

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

**LOK SABHA  
UNSTARRED QUESTION NO.3306  
TO BE ANSWERED ON 12<sup>TH</sup> JULY, 2019**

**VIOLATION OF MEDICAL ETHICS**

**3306. SHRI M.K. RAGHAVAN:**

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

- (a) whether the Government has conducted any study on the inducements to doctors and dubious deals with hospitals by pharma companies in the country and if so, the details and findings thereof;
- (b) whether the Indian subsidiary and dealers of major MNCs have violated major ethics of the medical sector;
- (c) if so, the details of these alleged violations including dodgy records, rigging bids inflated invoices etc.;
- (d) whether the faulty orthopaedic implant devices are being used resulting in major physical deficiency to the implanted patients and if so, the measures taken to help and compensate such patients; and
- (e) whether the Government proposes to come out with a regulator to control the otherwise unregulated medical bazar and if so, the details thereof?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SHRI ASHWINI KUMAR CHOUBEY)**

(a) to (c): The Department of Pharmaceuticals under the Ministry of Chemicals & Fertilizers, has prepared a Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) for voluntary adoption by pharmaceutical companies with effect from 01.01.2015 as guidance to the industry for promotion and marketing of drugs and medical devices. No instance of unsuccessful implementation of UCPMP by pharma Associations/companies has been brought to notice by Department of Pharmaceuticals.

Further, Clause 6.8 (Code of Conduct for doctors in their relationship with pharmaceutical and allied health sector industry) of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prohibits doctors from taking gifts, travel facilities, hospitality and

cash or monetary grants from pharmaceutical and allied health sector industry. The said regulation empowers the Medical Council of India and respective State Medical Council to award punishment to a doctor against any act in violation of code of Ethics for doctors. Such complaints are referred by MCI to the concerned State Medical Councils where the doctors/medical practitioners are registered. The MCI is an Appellate Authority.

(d): The issue of adverse effects of the product requiring higher rate of revision surgeries in patients implanted with the Articular Surface Replacement (ASR) hip implant imported by M/s DePuy Medical Private Limited (Now M/s Johnson & Johnson) was reported to Central Drugs Standard Control Organisation (CDSCO), Ministry of Health and Family Welfare by the said firm.

The Government had constituted a committee to examine the issues relating to faulty ASR Hip Implants. The committee, after detailed examination of the issue, submitted its report to the Government, which accepted the recommendations with some modifications. Based on the accepted recommendations, the Government constituted a Central Expert Committee under the Chairmanship of Dr. R.K. Arya, Director, Sports Injury Centre, Safdarjung Hospital, New Delhi inter-alia to determine the quantum of compensation.

A formula for determining compensation for the affected patients has also been formulated and placed in public domain. The affected patients can approach either the Central Expert Committee or State Level Committees constituted by the State Governments as per their convenience.

M/s Johnson & Johnson Pvt. Ltd. has been asked to comply with the recommendations of the Committee and to pay the compensation as per the formula approved by the Government in the interest of the patients. However, M/s Johnson & Johnson Pvt. Ltd. has challenged the expert committee report on payment of compensation before the Hon'ble High Court of Delhi.

The High Court of Delhi has, on 30.05.2019, ordered that the petitioner pay the sum of ₹25 lakhs to each verified claimant, without prejudice to the rights of the claimants. Based on Court order, the list of verified claimants along with supporting documents has been provided to M/s Johnson and Johnson for complying with the court's order.

(e): Medical Devices are already regulated under Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2017 thereunder.