IN THE HIGH COURT OF SINDH
AT KARACHI

Present : Ahmed Ali M. Shaikh, CJ
and Yousuf Ali Sayeed, J

C.P No. D-3537 of 2015

M/s. Well Come Pakistan (Private) Limited.....Petitioner

Versus

Drug Regulatory Authority Pakistan and others...Respondents

C.P No. D-1039 of 2016

M/s. Heal The World (Private) Limited.....Petitioner

Versus

Drug Regulatory Authority Pakistan and others.....Respondents

Patras Pyara, Advocate, for the Petitioner in C.P No. D 3537 of 2015.

Mahmood Anwar Hussain Balouch, Advocate, for the Petitioner in C.P No. D-1039 of 2016.

Khaleeque Ahmed, DAG, for the Federation of Pakistan, in both Petitions.

Chaudhry Muhammad Rafique Rajorvi, Additional Advocate General, Sindh.

Date of hearing : 08.11.2021.

JUDGMENT

YOUSUF ALI SAYEED, J - The respective Petitioners profess to be purveyors of food supplements, dietary products, health food, natural products and nutritional supplements, who apparently import, manufacture and market various products falling under such description during the course of their business.

2. Whilst it has been pleaded in both the Petitions that the Petitioners have submitted one or more applications to the Respondents for registration of such products, they have nonetheless contended that natural products and food supplements do not fall within the legal definition of "Drug", as defined in terms of Section 3 (g) of the Drugs Act, 1976 (the "**Drugs Act**"), hence are to be regulated under the framework of the Pure Food Ordinance, 1960 rather than by the Drug Regulatory Authority of Pakistan (the "**DRAP**") under the Drugs Act or Rules made thereunder in terms of Drug Regulatory Authority of Pakistan Act, 2012 (the "**DRAP Act**").

3. In this backdrop, the Petitioners have invoked the Constitutional Jurisdiction of this Court under Article 199 of the Constitution of Islamic Republic of Pakistan, 1973, eliciting final relief in the identical terms, with it being prayed in both the Petitions that this Court be pleased to:-

> "i. Declare that the Petitioner is entitled to sell the products as mentioned in Para 4 of the Memo of Petition.
>
> ii. Declare that the Natural Product and Food Supplements do not fall within the definition of "Drug", as prescribed under the Drugs Act 1976 and / or Rules made there under.
>
> iii. Declare that the Food Supplements fall within the definition of "Food" as defined in section 2(9) of the Pure Food Ordinance 1960 and Rules made thereunder.
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> iv. Declare that regulating (directly and / or indirectly) of the importation, manufacture, marketing and / or sale of Food Supplements falls within the sole jurisdiction of the respondent number 5.
>
> v. Direct the Respondent No. 2 to 5 not to create any hindrance in the smooth business of the petitioner.

vi. Permanently restrain the respondents, directly and / or indirectly through any person acting on their behalf, from taking any coercive actions against the petitioner.

vii. Declare that the petitioner is a lawful importer of its product and entitled for it sale.

viii. Issue declaration, directions, injunction and/or relief as deemed appropriate and award the petitioner the cost of this Petition."

4. Upon commencement of the hearing, the learned DAG at the very outset brought to the fore that the controversy raised had already been resolved through the judgment rendered by a learned Division Bench of this Court in the case reported as Messrs Azfar Laboratories Private Limited through Directors and others v. Federation of Pakistan through Secretary Ministry of National Health Services and 4 others PLD 2018 Sindh 448.

5. Indeed, upon examination the aforesaid judgment, it merits consideration that the relevant excerpts thereof, including the operative paragraphs, read as follows:-

> "44. When the foregoing analysis is applied to the facts of each petition that involves food, health or dietary supplements and animal feed, and the submissions that were made by learned counsel for the petitioners on the one hand and the learned Law Officers on the other our tentative assessment is that *prima facie* the various products could well come within the Rules and the Act, especially on a combined reading of the definitions taken above from the 2014 Rules. They could therefore be drugs within the meaning of the DRAP Act. However, we recognize that for there to be a conclusive determination it is more appropriate to carry out a factual inquiry. It seems to us that perhaps such a determination cannot be made simply by looking at the material on the record (consisting largely of brochures, advertising claims, downloads from the Internet, etc.). It does seem to require a determination by the officers of the Authority constituted under the DRAP Act after giving an opportunity of hearing to the party concerned. We therefore intend to dispose off the petitions where the subject matter is food or dietary supplements or animal feed etc. in the manner set out below.

45. In one petition, the products involved appear to be cosmetics, and the petitioner there contends that they do not come within the meaning of "medicated cosmetics". It will be recalled that the latter constitute the fourth part of Schedule I to the DRAP Act and hence are drugs' as defined. For substantially the same reasons as given above in relation to food supplements, animal feed etc., we are of the view that a proper factual inquiry is required before it can be concluded whether or not the cosmetics in question are "medicated cosmetics".

46. Before concluding, it is necessary also to consider certain provincial legislation that was referred to by learned counsel. We were referred to two Punjab statutes in addition to the Sindh legislation. Now as already noted it is the hallmark of provincial legislation that it is territorially bound. Therefore, the effect of the Punjab statutes is limited to that Province. Whether, and if so to what extent, this law impacts on or interacts with the DRAP Act, is a matter to be decided in that Province and not here, i.e., by the Lahore High Court and not this Court. We do not therefore say anything with reference to the Punjab statutes.

47. Turning to the Sindh legislation, reliance was placed on the Pure Food Ordinance, 1960 ("1960 Ordinance"). Clause (9) of section 2 defines "food" in the following terms (as presently relevant):

> " "food" means any article used as food or drink for human consumption other than drugs, and includes-
>
> Explanation- An article shill (*sic*) not cease to be food by reason only that it is also capable of being used as a medicine."

Learned counsel appearing in those petitions where the subject matter was food, dietary and health supplements relied on the foregoing to contend that the substances were "food" and hence regulated by the 1960 Ordinance and not the DRAP Act. With respect, we are unable to agree. The definition on the face of it excludes "drugs" from the purview thereof. The latter term is not defined in the 1960 Ordinance, and must therefore, on the statutory plane, take its meaning from the controlling statute, which is now the DRAP Act. As we have seen above, food supplements, etc. as defined in the 2014 Rules come within the meaning of "drug" as used in the DRAP Act. Therefore, if the petitioners' products come within the definitions contained in the 2014 Rules (a determination yet to be made) then they would fall outside the ambit of the 1960 Ordinance. This statute does not therefore, with respect, provide assistance to the petitioners.

48. The Sindh Allopathic System (Prevention of Unauthorized Use) Act, 2014 was also referred to and relied upon. This statute, which has its antecedents in an Ordinance of 1962 essentially seeks to ensure that a person who is not a "doctor" or "dentist" registered under the Pakistan Medical and Dental Council Ordinance 1962 should not be able to hold himself out as such or to perform procedures and operations without being so registered. It clearly has no relevance for the issues at hand.

49. This brings us to the Sindh Food Authority Act, 2016 ("2016 Act"). This defines "food" in s. 2(g) as follows (as presently relevant):

> " "food" means any article used as food or drink for human consumption other than drugs, and includes- ...
>
> Explanation I.—An article shall not cease to be food by reason only that it is also capable of being used as drugs.
>
> Explanation II—In this clause, the word "drug" has the same meaning as is assigned to in the Drugs Act 1976 (XXXI of 1976)"

This definition is similar to that found in the 1960 Ordinance. However, there is one crucial difference for present purposes. The second explanation expressly defines "drug" as having the same meaning as in the 1976 Act. Reference must also be made to section 59, which contains an overriding provision in the following terms: "The provisions of this Act shall have effect notwithstanding anything contained in any other law for the time being in force". Prima facie, the 2016 Act may well have important consequences for the DRAP Act as applicable in this Province. It therefore requires consideration, but at present that can be deferred. This is so because the statute, which is intended to repeal and replace the 1960 Ordinance, has apparently not yet come into effect. Section 1(3) provides that it shall come into force on such date as may be notified by the Provincial Government. It appears that no such date has yet been notified.

50. Reverting now to paras 44 and 45, in our view certain directions and orders are merited in relation to food, dietary and health supplements, etc, animal feed and medicated cosmetics. It is therefore directed as follows:

a. Within 30 days of announcement of judgment the Authority under the DRAP Act shall issue proper guidelines, consistently with this judgment, as to what is meant by "pharmaceutical dosage forms". The guidelines shall deal separately with humans and animals and in each category provide for such sub-. categories as are deemed appropriate. The dosage forms and routes of administration and any

other matters considered relevant or applicable by the Authority shall be properly set out in the guidelines. The Authority shall not, for purposes of complying with this para be entitled to rely on any order or determination earlier made or prior guidelines or directions, if any, issued by it or its officers. In other words, guidelines must be issued specifically with reference to this para. The guidelines shall be immediately and prominently posted on the opening webpage of the website of the Authority and shall be deemed issued for purposes of this para only when so posted.

b. Simultaneously with posting the guidelines on its website, the Authority shall issue notice to each petitioner in the petitions to which this para applies. Such petitioner shall in respect of each product or substance be given a hearing as to whether the said product/substance comes within the scope of the 2014 Rules or the DRAP Act, especially with reference to the definitions considered in the paras herein above. The person shall be entitled to rely on such material, record or evidence as is considered relevant. The Authority shall then, by way of a reasoned order, issue a determination as to whether the 2014 Rules or the DRAP Act are applicable or not. Preferably, such determination shall be issued within 10 days of the conclusion of the hearing. Any person aggrieved, by any such determination, in whole or in part, shall be entitled to seek such relief, before such forum and in such proceedings as are appropriate.

c. Interim orders made in any petition to which this para applies shall continue but will lapse 30 days from the date on which the guidelines are posted as above or the date on which the determination is made, whichever is later. However, if a petitioner fails or refuses to appear before the Authority or attempts to delay or frustrate the proceedings or the conclusion thereof, the Authority may, at any time after the expiry of the aforesaid period of 30 days, so declare by an order in writing setting out its reasons for doing so, in which case the interim orders shall lapse immediately on the making of such an order."

6. Under such circumstances, it is manifest that a determination of the true nature of the products imported/marketed by the Petitioners properly entails a factual inquiry to be undertaken by the functionaries of the DRAP, who may then make an appropriate determination in that regard, and that the declarations and directions sought by the Petitioners cannot be granted by this Court. We are also informed by the learned DAG that in compliance of the aforementioned judgment of this Court, the DRAP has formulated the guidelines envisaged in terms of Paragraph 50 thereof.

7. As such, the Petitions fail and stand dismissed accordingly, leaving the Petitioners at liberty to pursue the matter before the DRAP.

JUDGE

CHIEF JUSTICE