

DELHI HIGH COURT TO HEAR PETITION CHALLENGING NOTIFICATION ISSUED BY THE CENTRAL GOVERNMENT UNDER SECTION 26 (A) OF THE DRUGS & COSMETICS ACT, 1940, PROHIBITING THE SALE AND IMPORT OF OXYTOCIN BY PRIVATE PLAYERS.

BGP PRODUCTS OPERATIONS GMBH & ANR. Vs UOI & Ors.; W.P. (C) 6084/2018
(Next Listed on 20.08.2018)

Oxytocin is an **essential medicine** listed in the **National List of Essential Medicines, 2015** and as such a “**Scheduled Formulation**” under the **Drugs (Prices Control) Order, 2013**. Oxytocin has medical use for induction and augmentation of labour, to control post-partum bleeding and uterine hypo tonicity. Oxytocin is however also misused and used indiscriminately in most parts of the country by unscrupulous people on milching animals, vegetables, fruits and non-vegetarian consumable items. It is well documented that the misuse happens through clandestine channels and illegal manufacture and inter-state sale of Oxytocin, which the Government has failed to regulate. A series of reports of the DTAB are available which record that the illicit manufacture of Oxytocin is a clandestine activity.

After the publication of the notification prohibiting the manufacture, import and sale of Oxytocin by private players w.e.f. **01.09.2018**, it has been reported that doctors have expressed shock and helplessness on account of the impending shortage and hospitals are stocking up Oxytocin to prepare for the crisis. Meanwhile reports also suggest that **Karnataka Antibiotics Pharmaceutical Ltd.**, the only public-sector company which has been authorised to sell Oxytocin in India, has increased its price.

Background

- (i) Decision of the Hon’ble Himachal Pradesh High Court in “**Court on its own motion v. State of Himachal Pradesh**” [2016 SCC Online HP 244]

On 24.11.2015, the **Hon’ble Himachal Pradesh High Court** took suo motu cognizance of news reports wherein illegal use of Oxytocin in fruits, vegetables and milching animals were highlighted. With the assistance of the Amicus Curiae appointed in the matter, the Hon’ble High Court took note of various reports of the **Drugs Technical Advisory Board (“DTAB”)** reporting on the misuse of Oxytocin and also noted the State Government’s deliberate failure to check such misuse. The judgment records inter-alia, that:

- (a) In the last 3 years only 11 samples of fruits, 4 samples of vegetables, 11 samples of non-vegetarian food items and 91 samples of milk were lifted in the entire state of Himachal Pradesh. Out of 117 samples of food items lifted, only 65 were analysed.
- (b) The sole government Common Testing Laboratory at Kandaghat, District Solan did not even have the facility of detecting Oxytocin in food items;
- (c) The Government’s assertion that strict vigil was kept on illegal import of Oxytocin in the State of Himachal Pradesh fell flat as in the last 3 years there had been only one seizure of 254 injections.

Having regard to the material placed before it pointing to the inability of the State Government to curb the misuse of Oxytocin, the Hon’ble High Court directed both the State and Central Government to take specific steps to **restrict and regulate** the import, manufacture and distribution of Oxytocin.

- (ii) Notification by the Central Government prohibiting the import and sale of Oxytocin by private sector wef 01.07.2018

Pursuant to the decision of the Himachal Pradesh High Court, the Ministry Of Health And Family Welfare (“**MOHFW**”) issued a notification under **Section 26 A** of the **Drugs & Cosmetics Act, 1940 (“D & C Act”)** bearing no. **G.S.R No. 411**

(E) dated 27.04.2018, prohibiting private sector companies from manufacturing for sale in India, importing and selling Oxytocin in India.

The notification further directs that manufacturers of the active pharmaceutical ingredient (“API”) of Oxytocin shall supply the API only to the public sector manufacturers licensed under the D & C Rules, 1945 for manufacture of formulations of the said drug for domestic use.

Further, it directs that the manufacturers of the API of Oxytocin shall supply the said API to the manufacturers in public and private sector licensed under the D & C Rules, 1945 for manufacture of formulations of the said drug for export purpose only.

Further that public sector companies shall supply Oxytocin only to the registered hospitals and clinics in public and private sector directly; or to the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and Affordable Medicines and Reliable Implants for Treatment (**AMRIT**) outlets or any other Government entity which may be specified by the Central Government for this purpose in the country which shall further supply the drug to the registered hospitals and clinics in public and private sector. Oxytocin in any form or name shall not be allowed to be sold through retail Chemist.

The notification was to come into force on **01.07.2018**.

(iii) **Notification extending date of operation of notification dated 27.04.2018**

The MOHFW vide further notification dated **29.06.2018** bearing no. **G.S.R 602(E)** extended the date for commencement of the notification dated 27.04.2018 from 01.07.2018 to **01.09.2018**.

Legal proceedings challenging the prohibition

- (i) In May 2018, BGP Products Operations GMBH (“**BGP**”) moved a Writ Petition bearing **W.P (C) No. 6084/2018** before the Hon’ble Delhi High Court seeking stay of the operation of the impugned notification dated 27.04.2018. Vide order dated **30.05.2018** the Hon’ble Delhi High Court declined to grant such stay and listed the matter for further hearing on **04.09.2018**. On 30.05.2018 when such order was passed, further notification dated 27.04.2018 extending the date of operation of the impugned notification had been issued by the Central Government.
- (ii) Aggrieved by the order of the Hon’ble Delhi High Court declining stay, BGP preferred a Special Leave Petition (“SLP”) bearing no. **SLP(C) No. 015784 - 015784/2018** before the Hon’ble Supreme Court, against the said order.
- (iii) The Hon’ble Supreme Court, vide order dated **09.07.2018** dismissed the SLP while requesting the High Court to ensure expeditious disposal of the stay application filed by BGP, before the extended date of the prohibition, i.e. 01.09.2018.
- (iv) The matter was taken up by the Hon’ble High Court on **16.07.2018** when the Respondents were directed to file their counter and the matter was posted for early on **20.08.2018**.

ELP’s Assessment:

In **Union of India vs Pfizer Ltd. (2018) 2 SCC 39**, the Hon’ble Supreme Court has discussed at length the manner in which the Central Government must exercise its powers under **Section 26 A of the D & C Act** and has laid down *inter-alia*, the following parameters for examination of the fixed dose combination drugs (“FDC”), (the subject matter of the said case) by the DTAB or its sub-Committee.

- ♦ That the said FDC (i) are likely to involve any risk to human beings or animals; (ii) or the said FDCs do not have the therapeutic value claimed or purported to be claimed for them; or (iii) such FDCs contain ingredients and in such quantity for which there is no therapeutic justification.
- ♦ As to why, according to it, any one of the three factors indicated above is attracted;

- ◆ After arriving at the satisfaction as to why any of the abovementioned ingredients were attached, that in the larger public interest, it is necessary or expedient to (i) regulate, (ii) restrict, or (iii) prohibit the manufacture, sale or distribution of such FDCs;
- ◆ In case the DTAB/Sub- Committee is of the opinion that the FDC should be prohibited, why, restriction or regulation is not sufficient to control the manufacture and use of the FDC.
- ◆ The Central Government must have due regard to the report of the DTAB and to any other relevant information, and ultimately apply its mind to the parameters contained in Section 26-A of the Drugs Act and, accordingly, take action

The impugned notification records that there was large scale **clandestine** manufacture and sale of the drug Oxytocin leading to its grave misuse. It further records that the manner in which DTAB had recommended regulation was that Oxytocin should be sold only to registered hospitals and clinics in both, the public as well as private sector. The DTAB had not recommended regulation by prohibiting the private sector from selling Oxytocin in India. Regulation by prohibiting licensed manufacturers/traders from selling Oxytocin will not stop clandestine activity. It would appear that the action of the Central Government fails on many counts when examined against the Hon'ble Supreme Court's judgment.

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