Madras High Court
Laborate Pharmaceutical India ... vs Union Of India on 24 October, 2017

IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on : 20.09.2017

Date of Decision : 24.10.2017

CORAM :

The Hon'ble Ms.INDIRA BANERJEE, CHIEF JUSTICE
AND
The Hon'ble Mr.JUSTICE M.SUNDAR

W.P.No.37742 of 2015
and
W.P.No.29322 of 2016

W.P.No.37742 of 2015

Laborate Pharmaceutical India Ltd.,
Registered Office at
E-11,Industrial Area,
Panipet-132 103 .. Appellant

Vs.

1.Union of India
Through Secretary
Ministry of Healthy and Family Welfare
FDA Bhavan, ITO Kotla Road
New Delhi 110 001

2.E.Seshan .. Respondents

Writ petition filed under Article 226 of the Constitution of India to issue a Writ of Declarati

W.P.No.29322 of 2016

Alpa Laboratories Limited
Registered Office at
33/2 Pigdamber A.B.Road
Indore 453 446
Rep. by Paresh Chowia ... Petitioner

Vs.
Union of India
Through Secretary
Ministry of Health and Family Welfare
FDA Bhavan, ITO Kotla Road

New Delhi- 110 002 ... Respondent

Writ petition filed under Article 226 of the Constitution of India to issue a Writ of Declarati

For Petitioner : Mr.G.Masilamani
Senior Counsel
for Mr.Jose John
M/s.King and Partridge

For Respondents : Mr.G.Rajagopalan
ASG, Assisted by Mr.B.Ramarathnam
Central Govt. Standing Counsel for R1

Mr.M.Radhakrishnan
Counsel for Intervenor

Mr.A.Yogeshwaran for R2
in W.P.No.37742 of 2015

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COMMON ORDER

M.SUNDAR.J

We propose to dispose of both these writ petitions by this common order as the facts, i

2.Facts

necessary for appreciating and understanding our order are set out infra under the caption 'Factual Matrix'.

3. FACTUAL MATRIX:

3(i) 'Gyps bengalensis', 'Gyps tenuirostris' and 'Gyps Indicus' are what we are concerned with in these writ petitions.

3(ii) The aforesaid three are zoological names for three different species of vultures in the world, more commonly known as White-backed Vulture , Slender Billed vulture and Long Billed Vulture . All the three species are collectively referred to as 'Vultures' in this order for the sake of convenience and clarity.

3(iii) There is no dispute amongst the parties to the lis before us that the aforesaid vultures are critically endangered species.

3(iv) Vultures are universally accepted as sanitary workers, which clear carcasses of domestic livestock/cattle and thereby protect ecological balance. 'Vulture population in India is on the

decline, it has an adverse impact on the ecological balance / environment and therefore, such decline in vulture population needs to be arrested' - this is the central theme that is the genesis of this lis.

3(v) While the central theme of genesis of this lis is arresting the declining vulture population in India, the nucleus of this lis is a pharmaceutical product which goes by the name Diclofenac Sodium, which is hereinafter referred to as 'Diclofenac' for brevity and convenience. Diclofenac is a 'Non-steroidal Anti-inflammatory Drug' (NSAID for brevity). In simple terms, it is a pain killer.

3(vi) From 1992 large scale vulture deaths were reported in India. This led to the Government taking up the issue and doing a study on the cause for decline in vulture population.

3(vii) The studies/surveys in India revealed that the country's vulture population declined drastically over the years. While the Indian Slender billed vulture (Gyps tenuirostris) declined by 97% between 1992 and 2007, with regard to some other species of vultures it was even worse as drop in population was as high as 99.9% in the same period i.e., between 1992 and 2007. Further scientific investigation by the Government of India revealed that Diclofenac, an NSAID as aforesaid, administered to animals i.e., livestock/cattle was found to be the main cause for decline in vulture population. The study revealed that the drug (Diclofenac) was found to cause fatal gout or renal failure in vultures when the vultures feed on the carcasses of dead livestock/ cattle, which were administered with Diclofenac in the last 72 hours before their death.

3(viii) To be noted, in the counter affidavit filed by the Union of India, sworn by the Deputy Drugs Controller (India), Central Drugs Standard Control Organisation, South Zone, Shastri Bhavan, Haddows Road, Nungambakkam, Chennai 600 006, it has been averred as follows:

The vulture universally accepted as natural scavenger and protector of environment. (underlining done by us to highlight).

3(ix) Notwithstanding the above averment in the counter affidavit of Union of India sworn by the Deputy Drugs Controller, we choose to use the term Natural Sanitary Worker instead of the term Natural Scavenger , used in the counter affidavit of Union of India (hereinafter referred to as 'UOI' for brevity).

3(x) In the light of the fact that vultures are universally accepted as Natural Sanitary Workers and are absolutely necessary for maintaining ecological balance qua disposal of carcasses of livestock, in India based on the studies and surveys alluded to supra, UOI banned/prohibited manufacture, sale and distribution of Diclofenac and its formulations for animal use, by issuing a notification dated 04.07.2008 being Notification G.S.R.499 (E). To be noted, this notification was issued by UOI in exercise of its power under Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), which is hereinafter referred to as Drugs Act for the sake of brevity and convenience. In and by the said notification dated 04.07.2008, while prohibiting the manufacture, sale and distribution of Diclofenac and its formulations for animal use, Central Government has clearly stated that it has been done in public interest and it has also been set out therein that alternative to the said drug is

available. Further to be noted, we are informed that alternative to Diclofenac and its formulations is a product, which goes by the pharmaceutical name Meloxicam.

3(xi) It is not in dispute that the aforesaid notification dated 04.07.2008 was issued by the Government of India/UOI solely on the ground that decline in vulture population in India is directly relatable to Diclofenac, about which we have alluded to supra.

3(xii) The aforesaid notification dated 04.07.2008 was not challenged and is operating.

3(xiii) Under the Drugs Act, the Central Government/UOI, in exercise of its rule making power conferred on it by Sections 6(2), 12, 33 and 33-N, has made rules which go by the title 'The Drugs and Cosmetics Rules, 1945' (hereinafter referred to as 'Drugs Rules' for the sake of brevity and convenience).

3(xiv) Section 5 of the Drugs Act provides for constitution of a Board to be called 'Drugs Technical Advisory Board' to advise the Central Government and State Governments on technical matters arising out of the administration of Drugs Act and to carry out other functions assigned to the said Governments by the said Act. Drugs Technical Advisory Board, as provided for under Section 5 of the Drugs Act, has, in fact, been constituted and is hereinafter referred to as 'DTAB' for brevity. DTAB in its 63rd and 64th meetings held on 16.05.2013 and 19.07.2013 respectively, took a decision that Diclofenac injection for human use should be restricted to single unit dose packs only. Such a decision appears to have been taken by DTAB on the basis that multiple dose packs of Diclofenac injection are being diverted to animal/veterinary use, which has already been banned in India in and from 2008 as referred to supra.

3(xv) To be noted, we are informed that Diclofenac injections are manufactured and marketed in 1 ml and 3ml vials. It is also averred that one Pharmaceutical company has obtained patent for the 1 ml vials and therefore these writ petitioners and other similarly placed manufacturers market 3ml vials only and these 3ml vials are single dose packs used for human beings. 30 ml bottles were also manufactured and marketed by the writ petitioners and similarly placed manufacturers. The 30 ml bottles are obviously multi-dose packs for human beings as human beings are normally administered 1ml to 3ml depending on the requirements. To be noted, we are informed that animals such as cattle, say a fully grown cow is normally administered 11 to 15 ml.

3(xvi) After the ban of Diclofenac injections and its formulations in animal use, it is the case of the Government of India/UOI that it came to light that 30ml bottles meant to be used as multiple dose units in hospitals for human use are being diverted for animal use, animals are being administered the same in 11 to 15 ml doses and that post death, when carcasses of such animals are eaten by vultures, it causes death of vultures by gout or renal failure.

3(xvii) Therefore, in exercise of powers conferred on the Central Government/UOI under Sections 12 and 33 of Drugs Act, after consultation with DTAB, UOI made a rule amending the Drugs Rules. The amendment is by way of introduction of a 4th proviso to Rule 105 of the Drugs Rules. Rule 105 is captioned Packing of Drugs . This 4th proviso to Rule 105, which was brought in by the Central

Government in exercise of its powers under Sections 12 and 33 of Drugs Act was notified on 17.07.2015 vide G.S.R.No.558. Writ petitioners, arguing that the 17.07.2015 notification inserting the 4th proviso to Rule 105 of Drugs rules, is bad in law, have filed the instant writ petitions on various grounds and the pivotal ground is that there is no study to show that 30ml bottles being multi dose packs for human beings are being diverted for animal use.

3(xviii) As the matter involves a highly technical scrutiny, this Court, by order dated 17.06.2016 in these writ petitions, constituted a three member expert committee and called for its study report.

3(xix) The three member expert committee has since filed its report in this Court.

3(xx) Respondent/UOI in resisting and opposing the writ petition would support the introduction of 4th proviso to Rule 105 of Drugs rules (hereinafter referred to as 'Impugned Provision' for the sake of convenience and clarity) inter-alia relying on the report of the 3 member expert committee constituted by this Court.

4. We now proceed to examine the rival submissions, the buttressing material pressed into service by both sides and proceed to discuss the same under the caption 'Discussion' infra.

5. Discussion:

5(i) Writ petitioners assail the impugned provision on various grounds and to put it in simple terms, they can be crystallized and summarized as follows:

a) The basis for introduction of the impugned provision is that there is decline in vulture population, but the same is not supported by any systematic, scientific and long duration study and the same has not been documented by any Governmental Agency.

b) The impugned provision has been brought in, not on account of misuse on human beings, but on suspicion that vultures die on feeding carcasses of animals, which were administered the Drug, i.e., Diclofenac 72 hours before their death;

c) Diclofenac injections in 30 ml multi-dose packs are supplied only to speciality hospitals and Nursing Homes, besides registered Medical Practitioners. They are economical and efficacious;

d) Multi dose bottles of Diclofenac injection are absolutely essential for treatment as an analgesic i.e., as a NSAID for various conditions in human beings.

e) There are malafides behind the introduction of the impugned provision as the same has been brought in to promote one particular pharmaceutical company.

f) There is no evidence on record to show that Diclofenac has been misused and diverted in large scale for use in animals.

5(ii) Refuting and countering the above grounds of attack, the grounds on which Union of India defended the impugned provision, can be broadly crystallized and summarized as follows:

a) Vultures are universally accepted as Natural Sanitary Workers, absolutely essential for environmental and ecological balance. Therefore, preservation of vulture population is non-negotiable.

b) Impugned provision has been introduced in public interest.

c) Impugned provision has been introduced after taking into account the views of stakeholders. Views of stakeholders were obtained by publication of draft rules and inviting objections and suggestions from the stakeholders and public on the proposed impugned provision.

d) The possibility of misuse of 30ml packs in animals and the possibility of diversion for use in animals cannot be ruled out even according to the report of the Expert Technical Committee appointed by this Court.

e) As a corollary to the preceding point, Government of India would submit that they have brought in the impugned provision on the basis of the sanctified precautionary principle impelled by public interest.

5(iii) Two public spirited individuals viz., Seshan and S.Bharathithasan, sought to implead themselves as party respondents. This Court permitted the above said Seshan to be impleaded as second respondent in one of the two writ petitions i.e., W.P.No.37742 of 2015 and S.Bharathithasan to participate in the proceedings as an intervenor. Both the second respondent (in W.P.No.37742 of 2015) and the intervenor supported Union of India, in other words, they supported the impugned provision.

5(iv) The submissions of the aforesaid second respondent and the intervenor can be broadly summarized and encapsulated as below:

a) There is enough statistics and evidence to show decline in vulture population.

b) Impugned provision was introduced in public interest on the basis of sanctified precautionary principle and therefore, the same should not be disturbed lightly.

c) The impugned provision has been brought in after a scientific study.

d) The report of the 3 member expert committee appointed by this Court also supports the impugned provision.

e) Vultures have been declared as critically endangered species in 2000 by the World Conservation Union. India is a signatory to the 1992 Biodiversity Convention and therefore should not allow the decline of vulture population as the objective of the biodiversity convention is that wherever there is

threat of reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.

5(v) We have heard elaborate submissions made by Mr.G.Masilamani, learned senior counsel appearing on behalf of writ petitioners, Mr.G.Rajagopalan, learned Additional Solicitor General of India representing Union of India, Mr.M.Radhakrishnan, counsel for the intervenor and Mr.A.Yogeshwaran, learned counsel for the second respondent in W.P.No.37742 of 2015.

5(vi) As would be evident from our narrative supra, this Court in and by an order dated 17.06.2016, appointed a three member Expert Committee and the members of the three member expert committee are as follows:

i) Dr.S.D.Seth, Advisor, Clinical Trials Registry, Nizams Institute of Medical Sciences, Indian Council of Medical Research, New Delhi;

ii) Dr.Y.K.Gupta, Professor & Head, Dept. of Pharmacology, All India Institute of Medial Sciences, New Delhi; and

iii) Dr.N.K.Gupta, Director Professor, Department of Medicine, Maulana Azad Medical College, New Delhi.

5(vii) To be noted, the aforesaid three members are highly qualified technical experts and this has not been disputed by any of the parties to the lis before us.

5(viii) The three member technical expert committee appointed by us on 17.06.2016, sat through as many as 9 meetings. The first meeting was on 19.08.2016 and the last meeting was on 19.12.2016. To be precise, the dates of meetings of the said expert committee to examine the issue qua impugned provision were held on 19.08.2016, 30.08.2016, 19.09.2016, 13.10.2016, 19.10.2016, 22.11.2016, 09.12.2016, 15.12.2016 and 19.12.2016.

5(ix) After 9 meetings as aforesaid for examining the impugned provision qua its merits and demerits, the expert committee filed its detailed report in this Court on 01.02.2017 with advance copies to the parties at lis.

5(x)In accordance with our order dated 17.06.2016, while examining the technical background for the impugned provision, Expert Committee had taken the views of several stakeholders and most importantly the stakeholders include the writ petitioners herein.

5(xi) In its detailed report, the committee had made recommendations and we shall refer to the same infra in this judgment.

5(xii) As would be evident from our narrative supra, while decline in vulture population and control of the same is the central theme of this lis and while pharmaceutical product Diclofenac is the nucleus of this lis, the aforesaid report of the expert committee is the hub and fulcrum of this lis.

Adverting to the report of the expert committee, learned senior counsel Mr.Masilamani would submit that this is a post decisional enquiry and therefore should be viewed with caution.

5(xiii) Learned senior counsel also drew our attention to the findings returned by the expert committee to the effect that the possibility of misuse of Diclofenac in animals, has, as urged by Non-Governmental Organisations (NGOs) cannot be ruled out and would submit that this finding returned by the expert committee is not supported by any material before it.

5(xiv) Learned senior counsel for the petitioners also drew our attention to the counter affidavit of UOI, particularly Paragraph 2 and submitted that the Union of India has clearly admitted that as a result of prohibition of use of Diclofenac in animals, it was reported for the first time in 2012 (since the drug s, i.e., Diclofenac introduction) that India s Vulture population did not decline during the year. Stressing on this aspect of the counter affidavit, learned senior counsel advanced the argument that there is nothing on record to show that there is decline in vulture population post 2012. It is the further submission of the learned senior counsel for the petitioners that the drugs in 30 ml bottles / vials already manufactured and in circulation was available for some time and in the light of the fact that there is no evidence of decline in Vulture population post 2012, the introduction of the main provision more than two years later on 17.07.2015 is completely unjustified and illogical.

5(xv) Per contra, learned Additional Solicitor General Mr.G.Rajagopalan submitted that the writ petitions are not maintainable in this Court as both the writ petitioners are not in Chennai, the respondent is also not in Chennai and the seizures were done in Andhra Pradesh. In other words, learned Solicitor assailed the writ petition on the ground of lack of territorial jurisdiction for this Court. Learned Solicitor further submitted that the findings returned by the Expert Committee regarding possibility of misuse in animals, as alleged by NGOs, is in fact supported by material and learned Solicitor took us through Annexure 11 to the report, which is a Survey Report of Indian Veterinary Research Institute, which is the list of Diclofenac-positive ungulate injection samples in the order of increasing concentration in various States of India. We deem it relevant to extract that portion of pictorial depiction of Annexure 11 for ease of reference;

State-wise prevalence State-wise prevalence was as follows: Andhra Pradesh (0/163, 0.00%), Haryana (3/33, 9.09%), Jammu & Kashmir (4/87, 4.60%), Madhya Pradesh (11/230, 4.78%), Maharashtra (1/206, 0.49%), Punjab (18/198, 9.09%), Uttar Pradesh (1/178, 0.56%), West Bengal (7/236, 2.97%), Rajasthan (113/566, 19.96%) overall ; 44/256, 17.19% samples collected in 2010 and 69/310, 22.25% samples collected in 2008 . It is apparent that high diclofenac prevalence in Rajasthan is a cause of concern for vulture conservation as the prevalence in other states is declining and out of 1332 samples (excluding 566, Rajasthan samples), only 48 were positive for diclofenac residue indicating 3.52% prevalence.

Species - wise prevalence Out of 1898 samples analysed, only cattle and buffalo carcasses were found positive. Within these two species, diclofenac positive cattle carcasses (138/1303, 10.59%) were more than that of buffalo (19/537, 3.54%). Higher incidence of drug residue was observed in females than males in both the species. One out of four horses was also found to contain high concentration of diclofenac residue. Diclofenac was not detected in sheep, goat and dog tissue

samples. 5(xvi) Besides the above, investigation on causes of mortality in vultures have also been done and a detailed report on prevalence of diclofenac and other causes of mortality in vulture carcasses samples survey has also been given. No doubt all these surveys are between 2007 and 2012. There is no material post 2012 as pointed out by the learned senior counsel for the petitioners. However, the learned Solicitor would say that as a welfare State, it is absolutely essential for UOI to invoke the precautionary principle in matters of this nature rather than take a chance.

5(xvii) This precautionary principle is strongly supported by the second respondent and the intervenor with particular reference to the fact that India is a signatory to the notification on Biodiversity in 1992.

5(xviii) In this context we deem it appropriate to give the recommendations of the Technical Committee as summarized by the Committee. The same read as follows:

) Diclofenac is a non-steroidal anti-inflammatory drug and also commonly used as painkiller. The drug is commonly used in human being in different formulations. The presence of diclofenac residue in vultures was correlated with declining vulture population. Hence, the use of diclofenac in animal was prohibited. This prohibition resulted in significant decline in reduction rate of vulture as demonstrated by modeling studies. This justifies the continued prohibition of use of diclofenac in animals. Further, additional measures of reducing the environmental contamination of diclofenac and another pharmaceutical products namely other NSAIDS, antibiotics, anticancer drugs etc. be enforced. This can be done by a synergy and comprehensive approach by regulatory bodies, pharmaceutical industry, public awareness, stringent enforcement of biomedical waste regulations etc. Although the correlation of diclofenac residue has been shown with reduction in vulture population, still stronger evidence is required considering the multiple possibilities which may impact adversely on vulture health from other environmental factors. Therefore, continued adequately powered well-structured epidemiological and causality studies are required.

As far as the multi-dose pack size of diclofenac injection meant for human use in concerned, thee is no strong evidence of its pilferage leading to its misuse in animals which is sufficient to cause significant adverse impact in vulture population. However, the possibility of its misuse in animals as alleged by NGOs cannot be ruled out.

The Committee is of the opinion that no disadvantage to the patient community will occur by withdrawing the multi-dose pack size of diclofenac injection as a precautionary approach. More evidence based date and not the opinion or perception is required to take a considered view on withdrawal of multi-dose pack size diclofenac injection for human use. This should also include feedback from practicing physicians, clinics, nursing homes and hospitals. 5(xix) Learned senior counsel for the writ petitioners, in his usual fairness, submitted at the bar that though malafides have been pleaded and though there is a pleading that the impugned provision has been brought in to aid and help another pharmaceutical company, he is not pressing the same and though there is a pleading to this effect, it can be construed to be not pressed by the writ petitioners. We record this submission and also place on record that we have noticed the fairness and responsibility with which this submission has been made, by the learned senior counsel.

5(xx) Before proceeding further with our discussion with regard to the submission of the learned Solicitor that the writ petitions are not maintainable owing to lack of territorial jurisdiction, we accept the submission of the learned senior counsel for the petitioners that this being a challenge to a Central legislation (subordinate legislation though), in the light of the track and trajectory the constitutional amendments have taken qua Article 226 of the constitution of India, this Court certainly has territorial jurisdiction to entertain the writ petition.

5(xxi) As this is a challenge to a provision in a central legislation (subordinate legislation of course) and more so in the light of the fact that this is final hearing of the writ petition and not the Rule Nisi stage (this is final hearing post detailed enquiry report from an expert committee appointed by this Court), we negative the submission of the learned Solicitor and hold that these writ petitions assailing introduction of a provision in a central legislation i.e., a provision in a subordinate legislation made by the Central Government in exercise of rule making power conferred on it, are certainly maintainable and there is no lack of territorial jurisdiction in this regard.

5(xxii) Learned senior counsel pressed into service, a Judgment of the Delhi High Court dated 01.12.2016 made in W.P (C) No.2212 of 2016 etc., in Pfizer Limited and another Vs. Union of India and Ors. This is a case in which as many as 454 writ petitions, attacking some 344 notifications dated 10.03.2016, were disposed of and the said notifications which were made in exercise of powers of Central Government under Section 26A of Drugs Act were set aside. Our attention was drawn to Paragraphs 53, 65, 68, 69, 72 and 78 of the said judgment. We extract the said paragraphs:

3. Supreme Court in Centre for PIL Vs. Union of India (2011) 4 SCC 1 reiterated that an institution is more important than an individual and an institution has to satisfy the test of values, independence, impartiality and competence and so have the persons manning the institution to satisfy the said tests. If institutions though set-up, particularly those set-up statutorily are to be bypassed, the same would severally erode the faith in the functioning of the Central Government and the decisions taken by it under the law and dent good governance and constitutional trust. Supreme Court in Manoj Narula Vs. Union of India (2014) 9 SCC 1 held that the principle of constitutional morality basically means to bow down to the norms of the Constitution and not to act in a manner which would become violative of the rule of law or reflectible of action in an arbitrary manner; it actually works at the fulcrum and guides as a laser beam in institution building. It was held that institutional respectability and adoption of precautions for the sustenance of constitutional values would include reverence for the constitutional structure. Again in Board of Control for Cricket in India Vs. Cricket Association of Bihar (2015) 3 SCC 251 it was held that BCCI is a very important institution that discharges important public functions and demands of institutional integrity are therefore heavy and need to be met suitably in larger public interest.

65. No merit is found in the aforesaid contention also. There can be no estopple against the law. Once it is found that the law i.e. the Drugs Act requires the Central Government to exercise the power under Section 26A after taking advice from and in consultation with the statutory bodies created thereunder i.e. the DTAB and DCC, the exercise of power without such advice and consultation cannot be upheld even if exercised bona fide and in consultation with and on advice of other experts who may be as competent as the DTAB and DCC. The maxim, what is prescribed to be

done in a particular way must be done in that way and no other way, would apply. Reference if any required can be made to Selvi J. Jayalalithaa Vs. State of Karnataka (2014) 2 SCC 401, Mackinon Mackenzie and Company Ltd. Vs. Mackinnon Employees Union (2015) 4 SCC 544 and Zuari Cement Ltd. Vs. Regional Director E.S.I.C. Hyderabad (2015) 7 SCC 690 laying down that if the procedure prescribed is not followed then such act has to be held to be null and void ab initio in law.

68. The senior counsel for All India Drug Action Network, counsel for Veteran's Forum for Transparency in Public Life and the counsel for Wing Commander B.N.P. Singh, General Secretary of Veteran's Forum for Transparency in Public Life also opposed the petitions inter alia arguing that the Government has acted on the complaints of the patients and concerned groups and that the health and safety of the patients is paramount and that the FDCs which have been banned are indeed hazardous to the patient.

69. I have already held above that this Court in exercise of power of judicial review cannot adjudicate whether these FDCs are risky to the consumers or lack therapeutic value or therapeutic justification. The statute requires the said aspects to be considered by DTAB and DCC and to report thereon. That has admittedly not been done.

72. Before parting with this subject, for the sake of completeness I may record that CDSCO is not a Statutory Authority under the Drugs Act. Its website www.cdsco.nic.in describes it as the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs Act, with Drugs Controller at its helm. Interestingly, the Drugs Controller is not an office established under the Drugs Act; rather Section 5 of the Act prescribes the DTAB to be having the Drugs Controller as its ex-officio member. Rule 2(b) defines the Central Licence Approving Authority as the Drugs Controller appointed by the Central Government.

78. The petitions thus succeed. All 344 Notifications dated 10 th March, 2016 purportedly in exercise of power under section 26A of the Drugs Act are found to have been issued without following the procedure statutorily prescribed to be followed prior to issuance thereof and resultantly it is held that the Notifications are not based on satisfaction of the Central Government prescribed to be on the advice of and in consultation with the DTAB and DCC. Resultantly the said Notifications are quashed. 5(xxiii) Though there can be no dispute about the propositions laid down and the line of authorities of the Hon'ble Supreme Court as extracted in the Pfizer case supra, on a careful perusal of the judgment we are of the view that it does not help the writ petitioners as this is not a case of exercise of powers without following statutory prescriptions.

5(xxiv) Pfizer case is one where as many as 344 notifications, all dated 10.03.2016 made by Government of India in respect of 344 Fixed Dose Combination Drugs (FDC), were called in question. After detailed analysis, Delhi High Court came to the conclusion that all the 344 impugned notifications are bad as they are in purported exercise of powers conferred under Section 26A of Drugs Act and they have been issued without following the procedure statutorily prescribed to be followed prior to issuance thereof and resultantly the impugned Notifications were held to be not based on satisfaction of the Central Government and were therefore set aside.

5(xxv) In the instant case, as alluded to supra, in the course of hearing itself, considering the highly technical nature of the lis, this Court had appointed a three member Committee, constitution of which was not objected to by parties to this lis. In fact the eminence and competence of the three individuals was accepted by all the parties to this lis. Even when the three member committee was appointed, there was no doubt in the minds of the parties to this lis that this is a post decisional exercise. The Committee has returned a report after sitting through the matter over as many as 9 meetings as referred to supra. Therefore, the trajectory of this litigation is very different from the Pfizer case, owing to which the view taken in Pfizer case by the Delhi High Court that Section 26A of Drugs Act has been exercised by Central Government without following the statutory prescription by merely accepting the advice of DTAB, cannot be pressed into service in the instant case. Therefore, we have no hesitation in holding that the Pfizer case does not help the writ petitioners.

5(xxvi) Learned Additional Solicitor General of India, pressed into service a judgment of this Court in Macleods Pharmaceuticals Limited, Vs. Union of India reported in 2012 SCC Online 1735 to stress the importance of precautionary principle in matters of this nature.

5(xxvii) In Macleods Pharmaceuticals Limited case, which again dealt with challenge to a notification issued under Section 26A of Drugs Act, this Court had very lucidly elucidated the precautionary principle and the same is contained in paragraph 102 of the said judgment. We deem it appropriate to reproduce the same.

102. By a decision rendered on 11.9.2002, the Court of First Instance pointed out that precautionary principle is not only one of the principles on which the Community policy on environment is based, but also that it applies to cases where Community institutions take measures to protect human health. On the contention of the companies that there was no scientific assessment of the risks, the Court elicited the following principles:-

(i) Where there is scientific uncertainty as to the existence or extent of risks to human health, Community institutions may, by reason of the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.

(ii) Community institutions were not required, for the purpose of taking preventive action, to wait for the adverse effects of the use of the product, to materialise.

(iii) The only limiting factor on the application of the precautionary principle is that a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on a mere conjecture.

(iv) The precautionary principle can apply in situations in which there is a risk to human health, which, although it is not founded on mere hypothesis that have not been scientifically found, has not yet been fully demonstrated.

5(xxviii) On precautionary principle, Mr.A.Yogeshwaran, learned counsel for the impleaded second respondent, drew our attention to the judgment of the Hon ble Supreme Court of India in Vellore

Citizens Welfare Forum Vs. Union of India and others reported in AIR 1996 SC 2715. In a case where precautionary principle and its sanctity were pitted against development and sustainable development, Supreme Court held as follows:

3.The precautionary principle and the polluter pays principle have been accepted as part of the law of the land. Article 21 of the Constitution of India guarantees protection of life and personal liberty. Articles 47, 48A and 51A(g) of the Constitution are as under:

"47. Duty of the State to raise the level of nutrition and the standard of living and to improve public health. The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and in particular, The State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health.

48A. (g) Protection and improvement of environment and safeguarding of forests and wild life. The State shall endeavour to protect and improve the environment and to safeguard the forests and wild life of the country.

51A.(g) To protect and improve the natural environment including forests, takes, rivers and wild life, and to have compassion for living creatures."

Apart from the constitutional mandate to protect and improve the environment there are plenty of post independence legislations on the subject but more relevant enactments for our purpose are: The Water (Prevention and Control of Pollution Act 1974 (the Water Act), The Air (Prevention and Control of Pollution) Act, 1981 (the Air Act) and the Environment Protection Act 1986 (the Environment Act). The Water Act provides for the constitution of the Central Pollution Control Board by the Central Government and the constitution of one State Pollution Control boards by various State Governments in the country. The Boards function under the control of the Governments concerned. The Water Act prohibits the use or streams and wells for disposal of polluting matters. Also provides for restrictions on outlets and discharge of effluents without obtaining consent from the Board. Prosecution and penalties have been provided which include sentence of imprisonment. The Air Act provides that the Central Pollution Control Board and the State Pollution Control Boards constituted under the later Act shall also perform the powers and functions under the Air Act. The main function of the Boards, under the Air Act, is to improve the quality of the air and to prevent. control and abate air pollution in the country. We shall deal with the Environment Act in the later part of this judgement.

5(xxix) As alluded to supra, vultures have undoubtedly been classified as critically endangered species and there is no disagreement amongst the parties to this lis that this is indisputable. Mr.A.Yogeswaran, drew our attention to the judgment of the Hon ble Supreme Court of India in Centre for Environment Law, WWF-I Vs. Union of India (UOI) and Ors. Reported in (2013) 8 SCC 234. Lastly on endangered species, what the Supreme Court had to say is articulated in Paragraph 63 of the judgment and we deem its appropriate to extract the same, which reads as follows:

3.We are also inclined to highlight the necessity of an exclusive parliamentary legislation for the preservation and protection of endangered species so as to carry out the recovery programmes before many of the species become extinct and to give the following directions:

(a) NWAP (2002-2016) has already identified species like the Great Indian Bustard, Bengal Florican, Dugong, the Manipur Brow Antlered Deer, over and above Asiatic Lion and Wild Buffalo as endangered species and hence we are, therefore, inclined to give a direction to the Government of India and the MoEF to take urgent steps for the preservation of those endangered species as well as to initiate recovery programmes.

(b) The Government of India and the MoEF are directed to identify, as already highlighted by NWAP, all endangered species of flora and fauna, study their needs and survey their environs and habitats to establish the current level of security and the nature of threats. They should also conduct periodic reviews of flora and fauna species status, and correlate the same with the IUCN Red Data List every three years.

(c) Courts and environmentalists should pay more attention for implementing the recovery programmes and the same be carried out with imagination and commitment. 5(xxx) Further more , learned Additional Solicitor General of India pressed into service Vincent Panikurlangara Vs. Union of India and Others reported in (1987) 2 SCC 165 to drive home the proposition that Courts should be very slow to interfere when a Drug policy of the Government is laid down. In fact in this judgment, the Hon ble Supreme Court of India has gone as far as saying that it is not for the Courts to lay down the Drug Policy of the Government. Our attention was drawn to Paragraphs 17 and 23 of the of the said judgment and we deem it appropriate to extract the same, which read as follows:

17. None of the parties before us claimed, and perhaps tightly, that the prevailing state of affairs in this regard is a commendable one. The technical aspects which arise for consideration in a matter of this type cannot be affectively handled by a court. Similarly the question of policy which is involved in the matter is also one for the Union Government keeping the best of interests of citizens in view to decide. No final say in regard to such aspects come under the purview of the court. Yet there are certain contentions raised by the petitioner which deserve serious consideration and we would now proceed to deal with them.

23. Research in this field is of vital importance. Constant attention has to be devoted to get the best of results at the laboratories and put to use all useful findings. The traditional indigenous system of treatment in India had once upon a time made a lot of advancement. There is, therefore, sufficient scope for research on the basis of our own knowledge. Herbal preparations, as far as practicable, should be encouraged and appropriate laboratories should be set up, both in the public and the private sector to continue the system of research into every branch in this field relevant to gathering of knowledge and proper utilisation thereof in the field of treatment and manufacture of drugs. We reiterate that it is not for the Court to lay down the drug policy of the Government. We are aware of the fact that the State is concerned and anxious to improve the general condition and is willing to exercise adequate control; Parliament has in several legislations in recent years enhanced the penalities with a view to ensure elimination of injurious drugs and maintenance of the quality and

standard of drug preparations. There is, however, no scope for complacency in this field and constant and regular attention has to be bestowed in order that the flow into the market may be only of acceptable drugs. 5(xxxi) The impugned provision i.e., 4th proviso to Rule 105 of the Drugs Rules is undoubtedly and indisputably a piece of subordinate legislation. In other words, the impugned provision is a provision introduced in a subordinate legislation. Therefore, in a challenge to the impugned provision, all the well settled and well recognized principles on which a subordinate legislation can be assailed /challenged, come into play. This is contained in Paragraph 12 of the celebrated judgment of the Hon ble Supreme Court of India in what has come to be known as P.Krishnamurthy s case i.e., State of Tamil Nadu and another Vs. P.Krishnamurthy reported in (2006) 4 SCC 517 and we deem it appropriate to extract Paragraph 15, which reads as follows:

5. There is a presumption in favour of constitutionality or validity of a sub-ordinate Legislation and the burden is upon him who attacks it to show that it is invalid. It is also well recognized that a sub-ordinate legislation can be challenged under any of the following grounds :-

a) Lack of legislative competence to make the sub-ordinate legislation.

b) Violation of Fundamental Rights guaranteed under the Constitution of India.

c) Violation of any provision of the Constitution of India.

d) Failure to conform to the Statute under which it is made or exceeding the limits of authority conferred by the enabling Act.

e) Repugnancy to the laws of the land, that is, any enactment .

f) Manifest arbitrariness/unreasonableness (to an extent where court might well say that Legislature never intended to give authority to make such Rules)."

5(xxxii) A perusal of our narrative supra would reveal that the challenge of the petitioners to the impugned provision in the instant case does not fit into any of the six postulates laid down by the Hon'ble Supreme Court in P.Krishnamurthy's case with regard to challenge to subordinate legislation.

5(xxxiii)One crucial aspect of the matter to be noted is that the petitioners were given adequate opportunity by the Expert Committee. After the first opportunity to the petitioners on 13.10.2016, wherein as many as three representatives of one of the writ petitioner companies presented their view points, the Expert Committee gave one more opportunity to the writ petitioners and sought some specific replies from the writ petitioners, but the writ petitioners did not reply. The specific information sought for by the committee from the writ petitioners pertains to production data of Diclofenac injection, market share, financial loss owing to the restriction of pack size of Diclofenac injection, number of manufacturers of multi-dose vials etc., This aspect of the matter is well articulated in the report and we deem it appropriate to extract that portion of the report which runs as follows:

In the Committee meeting held on 13.10.2016, the following representatives of the petitioner M/s.Laborate Pharmaceuticals India Limited presented their case:

1. Mr.Surinder Kumar Bhatia, Head Finance and Accounts

2. Mr.Punit Bhatia, Regulatory Manager,

3. Mr.Hemant Mehta, Manager Corporate Affairs.

The petitioner also made written submissions to the committee in support of their case.

The Committee after hearing the petitioner asked them to submit specific replies on the following points:

a) Production data of diclofenac injection of all pack sizes manufactured by you year wise since 2008 till date. Please specify the production data of the diclofenac injection from 17.07.2015 (the date of Gazette notification) to till date separately.

b) Market share of your formulations of diclofenac injection vis-a-vis the overall market size.

c) Financial loss suffered by your company due to the restriction of pack size of diclofenac injection.

d) Number of manufactures of multi-dose vials of diclofenac. On this, the petitioner requested the committee time to submit this data. The petitioner was reminded by DCGI officials on telephone and by e-mail.

In the subsequent meeting held on 19.10.2016, the committee was informed by DCGI officials that the reply from the petitioner M/s.Laborate Pharmaceuticals Pvt. Ltd. has not been received. The committee deliberated on submissions made by the petitioner. In absence of specific information on the questions related to misuse of diclofenac injection in animals, the committee decided to obtain the views of the experts in veterinary sciences and environment. Therefore the attack of the report of the committee by the writ petitioners as a post decisional enquiry looses steam and writ petitioners not being forthcoming qua queries from committee takes the wind out of the sails of the writ petitioners' attack on the report. Writ petitioners' plea before us about the importance of multi dose packs for treatment of human beings deserves to be negatived as untenable.

5(xxxiv) As we are accepting the precautionary principle theory advanced as an argument by the learned Solicitor, lack of decline in vulture population post 2012 argument of writ petitioners also pales into insignificance.

6. CONCLUSION:

Owing to all that have been set out in our discussion/narrative supra we uphold the fourth proviso to Drug Rules negativing all the grounds of challenge to the same.

7.DECISION:

Both these writ petitions are dismissed. Considering the nature of the matter and the trajectory of the litigation, the parties are left to bear their respective costs.

(I.B.,C.J.) (M.S.,J.)

24.10.2017

Index: Yes/No
gpa
To
The Secretary
Ministry of Healthy and Family Welfare
FDA Bhavan, ITO Kotla Road
New Delhi 110 001

The Hon'ble Chief Justice
and
M.Sundar, J.

gpa

Order in
W.P.No.37742 of 2015 and
W.P.No.29322 of 2016

24.10.2017