

**GOVERNMENT OF INDIA  
HEALTH AND FAMILY WELFARE  
LOK SABHA**

UNSTARRED QUESTION NO:1827  
ANSWERED ON:16.08.2013  
GUIDELINES ON GOOD MANUFACTURING PRACTICES  
Kumar Shri P.;Owaisi Shri Asaduddin

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

- (a) whether the Government has issued/ proposed new guidelines for pharmaceutical companies to comply with the European Union's Good Manufacturing Practices (GMP) standards;
- (b) if so, the details thereof; and
- (c) the manner in which these new guidelines are likely to benefit the pharma sector in the country?

**Answer**

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a) & (b): The Government has issued guidelines on procedure for issuing 'Written Confirmation' for pharmaceutical manufacturers to comply with the requirements of Good Manufacturing Practices (GMP) as mandated by the European Union (EU) through Directives No. 2001/83/EC dated 8th June, 2011 for every consignment of Active Pharmaceutical Ingredient (API) from non-EU/ non-listed countries.

(c): The guidelines are likely to be helpful for pharmaceutical companies to export APIs to Europe.