Andhra Pradesh. Funds are released to the States by the Central Government under Centrally Sponsored and Central Sector Schemes, devolution of States' share in Central Taxes and Duties, Finance Commission Grants, National Disaster Response Fund etc. The monitoring of the utilization of the funds released, wherever applicable is carried out by the concerned Ministries/Departments as per scheme guidelines and GFR.

Unethical practices by companies in the medical devices industry

*26. SHRI HUSAIN DALWAI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the status of Medical Devices Regulation Bill;

(b) the steps being taken to investigate the unethical practices by companies in the medical devices industry' that have come to light due to the global investigation-Implant Files;

(c) the action taken against global pharma major for faulty hip implants;

(d) what action has been taken against that pharma major for suspected carcinogens in its baby care products;

(e) how will the patients who received the faulty hip implants be compensated; and

(f) the redressal mechanism for a patient if a medical device/implant turns out faulty?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA): (a) In order to have comprehensive regulatory provisions for import, manufacture, sale and distribution of medical devices, the Government has notified the Medical Device Rules, 2017 which have become effective from 01.01.2018. There is no Medical Devices Regulation Bill under consideration of the Government.

(b) Comprehensive provisions already exist in medical Device Rules, 2017 to deal with regulatory issues in the medical devices sector. Further, "Materiovigilance Programme of India (MvPl)" is run by Indian Pharmacopoeia Commission under the Ministry of Health & Family Welfare for strengthening the medical devices safety and performance through adverse events reporting.

The Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) announced by the Department of Pharmaceuticals in December, 2014 which is in operation since

01.01.2015 for voluntary adoption by pharma industry provides that the manufacturers should not use any unethical practices for luring doctors to boost sales of their products.

(c) In response to the reports of adverse events and recalls, the Import license of M/s. DePuy Medical Private Limited (Now Johnson and Johnson) was cancelled under the provisions of Drugs and Cosmetics Act, 1940 and Rules, 1945 thereunder.

(d) There were media reports that St. Louis jury in USA in July, 2018 had awarded nearly $4.7 billion in total damages to 22 women and their families after they claimed that asbestos present in Johnson and Johnson talcum powder had contributed to their ovarian cancer.

In light of the above, Central Drugs Standard Control Organisation, Ministry of Health and Family Welfare has asked its zonal offices to investigate the matter and draw samples under the provisions of the Drugs and Cosmetics Act, 1940 for verifying the compliance to the standards.

(e) 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 *inter-alia* to determine the quantum of compensation.

The Ministry of Health and Family Welfare has also requested all the States/UTs to form State Level Committees to examine the affected patients within their jurisdiction so that the process is less arduous for the patients.

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 Committee as per their convenience.

M/s Johnson and 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 and Johnson Pvt. Ltd. has challenged the expert committee report on payment of compensation before the Hon'ble High Court of Delhi.

(f) The adverse events due to use of medical devices/implants can be reported to the 10 dedicated Medical Device Adverse Event Monitoring Centres (MDMCs)

functional under MvPI all over the country. MvPI has introduced various tools for adverse event reporting to develop India-specific data for making regulatory decisions by the CDSCO.

Functioning of the Archaeological Survey of India

*27. SHRI PARTAP SINGH BAJWA: Will the Minister of CULTURE be pleased to state:

(a) the details of amount spent by Archaeological Survey of India for maintaining and preserving historical monuments across India during 2015-2018;

(b) the details of the top-ten revenue generating monuments during the said period;

(c) the details of current staff, including experts, and the total expenditure incurred on salaries and wages for the year 2017-18;

(d) whether there have been any concerns raised by ASI management or employees regarding unfilled vacancies;

(e) if so, the details thereof, and action taken thereon, including funds allocated; and

(f) the details of total expenditure incurred on the new ASI headquarters in New Delhi?

THE MINISTER OF STATE OF THE MINISTRY OF CULTURE (DR. MAHESH SHARMA): (a) The year-wise details of expenditure incurred for conservation of protected monuments under Archaeological Survey of India (ASI) during 2015-2018 are given below:-

Sl. No.	Year	Expenditure incurred (₹ in lakhs)
1.	2015-16	23746.25
2.	2016-17	30176.22
3.	2017-18	41076.79

(b) The top ten revenue generating monuments during 2015-18 are Taj Mahal, Agra Fort, Qutub Minar, Red Fort, Humayun's Tomb, Sun Temple Konark, Group of