TRANSPARENCY INTERNATIONAL - PAKISTAN

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TL2024/0903/1A

Principal Secretary to PM
Prime Minister House
Islamabad

(For attention of the Honorable Prime Minister)
Subject: Complaint Against Allegations of Contempt of Court of the High Court of Balochistan in Constitutional Petition No. 1766 of 2022 dated 17 June 204, by DRAP and MoH in Failure to Register Alternate Medicines etc since 2014, Causing Serious Risk to the Lives of Ordinary Citizens

Dear Sir,

Transparency International Pakistan has received a complaint against the allegations of Contempt of Court of High Court of Balochistan in Constitutional Petition No. 1766 of 2022 dated 17 June 2024, and DRAP Act 2012 by DRAP and MoH – in failure to Register Alternate Medicines etc since 2014 - safety and testing methods in the availability of around 60,000-70,000 Alternative Medicine/Nutraceuticals Products in the market, causing serious risk to the lives of the ordinary citizens and the failure of the Directorate of Health & OTC in controlling the situation.

The complainant has made the following allegations.

That;

1. After the promulgation of DRAP Act, 2012 and notification of Alternative Medicine and Health Products Enlistment rules (2014) SRO 412, notified in May 2014, the status of local and importers enlistment holders till date is as under;
    - Number of enlisted local manufacturer = **500**
    - Number of enlisted importers = **1200**
    - Number of enlisted products (Approximate) = **60,000-70,000**
    - Moreover around **30,000** enlistment application are in the pipeline of Health & OTC department.
2. Since 2014, the enlistment process has been going on and no effort has been made to start the licensing and registration process as mandated under DRAP Act 2012, due to the vested interest of few manufacturing companies.
3. 60,000-70,000 alternative medicine, nutraceuticals, food supplements, unani and homeo. etc. products are openly available in the market without any efficacy, safety and testing procedures.
4. **The High Court of Balochistan vide its judgement dated 27th June 2024 has ordered DRAP and MoH for compliance by 22nd July 2024** in a petition to "introduce proper Registration and Price fixation of products and Licensing process to Manufacturing Units/Importers for availability of low cost medicines in the market and ultimate" **(Annex-A)**
5. Good Manufacturing Practices (GMP) inspection needs to be initiated across the board to evaluate the actual status of Alternative medicine industry because since the grant of enlistment, no GMP inspection has been carried out to see the ground realities.
6. The Quality Control laboratories of the local manufacturers of Alternative Medicines are in pathetic condition especially those who are manufacturing vitamins & minerals as these products are directly nephrotoxic.
7. 80-90% of the manufacturers of alternative medicines are manufacturing the products without any analytical measures, technical staff, and laboratories, which is a serious threat to public health. Moreover, due to unregulated prices, the manufacturers make huge sums of money.

8. The manufacturers of alternative medicines / Nutraceuticals have possession of all types of manufacturing facilities that are involved in producing counterfeit drugs. That's why whenever there is a crackdown against counterfeit/spurious drugs, most of the time manufacturers of Alterative Medicines are always involved. The major source of counterfeit/substandard drugs are the Alternative Medicine / Nutraceuticals manufacturers.

Transparency International Pakistan Comments

Transparency International Pakistan has reviewed the allegations of the complaint. Prima facie, the allegations seem correct. Following are TI Pakistan's comments:

1. The High Court of Balochistan vide its judgement dated 27th June 2024, has required the federation and provinces to submit compliance report by 22nd July 2024 and non-compliance by DRAP of the High Court of Balochistan order amounts to contempt of court.
2. DRAP notification of Alternative Medicine and Health Products Enlistment rules (2014) clearly defines enlistment as provisional entry of the firm, in the enlistment register, as quoted below;

   "Enlistment" means provisional allocation or entry of proper number to the firm or the product in the enlistment register for the purpose of temporary manufacturing and marketing authorization till the procedure for manufacturing (authorization) license and product registration (marketing & authorization) is finalized and enacted.

3. DRAP Act 2012 defines mechanism of the registration of therapeutic goods through the registration board, as quoted below **(Annex-B)**;

   Section 2 (xxxii)"Registration Board" means a Registration Board constituted under Section 7 sub-section (u) of this Act to regulate the grant of registration to therapeutic goods"

4. CEO Drug Regulatory Authority of Pakistan (DRAP) may be directed to take serious action, if complaint allegations are proved correct, against the violation of safety and testing standards, posing threat to the lives of the citizens.
5. Quality Assurance department may be given the responsibility to conduct GMP inspections of alternative medicines/ nutraceutical manufacturers across the country.
6. The GMP inspections should be completed within 3-6 months and all those who were involved in violating the GMP rules should be dealt under the rules.
7. During this time, all types of new applications of enlistment (products, import or local) should be stopped till the enactment of licensing and registration rules as ordered by Balochistan High Court and given in the DRAP Act, 2012.

Transparency International Pakistan Recommendations

Transparency International Pakistan requests the Honourable Prime Minister to examine the allegations of the complaint, and if found correct, issue directives to DRAP to enact licensing and registration rules as per DRAP Act 2012 and start registration process within 30 days as per the orders of the High Court of Balochistan to avoid contempt of court.

Transparency International Pakistan is striving for across-the-board application of the Rule of Law, which is the only way to stop illegal practices and achieve Zero tolerance against corruption.

Regards

Advocate Daniyal Mursalfar,
Trustee/Legal Advisor
Transparency International Pakistan

Copies forwarded for the information with a request to take action under their mandate to:

1. Secretary, Ministry of Health, Islamabad
2. CEO, DRAP, Islamabad
3. Registrar, Supreme Court of Pakistan, Islamabad
4. Registrar, Balochistan High Court, Quetta

Note:
This is to clarify that Transparency International Pakistan is not a complainant, it acts as a whistleblower and operate under Article 19-A, of the Constitution of Pakistan which gives the right to public to know how government is being run by public officers. Article 19-A makes the right to access of information pertaining to a public authority a fundamental right, and a three-member bench in the case of Mukhtar Ahmad Ali vs the Registrar, Supreme Court of Pakistan, Islamabad, headed by Chief Justice Qazi Faez Isa in the landmark judgment on 16 October 2023, in CP No. 3532/2023, has declared that

"What previously may have been on a need-to-know basis Article 19A of the Constitution has transformed it to a right-to-know, and the Access to information is no longer a discretion granted through occasional benevolence, but is now a fundamental right available with every Pakistani which right may be invoked under Article 19A of the Constitution"

JUDGMENT SHEET

IN THE HIGH COURT OF BALOCHISTAN QUETTA.

Constitutional Petition No. 1766 of 2022.
(ID # 100107504583)

Mian Talayh Waheed

vs.

Federation of Pakistan through the Secretary Ministry of National Health Services Regulation and Co-ordination & others.

J U D G M E N T

Date of hearing: 12th June 2024. Announced on: 27th June 2024.

Petitioner by: Mr. Talat Waheed Khan, Advocate.

Respondent Nos. 2 & 3 by: Syed Muhammad Ghazanfar, Advocate.

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Muhammad Kamran Khan Mulakhail, J. Through this Constitutional petition under Article 199 of the Constitution of Islamic Republic of Pakistan, 1973 (The Constitution) the petitioner has prayed for the following relief:

> *"It is, therefore, prayed to the Honorable Court that this Hon'ble Court may be pleased, in interest of people of Pakistan to:*
>
> *i. That Respondents may be directed to introduce proper Registration and Price fixation of products and Licensing process to Manufacturing Units/Importers for availability of low cost medicines in the market and ultimate consumer/patient.*
>
> *ii. That the respondents may be directed to issue permanent Licenses instead of provisional licenses*

In view of the above, the petition is allowed and the matter is remanded to the respondent Nos. 2 & 3 to take concrete steps for registration of Alternative Medicines and Health Products, by devising a clear mechanism to regulate the said products coupled with all other products which are not registered but enlisted or pipelined for enlistment with regard to their manufacturing, standard, quality, storage, shipment, transportation, selling, pricing etc, however, the process of registration shall be commenced within one month from receipt of this order, which shall be completed within three months from the date of its initiation.

Office to transmit the copy of this order to the office of Additional Attorney General for its onward transmission to the Secretary, Ministry of National Health Services Regulations and Coordination Government of Pakistan, the Chief Executive Officer DRAP, and to the Advocate General/Additional Advocate General for its onward transmission to the Secretary, Health Department, Government of Balochistan, the Chief Drug Inspector Balochistan and the Chairman Quality Control Board of the Province, CEO DRAP For information and compliance.

The petition stands disposed of in the above terms, however, the compliance report on behalf of the Federation and the Province shall be submitted on 22nd July 2024, when other matters related to DRAP are fixed.

Annex-B

DRUG REGULATORY AUTHORITY
OF PAKISTAN

Drug Regulatory Authority of Pakistan Act, 2012

(Act No.XXI OF 2012)

(As amended till Februaary, 2022)

(xvi) "Inspector" means the Inspector appointed under the Act as specified in Schedule-V;

(xvii) "Licensing Board" means a Licensing Board constituted under Section 7 sub-section (u) of this Act to regulate the grant of licenses for the manufacture of therapeutic goods;

(xviii) "Medical Device" means medical devices as specified in Schedule-I;

(xix) "Medicated Cosmetics" means cosmetics containing drugs as specified in Schedule-1;

(xx) "Member" means a member of the Board;

(xxi) "OTC" mean over-the-counter non-prescription products;

(xxii) "penalty" means penalty as specified in Schedule III;

(xxiii) "person" means any individual or any legal entity;

(xxiv) "Pension Endowment Fund" means an endowment fund separate from the Fund of the Authority dedicated only for the payment of pension benefits of Authority's employees;

(xxv) "pharmaceutical field" means regulation, manufacturing, quality control, quality assurance, research, academia, import, export, and pharmacy services in drugs;

(xxvi) "pharmacy services" means services rendered by a pharmacist in pharmaceutical care, selection, posology, counseling, dispensing, use, administration, prescription monitoring, pharmacoepidemiology, therapeutic goods information and poison control, pharmacovigillance, pharmacoeconomics, storage, sales, procurement, forecasting, supply chain management, distribution, drug utilization evaluation, drug utilization review, formulary based drug utilization and managing therapeutic goods at all levels including pharmacy, clinic, medical store, hospital or medical institution;