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MATERIOVIGILANCE OF INTRAOCULAR LENSES IN INDIA: CURRENT PERSPECTIVE

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ABSTRACT

The intraocular lens (IOL) industry was predicted to be worth USD 4.5 billion globally; in India, it is anticipated to increase by roughly $1 billion during the following five years. According to the 2017 medical devices rules, IOL is primarily categorised as Class C (moderate high risk), which means that IOL has a higher risk of adverse events. It is therefore crucial to report any anticipated or suspected adverse events to the national regulatory body in order to comply with regulation requirements. TASS, post-operative endopthalmitis, and severe ocular inflammations have all been associated to materials like polypropylene, acrylic, silicon hydrophobic/hydrophobic acrylic, and hydrogels used in IOL, according to a recent case study presented by IPC. . They also provided CDSCO with information suggesting that the product may have quality problems. They are currently reviewing these reports and taking appropriate action against the marketing authorization holder. It is better to report any adverse event at the initial level since a lack of knowledge about adverse reporting can result in a significant adverse event or death-injury. As a result, a workable solution has been recommended in this article in accordance with contemporary MvPI standards. Digital platforms will significantly revolutionise how stakeholders report adverse events related to medical devices.

Keywords: Materiovigilance, MvPI, MDMC, IOL, TASS, Adverse event reporting

INTRODUCTION:

Substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood component collection bag with or without anticoagulant covered and mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides used for diagnosis, prevention, and treatment are defines as medical devices as per the medical devices rule, 2017.

According to the 2017 medical devices rule in India, medical devices are classified into Class A, Class B, Class C, and Class D based on the risks they pose, which are listed below (**Figure 1**) **[1]**.

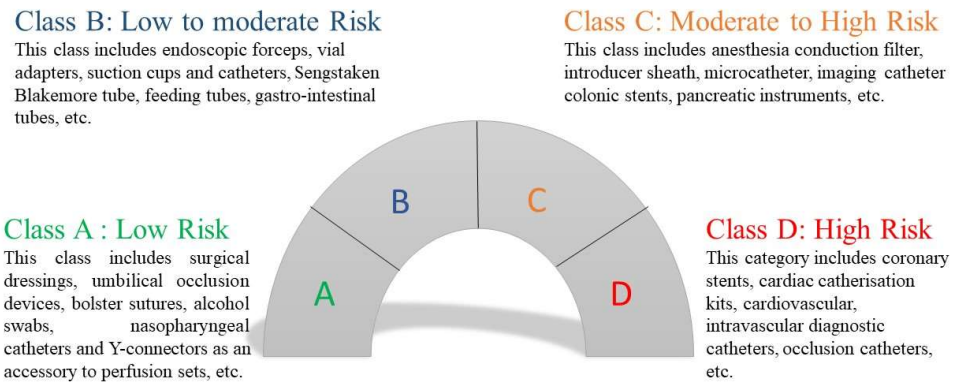

Figure 1: Classification of medical devices as per medical devices rule, 2017

There are currently about 7000 generic device groups and an estimated 2 million different types of medical devices available on the global market **[2]**.

The market for medical devices in India is projected to be worth Rs. 90,000 crore (US$ 11 billion) in 2022 and to reach US$ 50 billion by 2030 with a CAGR of 16.4%.

According to estimates, 1.65% of the global market for medical devices are sold in India. In general, 75–80% of India's medical gadget imports come from outside. In FY22, India exported medical products worth Rs. 19, 803 crore ($2.40 billion) **[3]**.

Between 2022 and 2027, the intraocular lens market in India is anticipated to expand at a CAGR of 9.2%. The market is expected to grow by USD 99.17 million in size. The incidence of ocular disorders, technical advancements, and campaigns to raise awareness of the advantages and developments in ophthalmic lenses are some of the factors that influence the market's growth **[4]**.

According to CDSCO, Intra ocular lenses has been classified as Class C (moderate to high risk) under the provision of the medical devices rules, 2017 **[5]**. There are 24

categories for non-notified medical devices, with 144 products in the ophthalmic. In this non-notified list of ophthalmic medical devices 6 ophthalmic lenses are divided based on their risk parameter in **Table 1 [6]**.

Table 1: Classification of Ophthalmic lenses according to CDSCO

Sr. No.	Device Name	Intended use	Classification
1	Intra Ocular lenses	This device intended to treat cataracts or myopia.	C
2	Contact Lens	Device intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eyes to correct vision conditions or act as therapeutic bandage.	B
3	Fresnel Lens	Thin flexible lenses used to focus light to focal point to manage vision conditions.	A
4	Hurby Fundus lens	Intended for use in examination of vitreous body and the fundus of the eye under slitlamp illumination and magnification.	A
5	Maddox trial lens	Associate with eye muscle dysfunction.	A
6	Spectable Lens	Intended to correct refractive errors of that pateint's eyesight.	A
7	Trial lens	Opthalmic lens for used in trial lens set.	A

C- Class C (Moderate High Risk); B- Class B (Low Moderate Risk); A- Class A (Low Risk)

There are 25 billion individuals worldwide who are suffering from blindness, 12 million of them are in India and are primarily from rural areas. Even though intraocular lens implantation (IOL) climbed from 5% in 1994–1995 to 83% in 2003–2004 due to a rise in the demand for IOLs and suture-less procedures **[7]**. Adverse event reporting of IOCL has been lacking from health care professions and other stakeholders. Ageing, underlying ocular pathology, surgical issues, as well as adverse responses and complications, like corneal and macular edoema, have a negative impact on the visual prognosis following intraocular lens implantation in the USA **[8]**.

Recently IPC found case studies which shows that IOL are including materials like polypropylene, acrylic, silicon hydrophobic/ hydrophobic acrylic and hydrogels leads to cases of toxic Anterior segment syndrome (TASS), post-operative endopthalmitis and severe eye inflammations. As a result, IOL is suspected of having a quality related problem, and IPC advises CDSCO to watch over these details and take appropriate action. Lack of awareness about adverse event reporting among stakeholders must be the root cause of these unfavourable outcome **[9]**.

The regulatory oversight of medical devices in India is governed by the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare. The Medical Devices Rules, 2017, outlines the regulatory framework for medical devices, which includes provisions for post-market surveillance.

Under the direction of the Indian drug controller, formal adverse drug reaction (ADR) monitoring was first implemented in India in 1986. In 1998, India attempted to

participate in the WHO's Programme for International Drug Monitoring, but it was unsuccessful. The Pharmacovigilance Programme of India (PvPI) was introduced in 2010 after the National Programme of Pharmacovigilance (NPP) was first introduced in 2004 and in 2015 Materiovigilance Programme of India has launched for medical device **[10]**.

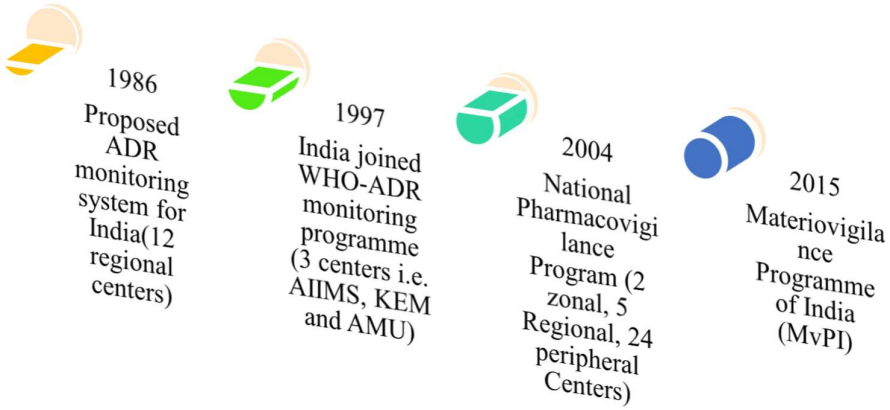

Figure 2: History of Pharmacovigilance in India

METHOD FOR ADVERSE EVENT REPORTING OF IOL:

Materiovigilance is a coordinated system for identifying, gathering, reporting, and analysing any untoward incidents related to the use of medical devices, with the goal of protecting patients' health by reducing the likelihood that they will occur again **[11]**.

The CDSCO establishes and maintains a National Pharmacovigilance Program for Medical Devices (PvMD) in order to monitor the safety of medical devices. Total 387 Medical Device Materiovigilance Centre are governed under IPC aims to aims to gather, analyze, and respond to reports of adverse events associated with medical devices **[12]**.

Use the Medical Device Adverse Event Reporting Form which is available on the official website of IPC (www.ipc@gov.in) to report any adverse event. Reporters from MDMCs after filling the above mentioned MDAE reporting form can submit it to the coordinator or Research Associate of the respective MDMC. A reporter who is not part of MDMC can submit the filled MDAE reporting form to the nearest MDMC or directly to the National Collaborating Centre. Reporter can also mail the scanned form at lab.ipc@gov.in and copy to mvpi.ipcindia@gmail.com. IPC having a facility of helpline number 1800-180-3024 to report adverse events associated with medical devices and medicines. A reporter

can also call on this number to report MDAEs **[13]**.

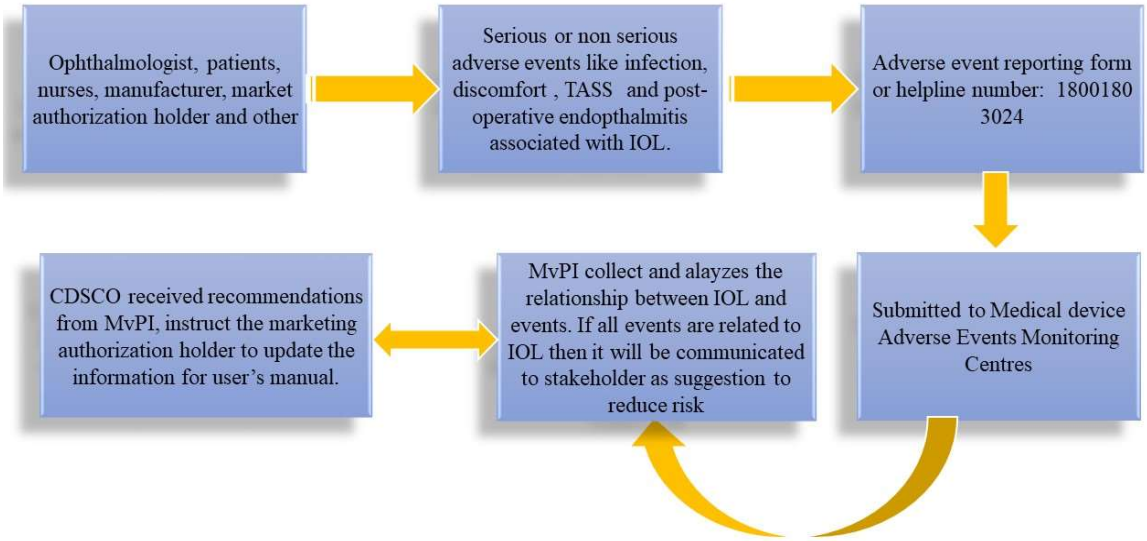

Figure 3: Flow of adverse event reporting of IOL

TIMELINE FOR ADVERSE EVENT REPORTING:

MvPI also suggest timeline based on seriousness of adverse events, mainly it is reported by marketing authorization holder or user facility, they submitted adverse report to CDSCO and NCC-MvPI within 15 calendar day of occurrence of adverse events **[13] (Figure 3)**.

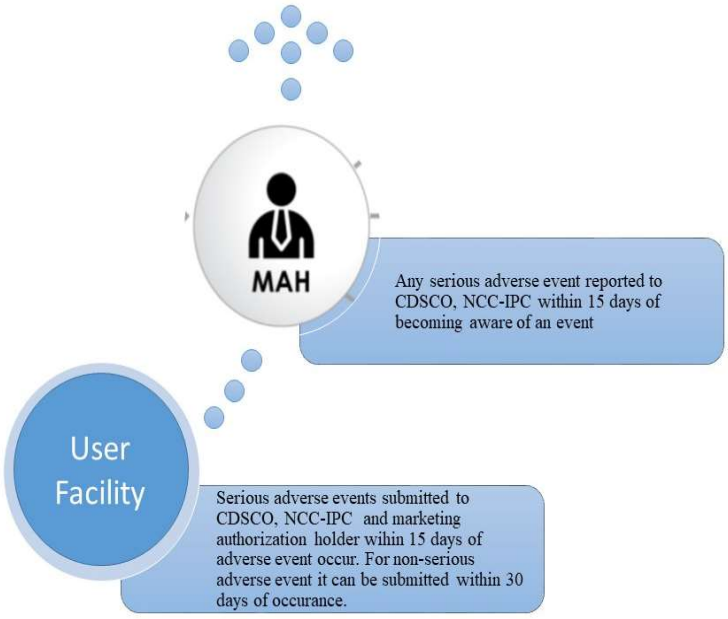

Figure 3: Timeline for adverse event reporting

CHALLENGES AND FUTURE ASPECTS:

Underreporting, the absence of standardised reporting criteria, and the complexity of signal interpretation are the main challenges in Materiovigilance. For adverse reporting, a mobile-based application will be more practical. It will also be simpler to gather data for MvPI, which helps synchronise events with products and offer the best solutions.

CONCLUSION:

Thus, IOL shares a sizable market for medical devices both internationally and in India. It has been the marketing authorization holder's duty to maintain the standard of IOL and the market share of IOL by balancing the quality. Post-market surveillance have major role in quality reflection but due to a lack of Materiovigilance awareness, market authorization holder haven't been doing it. Especially in India, Serious and non-serious adverse events, both expected and unexpected, are not reported to the national regulatory body leads to recalls of products. The toxic anterior segment syndrome (TASS), post-operative endopthalmitis, and severe eye inflammations are only a few of the major adverse events that IPC has recently discovered in case studies. These events are cause for concern for IPC. This study also reflects product quality difficulties and a lack of vigilance reporting. The majority of the recently announced IPC method of adverse reporting of orthopaedic implants is also relevant to IOL. Additionally, they have advised CDSCO to check into the information and take action. Low reporting rates may be caused by a lack of awareness and the complexity of the forms; nevertheless, digitization will help to make reporting more practical.

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