By hand.

E-76827/17

सत्यमेव जयते

डॉ. गिरीश साहनी
सचिव
Dr. Girish Sahni
Secretary

भारत सरकार
वैज्ञानिक तथा औद्योगिक अनुसंधान विभाग
विज्ञान और प्रौद्योगिकी मंत्रालय
टेक्नोलॉजी भवन, नया महरौली रोड़, नई दिल्ली-110016

DEPARTMENT OF SCIENTIFIC & INDUSTRIAL RESEARCH
Ministry of Science & Technology
Technology Bhavan, New Mehrauli Road, New Delhi-110016

D.O. No.DG/PS/2017/116
27 December, 2017

To

The Secretary,
Ministry of Health & Family Welfare
Nirman Bhavan,
New Delhi-110001

For kind attention : **Shri DN Sahoo, Deputy Secretary**

Dear Sir,

This refers to your letter dated 23rd October, 2017 regarding early submission of recommendations on Safety and tolerability of diethylene glycol monoethyl ether(DEGREE) (Transcutol-P) in Diclofenac injection.

I wish to inform that three meetings of the review committee have been convened. The Committee had thoroughly discussed the matter on the basis of papers submitted by M/s Themis Medicare and M/s Troikaa Pharmaceutiacals.

Now, we are herewith submitting the recommendations of the Committee, which are essentially corroborative of the First Committee set up previously.

Yours sincerely,

Girish Sahni

[Girish Sahni]
Chairman of the Committee

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Minutes of the Meeting of the Expert Committee held on 20th December 2017 at 1500 hrs at CSIR-Hqrs, New Delhi to examine the issue of Transcutol-P in injectable preparations of Diclofenac Sodium.

Members present:

1. Dr. Girish Sahni, Secretary, DSIR and Director General, CSIR — Chairman
2. Dr. S. Raisuddin, Professor of Toxicology, Jamia Hamdard University, New Delhi — Member
3. Dr. S.P. Vyas, Professor of Pharmaceutics, H.S. Gaur Vishwavidyalaya, Sagar (MP) — Member
4. Professor (Dr.) U.A. Kumar, Head of Department Rheumatology, AIIMS, New Delhi — Member
   Dr Uma Kumar.

The following members could not attend due to their prior commitments:

1. Dr. S.K. Agarwal, Professor & Head of Dept. of Nephrology, AIIMS, New Delhi
2. Dr. Chandeswar Nath, Toxicologist, CDRI, Lucknow
3. Dr. P. Rajvanshi, Consultant & Professor, VMMC, New Delhi

Transcutol-P as an excipient in parenteral formulation needs to be tested for its toxicity independently in order to establish its safety; since it is reportedly not an inert excipient. No evidence has been presented before the Committee that it can be used in parenteral formulations even including India Pharmacopoeia, especially on parenteral preparation for human use.

Like-wise, the data in cumulative form, is indicative of its toxicity which entails a detailed study on its toxicity and safety profile in line with the observations given above. Whether the same could be permitted for use especially in parenteral formulation has to be decided by Drug Regulatory Authority as per provisions of drug regulations on excipients to be used in parenteral form particularly those which are reportedly not inert, as in the present case.

The meeting ended with vote of thanks to the Chair.

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20/12/2017.
(Dr. S. Raisuddin)

(Dr. S.P. Vyas)

Uma Kumar
(Professor, ~~U.A. Kumar~~)

(Dr. Girish Sahni) 20/12/17