, FcyRIIIb, and FcyRn.</p> <p>The committee deliberated the protocol and presentation made and opined that the trial be permitted with a condition that the age group shall be not more than 65 years. The firm is required to submit pre-clinical and clinical reproductive and developmental toxicity study data with the innovator molecule (HUMIRA) before considering permission for this protocol in women of child bearing potential.</p>
8	Restylane Lidocaine		The Committee could not consider the proposal due to lack of in-vivo clinical pharmacokinetic and safety data on fixed dose combination of Lidocaine and Hyaluronic acid.
9	HemaGel		The protocol No. STE/12/001/v.1 presented by the firm was not found to be satisfactory. The committee recommended that the protocol should be amended and resubmitted to the committee for further deliberation.
10	Etanercept		The committee decided that the firm i.e. M/s Wyeth Ltd., should make a complete

			<p>presentation of all the PSURs and PMS study on Indian patients with all the adverse and serious adverse events reported, after the licensure of the product. Based on the complete review of safety profile of the subject drug, further decision about approval on the proposed clinical study will be made by the committee.</p>
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7. RECOMMENDATIONS OF THE NDAC (DERMATOLOGY AND ALLERGY) HELD ON 27.06.2014 –

The 7th NDAC (Dermatology & Allergy) deliberated the proposals on 27.06.2014 deliberated each proposal on the basis of:

(i) Risk / Benefit assessment (ii) Innovation Vs. current standard care of therapies and (iii) Unmet medical need and recommended the following:-

Item no.	Drug Name		Recommendations
1.	Clocortolone cream USP 0.1%w/w		The Committee deliberated the proposal in detail. Committee noted that the drug was approved in USA in 1977 and is a mild potent topical corticosteroid. Firm presented old published clinical trial reports of the drug comparing with placebo. Firm has proposed to conduct comparative clinical trial with Desonide, in adult subjects with atopic dermatitis in a total of 390 subjects. Desonide is a mild potency drug. Further, enrolling patients with this condition is difficult as it is not generally manifested in adults. After deliberation, the Committee recommended to submit the revised clinical trial protocol comparing Clocortolone with equally potent drug. The clinical trial sites should be multispecialty hospitals/Institutions having emergency medical care facilities and Institutional ethics Committee. The sites should be geographically distributed across the country.
2.	Levocetirizine orally disintegrating strips 2.5 mg/5mg		The firm presented the BE protocol before the committee. The committee opined that firm may be permitted to conduct BE study. The study report shall be placed before the committee for further consideration.
3.	Lipid based Tacrolimus ointment 0.1%W/V		The committee opined that proposed product may be useful in patients of oral lichen planus. The committee recommended that firm shall conduct a Phase II study with evaluation of Pharmacokinetic parameters after application of drugs on lesions on oral cavity and accordingly firm shall submit the revised protocol for further consideration
4.	Calcipotriol+Halobetasol Propionate		Firm did not turned up for the presentation. This proposal was differed.
5.	Clindamycin (1%) + Benzoyl Peroxide (5%) topical gel		This is a phase III, randomized double-blind, multicenter, parallel group, active and placebo controlled, three arm clinical study to compare the efficacy and safety of clindamycin 1% / Benzoyl peroxide 5% topical gel (of Cadila Healthcare Limited, India) versus reference product

			<p>Vs. placebo topical gel in the ratio of 2:2:1 respectively in patients with Acne Vulgaris”.</p> <p>The reference product is approved for marketing in USA and Canada for treatment of Acne Vulgaris.</p> <p>The purpose of this study is to assess the bio-equivalence of the test drug with that of the reference /innovator product.</p> <p>The committee opined that the data on synergistic efficacy, safety and tolerability of this FDC vs the individual products is to be presented to the committee .</p> <p>Acne patients receiving no treatment in the placebo group may be a issue of concern.</p> <p>The committee did not approve the conduct of this study .</p> <p>Dr Amrinder Jit Kanwar didnot take part in decision making process for this proposal.</p>
6.	Dapsone Gel 5%		<p>The proposed protocol is double-blind, randomized, parallel group, placebo controlled pilot study comparing Dapsone gel 5% of M/s Allergan Inc., USA) and Vehicle control (as placebo) of M/s Watson Pharma Pvt Ltd.</p> <p>The study is planned to be conducted in Malaysia and India.</p> <p>The use of dapsone in the treatment of acne vulgaris is limited. There are better / efficacious drugs existing in this therapeutic category. Therefore the committee does not recommend the conduct of this study.</p>
7.	Multidex Maltodextrin Wound Dressing (Powder/Gel)		<p>Firm did not turned up for the presentation. This proposal was differed.</p>
8.	Turafoam Hydrogel wound dressing		<p>Firm did not turned up for the presentation. This proposal was differed.</p>
9.	Hemagel		<p>The committee after deliberation recommended that the permission for conducting Phase III clinical trial may be granted.</p>
10.	Restylane Lidocaine		<p>The committee after deliberation recommended that permission to import for the said product may be granted with a condition to submit post marketing surveillance data after one year to this office.</p>
11.	Amorphous Hydrogel Wound dressing		<p>Firm did not turned up for the presentation. This proposal was differed.</p>
12.	V.A.C. Verlink Installation		<p>The committee after deliberation recommended that the firm needs to submit post marketing surveillance data in</p>

	Cassette		respect of vacuum assisted dressings previously approved by this office. Further the published study showing the effect of creating vaccum on the wounds infected from aerobics and anaerobic bacteria need to be submitted. The data submitted by the firm will be reviewed in next NDAC meeting for taking further necessary action in the matter.
13.	Omalizumab		The committee opined that the data is not sufficient and needs to generate data (Phase II) on Indian population. Accordingly protocol shall be submitted to NDAC for the consideration.