

ORDER SHEET  
**IN THE HIGH COURT OF SINDH AT KARACHI**  
**C.P. No.D-5476 of 2023**

Date

Order with signature of Judge

FRESH CASE:

1. For order on CMA No.25318/2023 (Urgent).
2. For order on CMA No.25319/2023 (Exemption).
3. For hearing of main case.

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**Dated; 14<sup>th</sup> November 2023**

Petitioner Samira Mahamadi present in person.

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1. Urgency granted.
2. Exemption granted subject to all just exceptions.
3. Through instant Constitutional Petition, the petitioner, who claims to be a public spirited citizen of Pakistan, has sought a declaration to the effect that all the provisions of “Biological Drugs” in the Drug Regulatory Authority of Pakistan Act, 2012 (DRAP Act) are ultra vires to the Drugs Act, 1976, whereas, it has been prayed that the Ministry of Health Services may be directed to publish the Pfizer Covid-19 Vaccine Adverse Events Report 2021 and also to grant stay against the Polio Vaccination in the country, as according to petitioner, under the DRAP Act, 2012 the definition of the terms “drugs” as defined under the Drugs Act, 1976 has been changed while introducing new category i.e. Biological Drugs, which includes vaccine based upon recommendation of World Health Organization (WHO) published in its reports, thus, bypassing the specifications as written in the Drugs Act to follow the “Pharmacopoeia” of Pakistan, Europe, Britain or U.S. According to petitioner, unless there is amendment under the Drugs Act, 1976 either in the definition of terms of “drugs” or the terms of “misbranded drugs specifications” and other provisions relating to regulating and prohibiting of import of drugs or its

registration under the Drugs Act, 1976 the new category for drugs called "Biological" cannot be entertained under the DRAP Act, 2012, which was enacted to establish a Drug Regulatory Authority of Pakistan (DRAP) to provide for effective coordination and enforcement of the Drugs Act, 1976 and not to enact new provisions over and above as already defined under the Drugs Act, 1976, therefore, according to petitioner, such provisions may be declared to be ultra vires to the Drugs Act, 1976. Through instant petition, petitioner has also raised various grounds to challenge the authority of the respondents while posing questions of law as detailed in memo of instant petition in the following terms:

1. Whether 'Vaccine Mandates' are provided by any Law of the Land including 'Civil Aviation Authority Ordinance'?
  2. Whether 'Vaccines' are Misbranded under the Provisions of the Drug Act?
  3. Whether 'International Covenants' are binding under the Constitution of Pakistan?
  4. Whether Article 7 of the 'International Covenant on Civil and Political Rights' forbids 'Vaccine Mandates'?
  5. Whether W.H.O. has the authority to require 'Unlicensed Drug Manufacturing' in Pakistan?
  6. Whether W.H.O. has the authority to require the use of 'Unregistered Drugs' in Pakistan?
  7. Whether any 'Emergency Use Authorization' approved by any Foreign Country can be applied to Pakistan, whilst there is no such provision in the 'Drug Act'?
  8. Whether the Definition of 'Drug' could be changed in the DRAP Act whilst the Regulatory Authority was established for 'Enforcement of the Drug Act'?
  9. Whether 'Unrestricted Special Permission/NOCs' granted by DRAP, to import 'Unregistered Drugs' is ultra vires to the 'Drug Act & DRAP Act'?
  10. Whether 'Non-declaration of Post Authorization Adverse Events' is violation of the Drug Act which mandates publishing of information relevant for the health and safety of the consumer?
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11. Whether 'Consumer' also means anyone who "Consumes" any drug, purchased by the Public Exchequer?

According to petitioner, unless response to above questions of law is received by the respondents and its fate is decided by this Court, the people at large, who continue to suffer in view of no regulatory control by the authority either Biological Drugs or the vaccine for Covid-19 imported for such purposes without adopting legal course. It has been prayed that in order to ensure the enforcement and the application of Drugs Act, 1976 and regulations and control by the Regulatory Authority over "biological drugs/vaccine" directions may be issued to the respondents as prayed through instant petition.

Contentions raised require consideration. Let pre-admission notice be issued to the respondents as well as to the Attorney General of Pakistan under Order XXVII-A, C.P.C., to be served through first three modes, for 29.11.2023, when comments/reply, if any, shall be filed with advance copy to the petitioner.

Mr. Khaleeq Ahmed, D.A.G, present in Court in some other cases, waives notice of instant petition on behalf of the Federation, claims its copy alongwith annexures and requests for time to file comments/reply. Petitioner undertakes to supply copy of the same to the learned DAG during course of the day.

**ACTING CHIEF JUSTICE**

**J U D G E**

A.S/\*Farhan/PS\*

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