

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 4946
TO BE ANSWERED ON 31ST MARCH, 2017**

BIO-TECHNICS

4946. SHRI KUNWAR PUSHPENDRA SINGH CHANDEL:

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

- (a) whether the Government has formulated any policy to promote the medicines manufactured through bio-technics and if so, the details thereof;
- (b) whether the Government has analysed the adverse effects of the use of these medicines;
- (c) whether the Government has constituted a specialist team to assess the impact of the use of the said medicines on the supply of generic medicines; and
- (d) if so, the details thereof?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)**

(a): The medicines manufactured through bio-technics (i.e. Bio pharmaceuticals, Similar Biologics, etc.,) are regulated as per provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945 and Rules for manufacture, use, import, export and storage of hazardous micro-organisms/ genetically engineered organisms or cells, 1989 notified under the Environment (Protection) Act, 1986. Further, a document titled "Guidelines on Similar Biologics: Regulatory requirements for marketing authorization in India" have also been prepared and placed in public domain. These guidelines clearly indicate data requirements for molecular biology, production, purification, quality attributes, bio-efficacy and stability studies in respect of biosimilars.

(b): No drug is 100% safe. Therefore, all drugs are approved and allowed to be manufactured and marketed in India based on their risk-benefit analysis.

(c): No.

(d): Does not arise.