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DELHI HIGH COURT SETS ASIDE NOTIFICATION BANNING A FDC AND REMANDS THE MATTER TO DTAB/SUB-COMMITTEE CONSTITUTED BY DTAB

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In its judgement dated 7 January 2019 (*Wockhardt Limited & Anr v Union of India - Writ Petition 9739 of 2018*), a single Judge of the Delhi High Court (High Court) has set aside the impugned notification dated 7 September 2018 which had prohibited the manufacture, distribution and sale of a particular fixed dose combination marketed by Wockhardt Limited (Wockhardt FDC) and remanded the matter to the Drug Technical Advisory Board (DTAB)/Sub-committee constituted by the DTAB. The judgement of the High Court lays down significant parameters in accordance with which the power under Section 26A is to be exercised by the Central Government and emphasises the need for transparency in such exercise of power.

Background Facts

- Notifications issued in March 2016

On 10 March 2016, the Central Government had issued 344 identically worded notifications (2016 Notifications) prohibiting the manufacture, sale and distribution of 344 fixed dose combinations. The 2016 Notifications banned the FDCs in question because they purportedly posed substantial risks to human life and safer alternatives were available. The 2016 Notifications were based on the findings and recommendations of an expert committee (the Kokate Committee) appointed by the Central Government, which stated that the FDCs in question were found to have no '*therapeutic justification*'. The Notifications were issued by the Central Government in exercise of its powers under Section 26A of the Drugs and Cosmetics Act, 1940 (the Act).

- Judgement of the High Court

The High Court **vide** its judgment dated 01 December 2016 set aside the 2016 Notifications issued by the Central Government. Although several issues were raised, the High Court set aside the 2016 Notifications on only one moot point i.e. - the Notifications has been issued by the Central Government without consultation with DTAB and Drugs Consultative Committee ("DCC"), which were statutory bodies created under the Drugs Act and that such consultation was mandatory. The said judgement was challenged by the Central Government before the Hon'ble Supreme Court of India (Supreme Court).

- Challenge before the Supreme Court

On 15 December 2017, the Supreme Court pronounced its judgment (Pfizer Judgement) in the FDC ban matters in an appeal filed by the Central Government against the judgment of the High Court dated 1 December 2016. The Supreme Court held that Section 26A of the Drugs Act does not necessarily mandate any previous consultation with the DTAB. However, since the Supreme Court was not satisfied with the reasons for conclusions reached by the Kokate Committee, the Supreme Court referred majority of the FDCs (post September 1988) to examination by DTAB or a committee appointed by DTAB. While referring the FDCs to DTAB, the Supreme Court directed that the DTAB/Sub-Committee would first satisfy itself that the FDC in question was likely to involve any one of the ingredients specified in Section 26A i.e. (a) that the FDC was likely to involve any risk to human beings or animals; or (b) that the said FDC did not have the therapeutic value claimed or purported to be claimed for them; or (c) that such FDC contains ingredients in such quantity for which there is no therapeutic justification. Additionally, the Supreme Court directed that the DTAB/Sub-Committee was also to apply its mind as to whether it is necessary or expedient, in the larger public interest, to regulate, restrict or prohibit the manufacture, sale or distribution of such FDCs. In doing so, the DTAB/Sub-Committee was mandated to clearly indicate in its report as to (i) why, according to it, any one of the three factors indicated above is attracted; (ii) post such satisfaction, that in the larger public interest, it is necessary or expedient to (a) regulate, (b) restrict, or (c) prohibit the manufacture, sale or distribution of such FDCs. The DTAB/Sub-Committee was also directed to indicate in its report as to why, in case it prohibits a particular FDC, restriction or regulation is not sufficient to control the manufacture and use of the FDC.

DTAB Report and challenge before the High Court

Pursuant to the directions of the Supreme Court, a Sub-committee appointed by the DTAB examined the FDCs and again banned majority of the same **vide** various notifications dated 07 September 2018. The Wockhardt FDC was also banned by one such Notification.

The said Notification was challenged by the Petitioners on various grounds including (i) that the same has been issued in violation of principles of natural justice; (ii) that the impugned notification was based on the recommendations of the Sub-committee of Drug Technical Advisory Board (DTAB), which has been made without application of mind; (iii) that the impugned notification has been passed without following the directives issued by the Hon'ble Supreme Court in the Pfizer Judgement and (iv) that the said FDC has a sound therapeutic justification and poses no risk to human beings. The absence of any reasons being given by the Sub-committee/Central Government was particularly emphasised by the Petitioners given that it was for this very reason that the Supreme Court had directed that the DTAB examine the FDCs in greater depth. The Petitioners also highlighted that even though extensive submissions were made by the Petitioners before the Sub-committee, the same were not taken into account by the Sub-committee or the Central Government.

The main contention of the Respondents i.e. Union of India was that since the power exercised by the Central Government under Section 26A of the Act is legislative, the Central Government is neither obliged to afford the Petitioners any hearing nor indicate any reasons for its satisfaction before issuing the Impugned Notification.

Judgement of the Delhi High Court

The High Court observed that despite not going into the question of whether the power exercising under Section 26A of the Act was legislative or not, the Supreme Court had set out specific directions in terms of which the FDCs were to be examined by DTAB. It also held that even if the powers to be exercised under Section 26A of the Act are legislative in nature, there could not be any dispute that such powers could be exercised

by the Central Government only upon being satisfied that it was necessary to exercise the same in larger public interest. Thus, it was held that the Central Government's satisfaction would be required to be based on the relevant considerations; cogent material; and by excluding irrelevant considerations. The Delhi High Court rejected the submission of the Respondent that the Sub-committee was not required to indicate its reasons for recommending that the said FDC be proscribed. The Delhi High Court also held that while Central Government may not be required to indicate its reasons in the notification but the material on which the decision was based – in this case the report of the Sub-committee – must provide a clear justification for issuing an order proscribing the manufacture and sale of a drug. The Delhi High Court observed that providing reasons was also necessary to indicate that the authority expressing its conclusion has done so after due application of mind. The Delhi High Court further affirmed that notwithstanding whether the principles of natural justice are applicable, the report of the Sub-committee was required to give sufficient reasons for its recommendation, as that report was required to be considered by the Central Government for determining the question as to whether to proscribe or restrict an FDC.

The Delhi High Court then analysed the material placed by the Petitioner before the Sub-committee as also the recommendations made by the same and concluded that while the scope of judicial review could not extend to supplanting the Court's opinion over that of the concerned authorities, in this case, it was clear that the contentions of the Petitioners had not been considered by the Sub-committee and it could not be said that the Sub-committee had applied its mind to the justification provided by the Petitioners.

The High Court accordingly set aside the Impugned Notification and remanded the matter to DTAB/ Sub-committee constituted by it to examine the Wockhardt FDC in accordance with the directions of the Supreme Court.

Comment

The Wockhardt Judgement is the first challenge to be adjudicated by the Delhi High Court in the second round of Central Government banning various FDCs. The judgement is likely to have a bearing in various other matters where similar challenge is currently pending before the Delhi High Court. The Wockhardt judgement is likely to bring much relief to the industry since it elaborately lays down the law in respect of the scope of exercise of power under Section 26A of the Act and firmly places an obligation on the Central Government to consider cogent material and provide clear reasons prior to exercising its power under Section 26A of the Act.

Khaitan & Co. represented Wockhardt Limited before the Delhi High Court in above referred proceedings

- *Sanjeev Kapoor (Partner) & Saman Ahsan (Principal Associate)*

For any queries please contact: editors@khaitanco.com

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Mumbai

One Indiabulls Centre, 13th Floor
Tower 1 841, Senapati Bapat Marg
Mumbai 400 013, India

T: +91 22 6636 5000
E: mumbai@khaitanco.com

New Delhi

Ashoka Estate, 12th Floor
24 Barakhamba Road
New Delhi 110 001, India

T: +91 11 4151 5454
E: delhi@khaitanco.com

Bengaluru

Simal, 2nd Floor
7/1, Ulsoor Road
Bengaluru 560 042, India

T: +91 80 4339 7000
E: bengaluru@khaitanco.com

Kolkata

Emerald House
1 B Old Post Office Street
Kolkata 700 001, India

T: +91 33 2248 7000
E: kolkata@khaitanco.com