GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4054
ANSWERED ON:25.08.2004
PERMISSION FOR EXPORT OF MEDICINAL PRODUCTS
Aaron Rashid Shri J.M.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether export of Plaster of Paris bandages and Adhesive Tapes from India are suffering due to wrong classification under Drugs and Cosmetic Act, 1940 as surgical dressing instead of medical devices or external preparations;

(b) whether the Drug Controller of other countries are issuing Good Manufacturing Practises (GMP) certificate for these products;

(c) if so, the details of the steps proposed to be taken by the Government to protect the industry and ensure that export of these products are not stopped as a result of circular dated 9th September, 2003 issued by the Drug Controller General, India;

(d) whether specific permission for every shipment of a new drug has to be taken from Drug Controller General, India even though the same company has exported the said drug in the past;

(e) if so, the details thereof; and

(f) the steps taken by the Government in the matter?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) to (c) Manufacture and sale of surgical dressings in India is regulated under the provisions of Drugs and Cosmetics (D&C) Act and Rules made thereunder Medical devices as notified from time to time under Section 3 (b)
(iv) are also regulated under the D & C Act. This Ministry has not received any specific report about export of surgical dressings suffering due to present regulatory system.

The procedure for issue of Good Manufacturing Practices (GMP) certificate for pharmaceutical products varies from country to country. WHO has not laid down specific guidelines in respect of surgical dressings for WHO GMP Certification Scheme for international commerce. In view of the lack of specific guidelines by WHO in this regard. State Drug Control Authorities have been advised vide letter No. NZ/DL403/2000/PART-II dated 9th September, 2003 that WHO GMP Certificate should not be issued by the State Licensing Authority for bandages and applications for issuance of WHO GMP Certificate should not be entertained.

(d) to (f) As per present norms, unapproved new drugs which otherwise cannot be manufactured and marketed by a firm in the country, are allowed to be manufactured for export purpose, for which No Objection Certificate (NOC) is to be obtained from the office of DCG(I) on the basis of specific export order.