

**IN THE HIGH COURT OF SINDH AT KARACHI**

BEFORE:

**Mr. Justice Mohammad Shafi Siddiqui**

Suits No. 2603 and 2543 of 2015, 53, 57, 122, 137, 138, 212, 235,  
329, 402, 641, 758, 777, 878, 1032, 1033, 1217 and 1677 of 2016

Novartis Pharma Pakistan Limited &  
other plaintiffs in respective suits

Versus

Federation of Pakistan & another in all suits

Date of Hearing: 24.08.2016, 26.08.2016, 29.08.2016, 30.08.2016,  
21.09.2016, 23.09.2016, 05.10.2016, 21.10.2016  
and 07.11.2016

Plaintiffs: Through Mr. Rasheed A. Razvi along with Mr. Abbas Razvi and Ms. Fareeda Mangrio Advocates, Mr. Anwar Mansoor Khan along with Ms. Umamah Mansoor Khan and Ms. Reem Niaz Advocates, Mr. Kazim Hassan along with Mr. Shahan Karimi Advocates, Mr. Raashid Anwar along with Mr. Mustafa Ali and Mr. Habib Niazi Advocates, M/s Faisal Siddiqui and Muhammad Vowda Advocates, Mr. Abdul Sattar Pirzada a/w M/s Mamoon N. Chaudhry and Umair Qazi Advocates, Mr. Omer Soomro a/w M/s. Haroon Dogal and Danish Nayyar advocates, Mr. Hyder Ali Khan a/w Mr. Sami-ur-Rehman Khan Advocate, Mr. Shaharyar Mehar Advocate.

Defendants: Through Mr. Salman Talibuddin, Addl. Attorney General along with Ms. Alizeh Bashir Advocate, Mr. Abdul Qadir Leghari, standing counsel & Departmental representatives Dr. M. Aslam CEO and Mr. Amanullah, Director Printing, in person.

**J U D G M E N T**

**Muhammad Shafi Siddiqui, J.-** This is a bunch of suits for declaration and injunction which involve fixation of Maximum Retail Price (MRP) in respect of the respective drugs of the plaintiffs and involve a question as to the applicability of notification No.F.9-12/2014-DDC(P) dated 05.03.2015 issued by Ministry of National Health Services,

Regulations & Conditions (Drug Regulatory Authority of Pakistan), termed as “Drug Pricing Policy 2015” (Policy 2015).

2. With the consent of all the learned counsel appearing for the parties, the precise question/issue as to the applicability of the Policy 2015 was framed on 06.04.2016 which is as under:-

*1. Whether the issue of hardship in relation to the enhancement or fixation of prices of drugs on account of hardship subjudice before DRAP, are to be dealt with in accordance with mechanisms provided in the Policy 2015 or otherwise?*

*2. What should the decree be?*

3. All the learned counsels appearing for the parties agreed that since the issues involved does not require recording of any oral evidence, the suits may be disposed of while hearing the applications on the basis of material available on record after hearing the counsels appearing for the parties. Accordingly, by consent the suits are being disposed of on the basis of material available on record after hearing the counsels.

4. M/s Rasheed A.Razvi, Anwar Mansoor Khan, Kazim Hassan, Raashid Anwar, Faisal Siddiqui, Abdul Sattar Prizada, Omer Soomro and Hyder Ali Khan have argued their respective suits. The substance and gist of their arguments is that the Drug Pricing Policy 2015 is not retrospective and would not apply to the applications filed before its enactment dated 05.03.2015. The policy is claimed to be carrying contradictory provisions and at point these are being arbitrary, unjust and capricious. The plaintiffs for present controversy have categorized the scope of the Policy into several heads. Firstly, the Maximum Retail Price (MRP), as prescribed by DRAP, over and above which price the drug cannot be sold in the market. The second limb relates to periodical increase in MRP of the drugs governed by Paragraph 8 of the Policy and third is category of

hardship cases and the increase in the existing MRP is subject to its non-viability to market.

5. Learned counsels for plaintiffs on the strength of the language of Paragraph 10 of the Policy itself, argued that the very language and terms of Paragraph 10 suggest that its application is only prospective and not retrospective. They argued that only those notifications which are beneficial in nature can apply retrospectively whereas Mr. Faisal Siddiqui learned counsel additionally argued that even if it is deemed to be beneficial in nature, the language of the policy expressly made it prospective and hence this principle is also not made applicable as far as its beneficial nature is concerned.

6. The counsels further argued that all such hardship cases which were pending before promulgation of Policy 2015 are to be dealt with in terms of Section 12 of Drugs Act, 1976 and shall be dealt with in a manner which was available prior to the enactment of Policy 2015. Learned counsels further argued that Section 9 of Drugs Act, 1976 is not a bar or restriction to the grant of relief by this Court. Mr. Faisal Siddiqui, in particular, has argued that the Drug Pricing Committee was formed by SRO No.707(I)/2013 dated 05.08.2013 and the Committee was obliged to fix and review Maximum Retail Price at which the respective drugs are to be sold subject to approval of the Federal Government. He submitted that the decision of the Drug Pricing Committee is subject to the decision taken by the Federal Government and hence it is deemed to be a decision of the Federal Government itself. It is argued that Section 9 of the Drugs Act, 1976 though is appellate provision but its structure and configuration does not render it an efficacious appellate forum and not conducive for a review jurisdiction as there is a distinction in review and appeal. The review lies before the same competent authority whereas the appellate forum means an independent forum different

from the one which passed the initial order or decision and since the Appellate Board in terms of Section 9 consists of representative of the Federal Government such as Secretary Health Division, Government of Pakistan, therefore, the Appellate forum would not be appropriate forum to challenge a decision of the Drug Pricing Committee.

7. Mr. Omer Soomro, in addition to the common contentions, argued that Clause 10 in its present form is full of inconsistencies and therefore cannot be applied with uniformity for determination of the prices of the hardship drugs. In particular he referred to Paragraph 10(2) and 10(6) of the Policy 2015 as an example of prime inconsistency. He submitted that defendants have not devised a transparent mechanism before the Committee could function accordingly. He relied upon a judgment of Aman Ullah Khan v. Federation of Pakistan reported in PLD 1990 SC 1092 and submitted that wherever wide worded powers conferring discretion exist, there remains always the need to structure the discretion. He relied upon seven instruments as highlighted in the referred judgment in structuring of discretionary powers such as open plans, open policy statements, open rules, open findings, open reasons, open precedents and fair informal procedure.

8. Mr. Soomro further submitted that orphan drugs are yet to be identified and the Addl. Attorney General has already proposed that price increase of orphan drugs shall be decided in accordance with orphan and critically needed drugs policy and the decision of ECC and the Cabinet and Federal Government in that regard. Such policy is yet to be framed, therefore, it is justified and stands to reason that DRAP is excluding orphan drugs from the clutches of Paragraph 10 of the Policy.

9. Mr. Raashid Anwar in addition to the arguments submitted that these hardship applications be remanded back to the DRAP with clarification that 2015 Policy, being a mere notification, cannot be

applied retrospectively in relation to the cases pending prior to its enactment. In the alternate, he argued that in case the Policy is made applicable it may be clarified that the policy does not laydown an absolute cap but can award whatever increase is sufficient to allow a reasonable return to the manufacturer. He further argued that even if this could not be the possible interpretation of the subject policy then it may be clarified that the Policy does not put cap of 8% to state that the maximum increase is 8% per annum since last price increase which in most cases was in 2001.

10. Mr. Abdul Sattar Pirzada has categorized two kinds of hardship cases; one to be dealt with in terms of sub-para (4) and (5) and the other in terms of sub-para (6) of Paragraph 10. In terms of sub-para (4) and (5) of Para 10 of the Policy the pending cases before promulgation of Policy 2015 were discussed whereas in terms of sub-para (6) fresh/new cases are to be decided within 90 days of the submission of hardship case. Mr. Pirzada submitted that the Committee in utter defiance of the mandate has not only dismissed and deferred the hardship cases but has wrongly interpreted sub-para (4) and (5) by providing the relief of 8% only on the existing MRP of respective drugs. He ultimately prayed that the decision of the Committee in terms of its meeting held on 4<sup>th</sup> and 5<sup>th</sup> of May, 2016 in its 16<sup>th</sup> Meeting be declared as illegal and the case be remanded for decision in accordance with law by defendant No.2.

11. Mr. Rasheed A. Razvi and Mr. Kazim Hassan also following the same principal with regard to prospective effect of the subject notification emphasized that the notification or executive orders cannot take away the rights already conferred and that the power of subordinate legislation, which is exercised by the Federal Government is very limited. For the above proposition Mr. Kazim Hassan has relied upon

the cases reported in PLD 1970 SC 439, PLD 1963 SC 633, PLD 1989 Karachi 621, 1992 SCMR 1652 and PLD 2001 SC 340.

12. Mr. Kazim Hassan in respect of the comments made in the written statement to the order of the Hon'ble Supreme Court dated 19.05.2015 submitted that the defendants have concealed that on 17.02.2016 Hon'ble Supreme Court in the case of Federation of Pakistan versus Zam Zam Corporation was graciously pleased to dismissed Civil Appeal No.488 of 2015 which emanated from CPLA No.501 of 2015 and since the written statement was filed on 22.02.2016 the Federation of Pakistan and DRAP were fully aware of the above fact.

13. Mr. Anwar Mansor Khan, in addition to the above arguments, has critically attacked the vires of the subject Policy and submitted that it is to be scrapped in terms of Competition Act, 2010 as the market forces in terms of competition amongst the pharmaceutical companies would determine the prices.

14. On the other hand, learned Addl. Attorney General, representing the defendants, submitted that the Policy 2015 was framed with the active contribution of all pharmaceutical companies and their association and at this stage they cannot criticize the policy framed with their assistance. It is contended that these plaintiffs in the present proceedings have neither challenged the policy nor they could in view of their pleadings. In fact and in substance the grievance of the plaintiffs is that relevant provisions of the Policy 2015 have been incorrectly applied by the Drug Pricing Committee (DPC). It is further agued by the learned Addl. Attorney General that the DRAP retains exclusive power to classify different drugs for the purpose of determining which of the respective mechanism for price fixation under Policy 2015 would be applicable in relation to pending applications and/or fresh ones.

15. Learned Addl. Attorney General has also replied to the contention of Mr. Anwar Mansoor Khan who has challenged the legality of Policy 2015 and submitted that same issues are currently pending in CP No.D-1286, 1279 and 1290 of 2015 and thus are not the issues to be decided in the present suits. He therefore prayed that the suits may be dismissed with costs.

16. I have heard the learned counsels for the parties and, with their assistance, have perused the material available on record.

17. On 07.11.2016 learned Addl. Attorney General while concluding his arguments has filed a letter of Ministry of National Health Services dated 04.11.2016 in which it has taken certain decisions which are relevant for the purposes of these cases. It was decided that the pharmaceutical companies, who are aggrieved with the decision of Drug Price Committee (DPC) and whose time of 60 days for filing appeal before the Appellate Board constituted under section 9 of the Drugs Act, 1976 has expired, the period of 60 days may be granted from the date of last hearing of this Court.

18. At the time of conclusion of arguments, the learned Addl. Attorney General has further conceded:

- i) the time for filing such appeals, as above, may commence from the date of final decision of these suits, if required;
- ii) for applicants whose applications for hardship cases were rejected by DPC on the ground of incomplete or shortfall in their documents, may be given an opportunity for submission of their shortfall documents within 60 days from the last date of hearing for reconsideration by the DPC. This time was also extended and to be reckoned from the date of final decision in these suits, if required;

- iii) that the application for price increase for orphan and critical needed drugs and IV infusions will be decided according to the orphan and critically needed drug policy and the decision of Economic Coordination Committee (ECC) of the Cabinet and the Federal Government.

19. In pursuance of this letter a short order was passed on 07.11.2016. Thus, as far as this order/judgment is concerned it shall not be in relation to orphan and critically needed drugs and IV infusion and the interim order for these drugs would continue till the policy in this regard is finalized.

20. The prime question which is to be addressed first is the retrospectivity of Policy 2015. The common judgment which has been cited is in the case of Hashwani Hotels v. Federation of Pakistan reported in PLD 1997 SC 315. In this case State Bank of Pakistan issued a notification in 1981 directing the banks to reduce the rate of interest on loan for the construction of Four Star Hotels. The appellant in the case had obtained loan prior to issuance of notification by the State Bank of Pakistan and relying on the notification sought direction to reduce rate of interest on the loans obtained. The Hon'ble Supreme Court rejected this contention and held that the notification could only apply prospectively.

21. The other judgment which relates to the retrospective and prospective applicability of the subject notification is the case of Army Welfare Sugar Mills Limited v. Federation of Pakistan reported in 1992 SCMR 1652. In paragraph 25 of this judgment the Hon'ble Supreme Court has observed as under:-

*“The High Court has wrongly placed reliance on the general proposition that a notification cannot operate retrospectively without realizing that there is a marked distinction between a notification which purports to impair existing/vested rights or imposes new liabilities or*



*obligations retrospectively and a notification which purports to confer benefit retrospectively.”*

22. Similarly in the case of State Bank of Pakistan v. Faisal Spinning Mills Limited reported in 1997 SCMR 1244 the Hon'ble Supreme Court held that there cannot be any cavil with the proposition that a notification operates prospectively however there is a marked distinction between a notification which purports to impair existing or vested rights or creates new liabilities or obligations retrospectively and a notification which purports to confer benefit retrospectively. The former is not legally permissible, whereas there is no legal bar as to the latter.

23. With the background of these three judgments when both the Acts i.e. Drugs Act, 1976 and DRAP Act, 2012 are critically scrutinized it reveals that there is nothing in the two Acts which could said to have been impaired or taken away by the subject notification i.e. Drug Pricing Policy. In fact a mechanism has been carved out for the benefit of the pharmaceutical companies. It is one point of argument that there was no prescribed limit of 8% per annum earlier which benefit is being taken away but the punch line is that there was no mechanism at all; it was only at the desire, mercy of the Federal Government who may by notification in the official gazette fixes the maximum price which mechanism itself has been seriously criticized by the pharmaceutical companies/plaintiffs and which led to the enactment of the present policy. The pharma companies may be aggrieved of the fact that the present policy is not up to the mark or upto their desire as far as fixation and/or enhancement of prices in terms of appropriate percentage but it is beneficial otherwise. If the pharmaceutical companies do not wish to enjoy the benefits of this beneficial notification it is their choice, they are not forced to but this is the mechanism available in case they wish to have their prices reconsidered by DPC.

24. The other way of looking at this notification/policy is that Policy 2015, on the basis of which hardship cases were decided, was notified on 05.03.2015. The policy was framed in terms of subsection (c)(vii) of Section 7 of the Drugs Regulatory Authority of Pakistan Act, 2012 (Act 2012). This Act was introduced on 13.11.2012 to establish a Drug Regulatory Authority of Pakistan to provide and cater effective coordination and enforcement of the Drugs Act, 1976. In terms of Section 7(c)(vii) of Act 2012 the authority was delegated with the powers for regulation of prices and mechanism for fixation of prices of various therapeutic drugs under its ambit. In terms of subsection (f) of Section 7 of Act 2012 the authority is further delegated with the power to coordinate at policy level and provide policy guidelines to the provincial government in performance of their functions with a purpose to bring uniformity. The regulation of prices is thus one of the functions under Acts of 1976 and 2012, therefore, notification issued would not be considered to be an alien in the system. The Act 2012 itself was enacted on 13.11.2012, which Act itself was toeing the object of the Act 1976. Though the structure under the Acts was available but there was no effective mechanism, as alleged by the plaintiffs, in relation to the enhancement or fixation of drug prices “regularly” and hence policy in pursuance of the law referred above was framed. It is but beneficial in spirit. These notifications and SROs could be enforced provided it is beneficial in nature as far as the affectees are concerned.

25. Let us scrutinize the Policy 2015 itself and in particular paragraph 10 thereof. Sub-Para (1) of Para 10 provides that a transparent mechanism shall be devised by the Policy Board to review MRPs of the drugs which have become unviable to market. This sub-para could only relates to those drugs which since years on account of non-increase or review of rate of MRPs have become unviable, therefore, the arguments

that this policy could only relates to future and prospective applicability, has no force. Sub-para (2) enables the manufacturers and importers to apply to the Authority once in three years for a review of MRP of any of its drugs. Sub-para (4) of Para 10 of the Policy deals with hardship cases of scheduled molecules submitted on a specified form and complete in all respects to be processed on priority on first come first serve basis but not later than nine months from the date of notification of this policy when their applications were to be decided. The word “*specified form*” may detract the thoughts and intent behind this sub-para but it actually deals with those hardship cases which were pending prior to the issuance of notification dated 15.03.2015 and/or promulgation of Policy 2015. The word “submitted” on specified form means that these hardship matters have already been submitted for their scrutiny and review of MRP. As against this, the language of sub-para 6 is different which provides the determination of hardship cases on “submission” of such hardship cases on the specified form. Thus the language of sub-para (4) and (5) is different and distinct from the language of sub-para (6). Sub-para 5 of Para 10 of the Policy provides a maximum increase cap in relation to hardship cases except for orphan drugs, lower price drugs, IV infusion which have already been segregated for a possible applicability of this decision. The maximum cap provided in pursuance of the above sub-para is 8% per annum of existing approved MRP of the respective drug whereas lower price drugs the increase was limited to 25 paisa’s per tablet, capsule, respule, caplet, patch, sachet, 5 ML of syrup, suspension and elixir.

26. A question would arise as to what is the existing approved MRP on which policy of 8% per annum could be applied. The last notification that reviewed the prices or which fixed the MRP is of 27.11.2013 in terms whereof 15% over and above the earlier fixation i.e. vide notification

SRO No.100(I)/2002 dated 14.02.2002 was fixed. This notification/enhancement is not challenged. Though it (notification) is claimed to have been withdrawn on 29.11.2013 but such notification was suspended in an independent proceeding challenging such withdrawal and the pharmaceutical companies continued to enjoy its benefit without any challenge to it on merit. This notification was issued under section 12 of Drugs Act, 1976 read with clause (a) of Section 7 of Act 2012. Thus, it was/is last increase of MRPs under the law. In view of suspension of the withdrawal notice, the last MRP fixed under the law is by virtue of notification dated of 27.11.2013 where across the board 15% on the earlier/ existing prices were reviewed. Therefore, last existing approved MRP is by way of a notification of 27.11.2013 on which maximum increase of 8% per annum could be considered in terms of subject policy. Hence all those cases which were pending when the present Policy was introduced shall be dealt with in terms of sub-clause (4) and (5) of Para 10 of the Policy.

27. Sub-para 6 is in relation to fresh and new hardship cases which cases are to be filed on specified form and in the manner as specified by the Policy Board and only in case no response is sent to the applicant of hardship cases under consideration of this Para within 90 days, the applicant may be allowed to increase its MRP up to maximum of 8% on the existing approved MRP. This option is available to the companies once after every three years.

28. The Policy/notification dated 05.03.2015 is not alien to the system of either Act of 1976 or of 2012. Since 1976 MRPs of different drugs were being set through notifications/SROs but none of the companies objected since they were beneficial and issued in pursuance of the Drugs Act 1976. Likewise the present notification, which is claimed to be a policy, is also carrying the object of the two Acts,

referred above, and hence beneficial in nature as it caters the grievances of the companies in fixation of MRPs of different drugs.

29. The next contention which relates to the Policy Board is also necessary to be resolved since the aggrieved persons in relation to the decision of the Drug Pricing Committee are required to be provided with a forum for redress of grievance, if any. Section 9 of the Drugs Act 1976 provides an Appellate Board for the disposal of appeals preferred by persons aggrieved of any decision of the Central License Board or the Registration Board or the Licensing Authority of the Board/ Authority to which the powers by the Federal Government under section 12 have been delegated under subsection 3 of that section and for review of any such decision on its own motion. Subsequent subsections of Section 9 provide formation of Appellate Board and its functioning. The contention that this forum could not be considered to be appropriate as far as the appeal is concerned has no force.

30. Firstly the Drugs Policy Board Rules 1976 in terms of Sub rule 1(a) provides that in the event of a conflict of interest a member of the Appellate Board or his representative was obliged not to participate in the proceedings or express any opinion in cases in which conflict of interest arises in respect of the matters, dealt with by such Member or Representative. Secondly, the vires of the Policy and/or Act 1976 and 2012 are not under challenge in these proceedings except the one filed by Mr. Anwar Mansoor Khan which challenges the policy. Thirdly, the Federal Government had already conceded and surrendered to the jurisdiction of appellate forum with above clarification hence there is no confusion left. Consequently, in view of the above all those persons aggrieved of the decision of DPC may approach the Appellate Board within the time as observed in Para 17 and 18 above.

31. The drugs are being considered as essential commodities. These are always subject to regulations and unbridled ways of dealing with the prices and allowing market forces to set the prices cannot be granted. This could not be taken as violative of Article 18 or 25 of the Constitution of Pakistan. These are reasonable restrictions and are being protected under the Constitution as often it happens the cartels are formed to manipulate the situation of these “essential commodities” and hence are always subjected to reasonable restrictions. However, in Suit No.1217 of 2016 in which Mr. Anwar Mansoor Khan learned advocate is appearing wherein Policy itself has been challenged I would dispose of the injunction application in the following terms and keep the lis pending as an issue in relation to the vires of subject policy had not been framed. Any finding here would not influence the trial of this suit.

32. In view of the above, the issue No.1 is answered in affirmative and the suits are dispose in the following terms:-

- i) That this Policy of 05.03.2015 shall apply to all pending hardship cases pending before issuance of notification dated 05.03.2015 in terms of Sub-para (4) and (5) of Para 10 of the Policy;
- ii) All fresh hardship cases filed subsequent to the issuance of Notification dated 05.03.2015 shall be dealt with in terms of Sub-Para (6) of Para 10 of the Policy.
- iii) For the pending hardship cases the maximum increase that could be considered is 8% per annum on the existing approved MRP which for the present controversy be considered as MRP in terms of last notification dated 27.11.2013;
- iv) All those hardship cases which were either dismissed or deferred on account of either non-availability of documents

or shortfall of documents shall be heard and decided after notices to the respective companies/plaintiffs with a specific instruction in relation to a particular document required by the DPC.

- v) All those companies who are aggrieved of a decision (other than those whose applications were dismissed and deferred as above) shall pursue their remedy in terms of Section 9 of Drugs Act, 1976 and the effective date for computation of 60 days limitation shall start from the date of this judgment;
- vi) Once decision in terms of clause (iv) above is made, aggrieved persons may also prefer appeals in terms of Section 9 of Drugs Act, 1976.
- vii) Till such time the decision is made in terms of Para (iv), no adverse action shall be taken against the plaintiffs.
- viii) As far as the orphan drugs and IV Infusions are concerned no coercive action be taken until decision by the Economic Coordinate Committee of the Cabinet and Federal Government takes place whereafter the parties including the plaintiffs herein and DPC may act accordingly.

33. Suits stand disposed of along with pending applications except Suit No.1217 of 2016 in the above terms.

Dated: 19.12.2016

**Judge**