

Recommendations:

I agree the minutes of 1stSEC-Dermatology meeting held on 28.03.2017 at CDSCO HQ New Delhi

Agenda no.	File no./Drug Name	Name of firm/ Institute	Recommendations
New Drugs Division Proposal			
1	12-42/16-DC Benzoyl Peroxide Gel (2.5% & 5.0%) with Polysiloxanes and Zinc oxide	M/s. Dr. Reddy's Laboratories Limited	Firm has submitted application for grant of permission to manufacture and market the topical gel - Benzoyl Peroxide Gel (2.5% & 5.0%) with Polysiloxanes and Zinc oxide to be indicated for the treatment of acne vulgaris and scar. The firm has presented Phase II protocol to evaluate the reduction in the incidence of scar. After detailed deliberation the Committee recommended that the protocol should be revised with respect to the following 1. Treatment duration should be increased to 16 weeks and follow up for additional 8 weeks. 2. The assessment of scars to be done on the basis of global assessment scale for acne scars. 3. The photographic assessment to be done by uniform lighting fixed distance cameras and evaluated by independent expert not associated with the study. Accordingly the firm should submit revised protocol to the office of DCG (I).
2	12-28/15-DC (Pt-A) Apremilast 10/20/30 mg tablets	M/s. Ajanta Pharma	Firm has submitted the application for the grant of permission to manufacture and market Apremilast 10/20/30 mg film coated tablets for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. The firm has presented the

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			Phase III protocol. After detailed deliberation the committee recommended for the conduct of the study subject to the condition that the patient withdrawn from the study from either arm should be provided standard of care treatment, including patients with suicidal tendencies. Accordingly the firm should submit the revised protocol to the office of DCG (I).
Subsequent New Drugs Division Proposal			
3	12-130/2016-DC (Pt- Galderma-Snd) Clostridium botulinum type A toxin haemagglutinin complex injection 300mg units/vial	M/s Galderma	After detailed deliberation the committee observed that the product Clostridium botulinum type A toxin haemagglutinin complexes marketed in India since 1994. This product is also approved in UK and USA for the same indication. The committee recommended the product for this new indication and additional strength with the condition to conduct Phase – IV Clinical Trial within six months of approval. It is also recommended it should be administered by specialist like Dermatologist, Plastic Surgeons, anesthesiologist, Ophthalmologist, Neurologist and ENT Surgeons
4	12-75/2016-DC(Pt- Akums-SND) Minoxidil topical solution 2% to sell without prescription in Indian market	M/s Akums	The method, area, duration and quantity of Minoxidil topical solution 2% is crucial to the success of treatment and general public is not aware of these facts and the indications of use (various types of alopecia). After detailed deliberation the committee did not consider the request of the firm for making Minoxidil topical solution 2% as an OTC product.

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5	12-22/2017-DC (Pt-Sun-Snd) Desloratadine tablet USP 10mg	M/s Sun Pharma	The firm presented the justification for the 10mg strength and Clinical Trial protocol before the committee. The committee after detailed deliberation recommended conduct of the Clinical Trial with Desloratadine tablet USP 10mg and waiver of BE study.
Lunch Break			
Medical Devices Division Proposal			
6	31-1622-MD/2014-DC Application for grant of permission to import and Market product i.e., “UrgoTul SSD” under Rule 122A of Drugs & Cosmetics Act & Rules.	M/s Emergo (India) Consulting Private Limited.,Hyderabad-5000009	The firm presented their proposal before the experts. After detailed deliberation, the committee recommended that the import permission may be granted to the firm with the condition that the firm shall conduct Phase-IV clinical trial. The firm shall submit the Phase-IV clinical trial protocol within six months.
7	4-MD/CT-162/2016-DC Application for the grant of new drug permission to import “ Altrazeal Transforming Powder Dressing- regarding” under the provision of Drugs & Cosmetics Act & Rules.	M/s Sandor Medicaids Pvt.Ltd, 8-2-326/5, Road No.3, Banjara Hills, Hyderabad-500034, AP, India	The firm presented their proposal before the experts. The firm has informed that the product is approved in ICH countries like US, EU, Australia. The product is classified as Class I device in US. After detailed deliberation the committee recommended that the import permission may be granted to the firm with the condition that the firm shall conduct Phase-IV clinical trial. The firm shall submit the Phase-IV clinical trial protocol within six months.
8	4-MD/CT-156/2016-DC Application for grant of permission to import and market product i.e., Nasaleze Allergy (contains 98.5 % natural cellulose powder (hydroxypropyl methyl cellulose-HPMC) and 1.5% high quality peppermint powder) under Rule 122A of Drugs & Cosmetics Act &	M/s Nexus Novus Import and Distribution	The firm did not turn-up for the meeting.

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	Rules.		
Biological Division Proposal			
9	75/Reliance/Phase IV/17 BD Infiximab	M/s Reliance life sciences	After detailed deliberation of the Phase IV clinical trial protocol of Infiximab powder for concentrate for solution for infusion in the indication of Plaque Psoriasis, the committee opined the following: 1. The earlier committee had recommended for additional indication of Infiximab in Plaque Psoriasis with condition to conduct Phase IV clinical trial and protocol to be submitted within 3 months. 2. CDSCO has approved the said drug in said indication on 03.11.2015. However, firm has submitted Phase IV clinical trial protocol to CDSCO on 29.12.2016 (i.e. in 13 months instead of 3 months as recommended by earlier SEC). Therefore, CDSCO may take appropriate action in this regard. 3. The committee recommended for conduct of Phase IV clinical trial protocol no RLS/PMS/2016/08, version 1.0 dated 28.10.2016 with condition to adhere the requirement laid down in Schedule Y of Drugs and Cosmetics Rules.

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Global Clinical Trial			
10	CT/61/16 Povidone-Iodine (PVP-I, 2%)	JSS Medical Research	Risk versus benefit to the patient: Povidone Iodine is approved as a broad spectrum antimicrobial with a known safety profile for 2% formulation which justifies the conduct of the study. Innovations Vs existing therapeutic option: There are no approved agents indicated for the treatment of MC in children or adults. Study drug may provide a treatment option for the treatment of Molluscum Contagiosum. Unmet medical need in the country: The study drug may provide a treatment option for the treatment of Molluscum Contagiosum in Pediatric patients. After detailed deliberation committee recommended the conduct of the study subject to submission of safety data on DMSO used in the formulation for the topical preparation to CDSCO.