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

LOK SABHA
UNSTARRED QUESTION NO. 2997
TO BE ANSWERED ON 6TH DECEMBER, 2019

CASE AGAINST JOHNSON & JOHNSON

2997. SHRI LAVU SRI KRISHNA DEVARAYALU:

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

(a) whether it is a fact that Food and Drug Administration (FDA), USA, found asbestos in Johnson baby powder;

(b) if so, whether Indian Drugs Standard Control Organization has started investigation in this regard;

(c) if so, the details thereof and the kind of help sought/obtained from FDAUSA;

(d) whether it is also true that there was a case against Johnson and Johnson baby powder where Maharashtra Food and Drug Administration had cancelled license when it found that baby powder was sterilized by using ethylene oxide which causes cancer; and

(e) if so, the action taken by the Government and the reasons for repetition of issues with the same product from same company?

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

(a) to (c): As per media reports and information provided by M/s Johnson & Johnson India Pvt Ltd., the said firm in USA, had recalled 33000 bottles of Johnson & Johnson's Baby Powder following US FDA's test on a single bottle of the said baby powder that indicated presence of sub-trace levels of chrysotile asbestos contamination.

In 2018, due to widespread media reports regarding the presence of cancer causing asbestos in Johnson & Johnson's Baby Powder, Zonal and Sub-zonal offices of Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare had drawn samples of the said baby powder and of bulk talc raw material used in its manufacturing under the provisions of the Drugs and Cosmetics Act, 1940 & Drugs and Cosmetics Rules, 1945 thereunder.

Further, investigation was conducted at the manufacturing units of Johnson & Johnson Baby Powder located at Mumbai and Baddi. The samples drawn were sent to Regional Drugs

Testing Laboratory (RDTL), Chandigarh for testing. Government Analyst of RDTL Chandigarh declared the samples as of standard quality and also stated that asbestos was not detected in the samples analysed.

(d) & (e): As per the information provided by Food and Drug Administration (FDA), Maharashtra, they had conducted an inspection on the basis of complaint and based on the findings, a show cause notice was issued to the company and thereafter the license was cancelled on 30/03/2013. The firm made an appeal to the Appellate authority of FDA Maharashtra which rejected the appeal vide order dated 20/06/2013.

Subsequently, the firm filed a Writ Petition No.1714/2013 in Hon'ble High Court of Bombay challenging the order dated 30/03/2013. The court, vide order dated 19/09/2013, set aside the order dated 30/03/2013 and also directed that the Appellate Authority should decide the matter afresh. After re-examination of the entire issue, the licensing authority of the FDA, Maharashtra cancelled the manufacturing license of M/s Johnson & Johnson vide order dated 15/03/2014.

M/s Johnson & Johnson filed a Writ Petition No.984 of 2014 in Hon'ble High Court of Bombay challenging the order dated 15.03.2014. The Court, vide order dated 23.06.2014, granted interim order to the petitioner i.e. M/s. Johnson & Johnson.

Further, special drive for the testing of talcum powder for the presence of asbestos was carried out in March 2016 by FDA, Maharashtra and 14 samples of talcum powder were collected and tested for traces of asbestos. However, asbestos was not found present in any of the 14 samples including baby powder manufactured by Johnson & Johnson.

…….