TOPIC2: HIP IMPLANT SCANDAL AND INDIA' REGULATORY FAILURES

THE CONTEXT

Recently, it was found that Johnson and Johnson fitted faulty hip implants among Indian patients despite the fact that it was aware of being of substandard quality. This has come out to be one the greatest scandals in the list of medical devices in the history of independent India.

About Johnson & Johnson: Johnson & Johnson is an American multinational medical devices, pharmaceutical and consumer packaged goods manufacturing company founded in 1886.

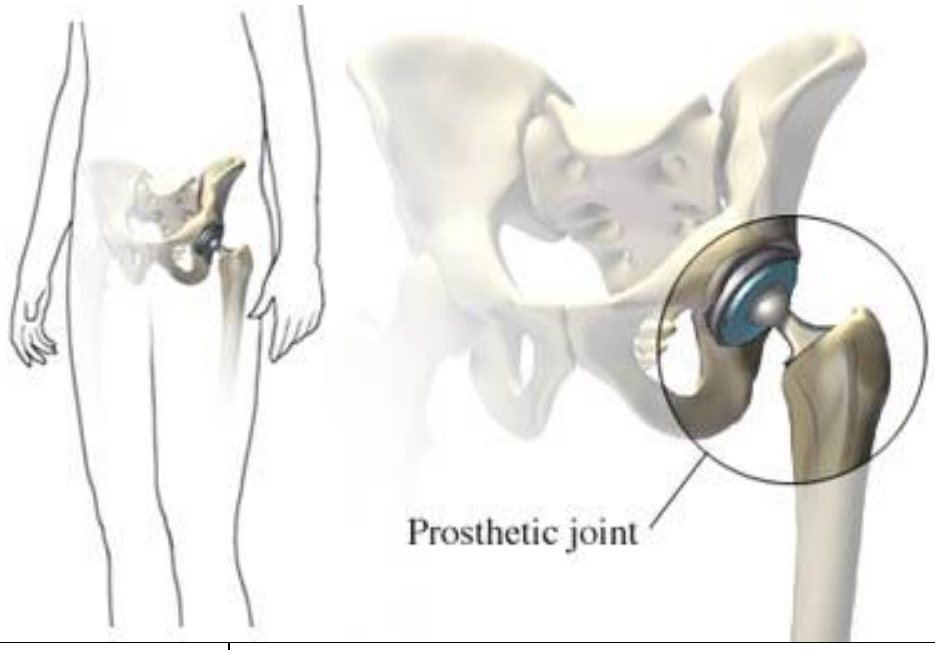
HOW IS HIP REPLACEMENT DONE?

a) The hip joint consists of a ball and a socket, which are covered with cartilage and surrounded by a lubricating membrane to protect against wear.
b) In total hip replacement, all components are replaced with prosthetic components. While a metal stem is placed into the hollow centre of the thighbone (femur), the prosthetic ball, socket and cartilage can be made of strong plastic, metal or ceramics.
c) The commonest hip implants are metal on polythene, and ceramic on polythene.
d) The metal-on-metal technology promised reduced risk of fracture and dislocation, good positional sensitivity, and greater longevity with quicker recovery rates and the potential for greater and lasting mobility

WHAT ARE THE MAIN ISSUES?

a) The Australian National Joint Registry reported that DePuy ASR Hip Implants are defective and had a 44% revision rate at seven years as opposed to the 6% revision rate at ten years of all other total hip replacement devices.
b) Around 4,700 ASR surgeries were carried out in India between 2004 and 2010, though only 1,080 patients have been traced through the ASR helpline.
c) It was found that the Particles from the chrome cobalt metal alloy in the devices broke down and caused tissue around the implant to rot and die, causing significant pain for patients.
d) There are currently no specific legal provisions to provide compensation to patients. Presently, the Drugs and Cosmetics Act has penalties, even punishment, for substandard products. But that is only limited to **drugs and not devices**.
e) Affected patients say that compensation should be based on physical, mental, social and economic harm.

TIMELINE FOR J & J ACTIVITIES FROM 1998 TO 2018



TIME PERIOD	ACTIVITIES	EXPLANATION
1998	launch of the articular surface replacement (ASR) hip	DePuy Orthopedics (a subsidiary of Johnson and Johnson) launches the articular surface replacement (ASR) hip. The hip used metal-on-metal technology with components made from cobalt, chromium and titanium.
2006	Import to india	DePuy International registers for import and marketing in India. Gets Import Licence under Drug Act, 1940 from the Drugs Controller (India) and the Directorate General of Health Services.

2009	Product found defective	a) J&J suo-moto sponsors clinical trials. Finds out that their product is indeed defective. Later investigations in USA, UK and Australia reveal that J&J &DePuy were already aware of this since June 2005. b) The Australian National Joint Registry reported that DePuy ASR Hip Implants had a 44% revision rate at seven years as opposed to the 6% revision rate at ten years of all other total hip replacement devices.
2009	Removal of product	**DePuy removes products from Australia upon its regulator's intervention** (J&J spokesperson claims it decided to discontinue the systems due to declining demand).
2010	Fresh license by India	**India's central drug regulator (CDSCO) gives DePuy's fresh imports license for implants on the basis of renewed registration**.
2010	Voluntary recall of product by the J & J	a) DePuy initiates voluntary recall 93,000 ASR implants worldwide. By this time, 4,700 ASR surgeries had been carried out in India on nearly 4,700 patients. b) A total of 15,820 implants were imported and sold in Indian Market. Out of that, 14,525 implants are used in Indian patients. c) Even during 2005-06, **J&J imported, marketed and sold these Implants in India illegally before it got license in December 2006.**
2011	BASIS FOR LINCENSE WAS FLAWED FOUND IN EUROPE	British Medical Journal (BMJ) BMJ also reports that the DePuy ASR devices that were licensed in Europe were based on simulator and laboratory tests. There was no complementary data through clinical trials that could support the laboratory-based tests.
2011	CDSCO SEEKS DETAILS	CDSCO asks DePuy to share details such as recall procedure, reason and compensation details. CDSCO asks DePuy for details of patients paid compensation again. DePuy says **information is confidential** and only with surgeons and hospitals.
2012	FIR AGAINST J&J	a) Maharashtra FDA tells CDSCO it has filed an FIR against DePuy and asks it to cancel import licence for ASR implants.

		b) This was challenged by the manufacturer of Implants before the Mumbai High Court. However, the same was withdrawn in October 2013 as Mumbai High Court refused to stop the investigation in the matter.
2012	CDSCO cancels LINCENSE	CDSCO cancels import and marketing permissions "in public interest" and tells DePuy it failed to take proper measures to make patients aware implants were recalled due to "defectiveness"
2013	BIGGEST SETTLEMENT IN US	**J&J announces $2.5-billion ASR settlement for around 8,000 patients in the US. Believed to be the highest payments on a medical device recall.**
2014	ISSUING CIRCULAR	CDSCO asks **Indian orthopedic association** (IOA) to circulate the ASR device alert to all members and design a protocol to receive complaints about the implant and ensure patient safety. Directors of IOA claim that they have never received any communication of that type.
2017	Regulatory change by the EU	The European Union tightens regulations to require more detailed clinical studies for medical devices, among other things, by 2020 to include changes in technology.
2017-2018	COMMITTEE FORMED	Health ministry constitutes an expert committee to look into the issue. **FEB 2018:** Expert committee submits its report, suggesting a base compensation of Rs 20 lakh per patient, among other recommendations. **AUG 2018:** REPORT is made public.
September 2018	Process for compensation begins	An expert panel has been constituted by central government.

FINDINGS OF THE EXPERT COMMITTEE

Negligence of responsibility towards the national institutions	The company did not inform the national regulator – Central Drugs Standard Control Organisation – about the number of patients who had used these devices, the adverse reports following such surgeries and the corrective operations subsequently conducted.
Neglect of responsibility towards the patients	a) The firm has not provided any conclusive response on compensation in India. b) The firm was found to have paid no compensation and gave reimbursements only for diagnostic tests and revision surgeries.

Negligence in maintaining records	a) According to the report, around 4,700 people in India underwent surgery for hip replacement to implant the device. But, only 1,032 patients were registered with the ASR helpline, of which 254 patients underwent a revision surgery. b) Over 3,600 patients with the faulty implants were untraceable, and at least four people had died after undergoing surgery to implant the devices
Underrating of data	The committee also found that the revision surgery rate was not 12% as the company had reported. It was found to be very high in 2014, almost 35%.

RECOMMENDATIONS BY THE COMMITTEE

Committees to confirm the damage	a) A central expert committee and a regional expert committee should be constituted by the Ministry for evaluation of patients' claims in "respect of disability and suffering caused due to use of faulty ASR". b) The regional committee will determine whether there is permanent disability, and whether such disability has affected or will affect the patient's earning capacity, and then submit its report to the central expert committee.
Compensation	a) According to the committee that examined ASR implants, the base amount should be Rs 20 lakh, and the reimbursement programme be extended until August 2025. b) In addition to this, the patient should be given compensation on the basis of suffering on "account of monetary loss due to wages and other loss" and percentage of disability. c) It has recommended that the maximum amount be at par with the maximum granted for clinical trial-related death and permanent disability as per rules and guidelines of the Drug Controller General of India.
Trace the patients	a) With 3,600 patients yet to traced, the "firm has to give due diligence to trace those remaining patients who have received ASR but have not registered with the helpline". b) Health assessment of patients should be reported once a year till 2025 and compliance report periodically, preferably six-monthly, submitted to the Ministry. Follow-up should be done regularly.

Dynamic registry for medical devices	a) An independent registry should be established for tracking usage of high-risk medical devices. b) Provisions for compensation should be included in Medical Device Rules if any serious adverse event or death is caused due to the sole use of a medical device.

CRITICISM OF COMMITTEE REPORT

a) The expert committee says nothing about the failure of the hospitals and doctors to trace these patients.
b) The government is empowered to seek these records but has done nothing in this regard. The expert committee does not make any mention of the 'missing' 9,834 implants which J&J is unable to account for.

WHAT WERE THE FACTORS THAT LED TO THIS MASSIVE SCANDAL IN DEVICE IMPLANTS?

Lack of tracking mechanism	a) While more than one lakh joint replacement surgeries are carried out in India annually, the joint registry established by the Indian Society of Hip and Knee Surgeons (ISHKS) has recorded only 1.71 lakh knee and 14,000 hip replacement surgeries since it began collecting data in 2007. b) A common refrain is that companies sell through hospitals and are not allowed to contact patients directly, as that could be seen as influencing them. c) Thus, an orthopaedic register is must so that the drug regulator can contain the damage and take steps to protect the patient.
Lack of vigilance	a) India believes in post market follow up than pre-market follows up that can be easily done by analyzing data obtained during clinical trials. b) Thus, in the present case scenario, India struggles to generate adequate local data on the safety of healthcare products, only once they are marketed. c) The government has introduced a policy to monitor the performance of medical devices during their operational period called the Materio-vigilance Programme (2015). However, reports suggest that even in 2018, it is progressing at a snail's pace.
Improper execution	Since health is a part of state list, the effectiveness of any legislation of this kind also depends on the involvement and co-operation of the state governments.
Lack of seriousness	a) In 2013, J&J agreed to pay an estimated $2.5 billion to 8,000 US patients for the defective hip implant. The compensation, tipped to be the highest ever for any medical device.

	b) India is addressing this problem after 6½ years of recall i.e. in February 2017. This shows the lack of seriousness on the part of bureaucracy.
Conflict/s of interest	a) The surgeons had a conscious or unconscious bias due to the relationships they share with the device manufacturers. b) Other than that, it is also found that conflicts of interest exist among institutions, hospital administrators and other agencies involved in supply chain. c) A clear message must be sent out to people and agencies involved in medical and health sector that the lives of Indian patients matter. For this, the government needs to take immediate steps to resolve the issue.
Lack of accountability	a) Ideally, they should have informed the higher authority and informed the patient, once they realized that the quality of ASR is substandard that can deteriorate one' health and career. b) This kind of 'moral hazard' situation (wherein the physician has full information on patient fitness whereas the patient is less informed) is usual in the healthcare industry in India.
Legal loopholes	a) Our country's regulations have not evolved as fast as medical technology. Currently, there is an absence of an ecosystem to evaluate regulatory compliance b) The US government could claim compensations from J&J as they have a robust mechanism to calculate it. The victims of the 1984 Bhopal Gas tragedy are still fighting for compensation.
Lack of and updated framework for patient compensation	a) Under the Indian legal system, damages may be awarded under general principles of tort law (which is largely judge-made 'common law'), or under any of the specific statutes, such as the Consumer Protection Act (CPA), contracts act or Drugs and Cosmetics Act (DCA). b) Presently, the Drugs and Cosmetics Act has penalties, even punishment, for substandard products. But that is only limited to **drugs and not devices**. Additionally, the law does not address recall and the penalty for collateral damage like the physical and mental trauma caused by the substandard device. c) The National Medical Device Policy 2015 that can resolve this issue is still being debated in policy circles. Thus, in absence of a framework, J&J cannot be legally compelled to pay penalty of 20Lacs to every patient

OVERVIEW OF MEDICAL DEVICE INDUSTRY IN INDIA

a) The Indian medical device market was valued at US$3.5 billion in 2015 and will expand to approximately US $4.8 billion by 2019.
b) As India's economic, healthcare, and social landscapes evolve with Ayushmann Bharat programme, its medical device market emerges as a promising opportunity for foreign manufacturers.
c) India mostly relies on imports to supply its healthcare system with medical technology. There is consistent demand for surgical instruments, cancer diagnostics, orthopedic and prosthetic equipment to name a few.

THE PRESENT STATUS OF THE ISSUES

a) A central expert panel has been constituted by the central government as per the recommendations of the committee, which has issued directions and appealed to people to apply for compensations.
b) The committee is working on a formula as the most simple, easy and legally acceptable formula.
c) This will be the first-ever instance of compensation being paid for substandard treatment in India.
d) J&J has been in the dock over double standards for failing to pay compensation in India, in contrast to the hefty compensation of $2.5 billion that it has agreed to pay to around 8,000 US citizens, who sued the firm for faulty hip implants.
e) The Supreme Court (September 2018) has sought the views of the expert panel on the J&J hip implants, directing it to file its report in two months.

WAY FORWARD

The government needs to overcome policy uncertainty and develop a robust mechanism for fixing accountability to prevent any scandal of this kind. Additionally, the policy needs to be accompanied with an allocation to build a hard infrastructure to manage the same. The health sector has been facing many problems and there are also recommendations by committees but they are yet to be fully implemented such as Ranjit Roy Committee.