(56th Session)

NATIONAL ASSEMBLY SECRETARIAT

UN-STARRED QUESTION AND ITS REPLY

for Wednesday, the 30th May, 2018

10. Mr. Siraj Muhammad Khan

Will the Minister for National Health Services, Regulations and Coordination be pleased to state:

a) whether it is a fact that the Drug Regulatory Authority of Pakistan (DRAP) is discouraging commercial exporters of psychotropic pharmaceutical products; if so, the reasons thereof;

b) whether it is also a fact that the International buyers are now purchasing the same alongwith their regular pharmaceutical requirement from neighboring countries in the region due to said discouragement;

c) whether it is further a fact that pharmaceutical exporters are being held liable for quality of products that are manufactured, inspected and approved through DRAP licensed manufacturers which contradicts World Health Organization Blue Book Guidelines?

Minister for National Health Services, Regulations and Coordination (Mrs. Saira Afzal Tarar): (a) Denied: There is no such policy or procedure under implementation by Drug Regulatory Authority of Pakistan (DRAP) which discourages the Exporters of any Pharmaceutical product in general and/or Psychotropic Pharmaceutical products specifically.

Within the legal framework, Drug Regulatory Authority of Pakistan is facilitating the Exports of Pharmaceutical products including the Psychotropic Pharmaceutical products.

(b) There is no such international data available with Drug Regulatory Authority of Pakistan for the International Markets. However, DRAP issues the Export Authorizations after approval from the Competent Authority under Control of Narcotics Substance Act, 1997.

During last year and current year DRAP after NOC from the Competent Authority has issued 13 (Thirteen) Export Authorizations/Permits to different Licensed Pharmaceutical Manufacturers having valid drug manufacturing license and Drug Registration of the finished pharmaceutical products/drugs containing Controlled Substances (**Psychotropic Substances** Narcotic Drugs and precursor Chemicals) as Active Pharmaceutical Ingredients (API's).

The countries for which the permits were issued during last year and the current year include **Afghanistan, Kenya, France and Philippines.**

(c) The export of therapeutic good /drugs is regulated by DRAP under the provisions of The Drugs (Import & Export) Rules, 1976 framed under The Drugs Act, 1976/ The DRAP Act, 2012.

Under Rule 24(iv) of the said rules, if any batch of a drug is found not in conformity to the required specifications, the licensee (to whom the license for export of drugs is issued) shall withdraw the remainder of that batch from export and recall the issues already made from that batch.

Furthermore, under per Rule 27(b) of the said rules, if any batch of a drug is found in contravention of any of the provisions of the act or the rules made thereunder, the exporter shall withdraw that batch from export, and recall the issues already made from that batch and dispose of, as the board or the licensing authority may direct.

It is also pertinent to mention here that exporter is responsible for maintaining record of all exports of drugs made by him, which shall be open to inspection. Inspection book is maintained, which is signed by inspector as well as the licensee, which precludes the risk of export of substandard, spurious or counterfeit drugs to other countries on behalf of exporters.

Furthermore, as per rule 26 of the said rules, the exporter is responsible to acquire invoice or other statement showing name and address of the manufacturer alongwith the consignment of drugs to guarantee that manufacturer is licensed. This consequently reduces the potential harm on reputation of Pakistani manufacturers and exporters in global market.

Resultantly, to avoid responsibility evasion DRAP encourages licensed manufacturers for direct exports and it is a recommended procedure to buy directly from manufacturer that provides a complete traceability, warranty etc.

ISLAMABAD:
The 29th May, 2018

TAHIR HUSSAIN,
Secretary.