

F No.X.11035/25/2015-DFQC
Government of India
Ministry of Health and Family Welfare
(Department of Health & Family Welfare)

Nirman Bhawan, New Delhi
Dated 8th Feb., 2017

ORDER

Subject: Constitution of a Committee to address the issue of Faulty ASR Hip Implants manufacturer by M/s DePuy International Limited, U.K – reg

The Government has decided to constitute a Committee under the Chairmanship of Dr. Arun Agarwal, Professor of ENT, Maulana Azad Medical College to examine the issues relating to faulty ASR Hip Implants manufactured by M/s. DePuy International Limited, U.K. The Committee will comprise the following:

(i)	Dr. Arun Agarwal, Professor of ENT, MAMC New Delhi.	CHAIRMAN
(ii)	Dr. Rajesh Malhotra, Professor & Head, Department of Orthopaedics, AIIMS, New Delhi.	MEMBER
(iii)	Dr. Y. K. Gupta, Head Department of Pharmacology, AIIMS, New Delhi.	MEMBER
(iv)	Dr. R. K. Arya, Professor and HOD, Department of Orthopaedics, RML Hospital, New Delhi.	MEMBER
(v)	Dr. V. K. Sharma, Ex-Director, Central Institute of Orthopaedics, VMMC & Safdarjung Hospital, New Delhi.	MEMBER
(vi)	Dr. Sudhir Kumar, Prof and Head of Department of Orthopaedics, GTB Hospital, New Delhi.	MEMBER
(vii)	Dr. C. Nath, Chief Scientist, Division of Toxicology, CDRI, Lucknow.	MEMBER
(viii)	Mr. Bejon Mishra, Founder Trustee, Jago Grahak Jago, Consumer Online Foundation.	MEMBER
(ix)	Mr. D. N. Sahoo, Deputy Secretary, Ministry of Health and Family Welfare, New Delhi.	MEMBER
(x)	Dr. BT Kaul, Professor of Law, Delhi University, Delhi Law Centre – II, Dhaula Kuan, New Delhi - 110 021.	MEMBER

(xi)	Dr. S. Eswara Reddy, Joint Drugs Controller (I), CDSCO.	MEMBER SECRETARY
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2. The Terms of Reference of the Committee will be as follows:

- i. to assess all pertinent issues relating to Faulty ASR Hip Implants manufacturer by M/s DePuy International Limited, U.K;
- ii. to review actions taken by the firm to replace Faulty ASR Implants and adjudge adequacy thereof;
- iii. to review the Medical Management and compensation provided by the firm to victims of Faulty ASR Implants;
- iv. to review all Adverse Event reports of Faulty ASR Implants and Corrective and Preventive Action (CAPA) taken by the firm;
- v. to make specific recommendations to the Government on further course of action in the matter in the light of the entirety of facts.
- vi. to assess the regulatory action taken by NRAs from ICH countries on faulty ASR Hip Implant.

3. The Committee shall submit its recommendation to the Ministry within two (2) months from the date of issue of this order.

4. TA/DA of the outstation experts will be borne by the Central Drugs Standard Control Organization.

5. The Committee may coopt any other member and invite other experts to assist in its examination of the matter.

(R. G. Singh)

Under Secretary to the Govt. of India
Tele: 23063019

To,

- (i) All the Members of the Committee.
- (ii) DCGI, CDSCO, FDA Bhawan, New Delhi.

Copy to:

PS to Secretary (HFW)/PPS to DG, DGHS/PS to AS(RKV)/PPS to KS(KLS).