IN THE HIGH COURT OF JUDICATURE AT MADRAS

Dated : 20.03.2018

CORAM:

THE HON'BLE MR.JUSTICE K.K.SASIDHARAN
AND
THE HON'BLE MR.JUSTICE P.VELMURUGAN

W.A No.2866 of 2012 and
M.P.No.1 of 2012.

Macleods Pharmaceuticals Limited
Rep. by its Zonal Sales Manager
G.Elangovan
Regional office at
No.44, Perambur High Road,
Jamalia, Chennai - 600 012. ... Appellant

-Vs-

1.The Union of India,
Rep. by its Secretary,
Ministry of Health and Family Welfare
FDA Bhavan, ITO Kotla Road,
New Delhi 110 002.

2.The Drug Controller General of India
FDA Bhavan, ITO Kotla Road,
New Delhi - 100 002. ... Respondents

PRAYER: Writ Appeal filed under Clause 15 of Letters Patent against the order passed in W.P No.21933 of 2011 dated 26.04.2012.

WP.NO.21933/2011:

Wp.No.21933/2011 filed under Article 226 of the Constitution of India praying the issue of a Writ of Certiorarified Mandamus, Calling for the entire records in connection with the impugned notification issued by the 1st Respondent in GSR No.218 (E) published in Gazette of India Extraordinary Part II- Section 3 - Sub-Section (i) dated 16.03.2011 in so far as it relates to item No.(i) i.e. Gatifloxacin Formulation of systemic use in human by any route including oral and injectable and direct the respondents to review the prohibition after giving an opportunity to the Petition.

For Appellant : Mr.A.Kevin Thomas for
M/s.King and Partridge

For Respondents: No appearance

J U D G M E N T

[Judgment of the Court was delivered by
K.K. SASIDHARAN,J.]

The writ petition filed by the appellant in W.P.No.21933 of 2011 challenging the notification dated 16 March 2011 in GSR No.218(E) prohibiting the manufacture, sale and distribution of Gatifloxacin formulation for systemic use in human by any route including oral and injectable; and Tegaserod and its formulations for human use, was dismissed by the learned single Judge primarily on the ground that it was a conscious decision taken by the statutory committee formed by the Government. The order is under challenge at the instance of the writ petitioner.

2. The learned counsel for the appellant contended that the Central Government constituted a Committee comprising seven members to look into the issue as to whether the drugs manufactured by the appellant is likely to involve risk to human beings. However, the decision was taken only by three members. According to the learned counsel, the order is bad in law on account of non-participation of the other members, who were members of the Committee originally constituted by the Central Government.

3. We have perused the documents available on record.

4. There is no dispute that a Committee was constituted by the Central Government to look into the issue. The Committee consists of seven members. It is also a matter of record that only three members of the Committee participated in the meeting held on 27 January 2011 at New Delhi. The minutes of the meeting of Expert Committee constituted to examine the issues of marketing of certain drug formulations reported to be prohibited, which includes the drug referred to in the notification dated 16 March 2011 in GSR No.218(E), indicates that in addition to those three members, there were other members who are stated to be the experts in the field. It is clear that instead of seven members examining the issue, a Sub-Committee was formed to examine the Safety aspect of the drugs. The Sub-Committee comprising three members, who were part of the Expert Committee along with several other experts said to have examined the safety aspects of the drug and arrived at a finding which is found in the notification dated 16 March 2011 in GSR

218(E). This aspect was considered by the learned single Judge and the writ petition was rightly dismissed.

5. The learned counsel for the appellant fairly submitted that the issue is also covered by a recent decision of the Hon'ble Supreme Court in Union of India and Others v. Pfizer Limited and Others [(2018) 2 SCC 39]. The Supreme Court in the said judgment made it clear that it is open to the Central Government to arrive at satisfaction by considering any relevant material that a drug is likely to involve any kind of risk to human beings etc., as a result of which it is necessary in public interest to regulate, restrict or prohibit manufacture, sale or distribution thereof. The Supreme Court further observed that so long as the Central Government's satisfaction is based on relevant materials, it is not possible to say that not having consulted the Drugs Technical Advisory Board (DTAB), the power exercised under the said Section would be non est.

6. In view of the binding judgment of the Hon'ble Supreme Court cited supra, there is no case made out by the appellant for interfering in the order passed by the learned single Judge.

7. In the upshot, we dismiss the intra court appeal. No costs. Consequently, connected miscellaneous petition is closed.

Sd/-
Asst.Registrar (CCC)

/true copy/

Sub Asst. Registrar

+ 2 cc to M/s.King and Partridge Advocate,SR.21578

+ 1 cc to M/s.P.Ayyasamy, Advocate,SR.21198

W.A No.2866 of 2012

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