

**REGULATORY REQUIREMENTS FOR POST-MARKETING SURVEILLANCE OF
DRUG-ELUTING STENTS AS PER CDSCO IN INDIA COMPARISON WITH MHLW
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ABSTRACT

Drug-eluting stents (DES) are established coronary devices that combine a mechanical scaffold with local delivery of an antiproliferative agent. Although contemporary DES have substantially reduced restenosis and repeat revascularization, late device-related events and performance in broader real-world populations require continued post-marketing surveillance (PMS). This contemporary review compares the regulatory and PMS approaches to DES in India and Japan, using the submitted project document as the primary source. In India, the framework centers on the Central Drugs Standard Control Organization (CDSCO), the Medical Devices Rules, 2017, and the Materiovigilance Programme of India (MvPI), with complaint handling, adverse-event reporting, periodic safety activities, and field safety corrective actions forming the principal post-market mechanisms. Japan operates under the Pharmaceuticals and Medical Devices Act through the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA), with Good Vigilance Practice, Good Post-Marketing Study Practice, structured post-market studies, and re-examination providing a more formal longitudinal evidence-generation framework. The source document summarizes Japanese post-market data from a 2,010-patient cobalt-chromium everolimus-eluting stent cohort, in which 3-year major adverse cardiovascular events were reported at 6.8%, and Indian multicenter evidence reporting a 1-year unadjusted mortality of 3.8% with DES versus 5.0% with bare-metal stents. These findings are presented as source-derived evidence rather than as a new pooled analysis. Both countries emphasize lifecycle safety, but their surveillance infrastructures differ in structure and intensity.

INTRODUCTION

Drug-eluting stents are implantable vascular devices designed to maintain arterial patency while releasing an antiproliferative drug at the site of vascular injury. The technology evolved from balloon angioplasty and bare-metal stents, primarily to address restenosis caused by neointimal hyperplasia. The source document describes the progression from plain old balloon angioplasty in the late 1970s, through the introduction of coronary stents in the 1980s, to first-generation DES and later thin-strut, biocompatible-polymer and bioresorbable-polymer platforms. The clinical rationale for DES is therefore closely linked to the biological response produced by vascular intervention: mechanical expansion opens a stenotic vessel, while controlled local drug delivery limits excessive cellular proliferation that can re-narrow the treated segment.^[14]

Despite substantial improvements in DES design, post-market monitoring remains essential. Pre-market clinical investigations are conducted under controlled conditions and generally involve selected populations, whereas routine clinical use exposes devices to broader anatomical, demographic and procedural variability. Rare adverse events, manufacturing defects, coating problems, delivery-system failures, stent thrombosis, myocardial infarction, cardiac death, target-lesion revascularization and other clinically important outcomes may become clearer only after widespread use. PMS therefore functions as a lifecycle activity rather than a single regulatory event. It links clinical experience, complaint handling, adverse-event reporting, manufacturing quality, corrective action and regulatory decision-making.^[5]

The regulatory challenge is particularly important for DES because they combine a mechanical scaffold with a therapeutic drug and polymer or coating technology. Their performance depends not only on the mechanical properties of the stent but also on drug selection, dose,

coating integrity, elution kinetics, biocompatibility, sterilization and delivery-system characteristics. The source document consequently treats DES as high-risk implantable devices and compares the regulatory pathways used in India and Japan.^[1,3,4]

Post-Marketing Surveillance of Drug-Eluting Stents

Comparative regulatory review: India vs Japan

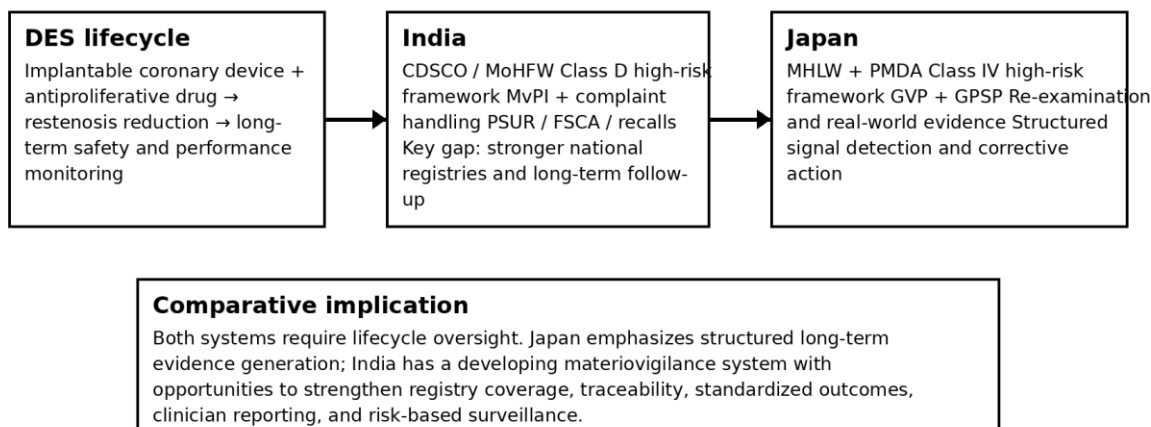


Fig no 1: Graphical Abstract. Lifecycle surveillance of drug-eluting stents and the principal regulatory differences identified between India and Japan.

Clinical Perspective

- Clinical implication: Strengthening Indian DES registries, traceability, standardized outcomes, long-term follow-up, and risk-based signal detection could improve the ability to identify and act on device-specific safety signals.
- What this review adds: The source comparison shows that Japan combines spontaneous vigilance with structured post-marketing studies and re-examination, whereas India's framework is centered on CDSCO, MvPI, complaint handling, and evolving real-world evidence generation.
- What is known: Drug-eluting stents require post-market surveillance because rare, delayed, or population-specific safety signals may not be fully characterized before approval.
- India and Japan provide useful contrasting models. India's system is centered on CDSCO and the Medical Devices Rules, 2017, with MvPI providing a dedicated materiovigilance pathway. Japan operates through MHLW and PMDA under the Pharmaceuticals and Medical Devices Act and has developed a highly structured framework incorporating GVP, GPSP, re-examination, long-term safety evaluation and detailed corrective-action mechanisms. Comparing the two systems can identify areas in which Indian post-market surveillance can become more systematic while recognizing the differences in national regulatory structures, healthcare systems and commercial environments.^[6-11]

Review Scope and Objectives

The aim of this review is to examine and compare the regulatory requirements governing post-marketing surveillance of drug-eluting stents in India and Japan and to identify features that may strengthen continued safety and performance monitoring.

- To describe the clinical and technological basis of drug-eluting stents and the reasons for continued post-market monitoring.
- To summarize the roles of CDSCO, MvPI, MHLW and PMDA in the regulation and surveillance of DES.
- To compare requirements for manufacturing, importation, quality management, adverse-event reporting and field safety corrective actions.
- To summarize the post-marketing clinical findings presented in the source material for India and Japan.
- To identify regulatory and evidence-generation challenges and areas for strengthening DES surveillance in India.

Review Methodology

This article was developed as a narrative regulatory review using the submitted project document as the primary source. The source document contained sections on DES history and applications, Indian and Japanese regulatory authorities, manufacturing, sales, import and export requirements, recent technological advances, post-marketing surveillance, comparative regulatory features, clinical PMS findings, and a reference list. The information was reorganized from dissertation-style chapters into a journal-style narrative review. Repetitive institutional front matter, declarations, acknowledgments, page-specific headings and duplicated reference entries were excluded from the article body. The terminology and substantive claims were retained from the source material, while sentences and paragraph structures were newly written to improve readability and reduce textual similarity.

The review does not present a new clinical dataset or statistical analysis. Clinical percentages and regulatory details reported below are therefore presented as findings summarized in the source document rather than as independently generated results. Where the source document provides a regulatory claim without sufficient detail to establish its legal scope, the claim is described conservatively rather than expanded with unsupported assumptions.

Clinical Background and Technological Evolution of DES

From balloon angioplasty to DES

Balloon angioplasty provided a minimally invasive means of restoring blood flow in stenotic coronary arteries but was limited by acute vessel recoil, abrupt closure and subsequent restenosis. Bare-metal stents improved acute vessel support and reduced recoil, but the foreign metallic scaffold could stimulate neointimal tissue growth. The source document describes restenosis with earlier BMS platforms as occurring in approximately 20–30% of patients within six months, establishing the clinical need for a pharmacological approach.^[2,3]

First-generation DES combined a metallic scaffold with a polymer coating capable of releasing an antiproliferative drug. The RAVEL trial, as summarized in the source, demonstrated a major reduction in restenosis with a sirolimus-eluting platform compared with BMS. Commercial development subsequently expanded with sirolimus- and paclitaxel-eluting systems. However, first-generation devices also raised concerns about late stent thrombosis, particularly in association with durable polymers, delayed endothelial healing and chronic inflammatory responses. This history illustrates why post-market surveillance is integral to implantable-device regulation: an important risk may become apparent only after longer and broader exposure.^[1]

Second- and later-generation platforms

Later DES generations introduced thinner struts, improved metallic alloys, more biocompatible polymers and more predictable drug-release systems. Cobalt-chromium and platinum-chromium platforms permitted thinner structures while maintaining mechanical strength. Limus-family agents such as everolimus and zotarolimus became prominent, and biodegradable polymer systems were developed to reduce the duration of polymer exposure. The source document also describes polymer-free designs and bioresorbable vascular scaffolds as important attempts to reduce permanent implanted material.^[3,12]

Current development described in the source focuses on ultrathin struts, improved deliverability, biodegradable or polymer-free coatings, optimized drug-elution kinetics, imaging-guided implantation and 'leave-nothing-behind' approaches such as drug-coated balloons. These innovations change the surveillance burden because new materials, coatings, delivery systems and clinical indications can introduce new failure modes or new long-term questions. PMS must therefore evolve with device technology.^[4,12]

Regulatory Framework and Post-Market Surveillance in India

In India, medical devices are regulated through the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017. The source document identifies CDSCO, functioning under the Ministry of Health and Family Welfare, as the principal national regulatory organization. The Medical Devices Rules introduced a risk-based classification system with Classes A through D, ranging from low-risk to high-risk devices. The source document places DES within the high-risk Class D category and emphasizes central oversight for high-risk implantable devices.^[7,9]

CDSCO's responsibilities extend across import, manufacturing, clinical investigation, testing, licensing, distribution-related requirements and post-market surveillance. The Central Licensing Authority has responsibility for importation of medical devices of all classes and for manufacturing Class C and Class D devices. For DES, this centralized oversight is important because the device is implanted in the coronary circulation and combines mechanical performance with localized pharmacological activity.^[7,9]

Materiovigilance and post-market monitoring

The Materiovigilance Programme of India is a central component of the Indian post-market system for medical devices. According to the source document, MvPI is intended to collect and evaluate medical-device adverse events and product malfunctions. Manufacturer complaint systems, documentation of failures, root-cause investigation and field safety corrective actions complement spontaneous reporting. If a systematic defect is identified, corrective measures may include safety communications, product modification or recall.^[6,13,14]

The source document describes reporting categories for DES in which serious adverse events, including death, life-threatening injury or permanent impairment, are associated with a 15-calendar-day reporting timeline, while non-serious technical malfunctions are associated with a 30-calendar-day timeline. It also describes the involvement of CDSCO and the Indian Pharmacopoeia Commission/National Coordination Centre for MvPI. These timelines should be interpreted in the context of the applicable reporting provisions and current regulatory guidance rather than as a substitute for the latest official reporting forms.^[14]

Quality, complaints and field safety actions

Effective surveillance requires more than adverse-event submission. Manufacturers must maintain complaint-handling processes capable of linking an event to the device, batch, manufacturing history and distribution chain. The source document identifies field safety corrective action as an important response when surveillance data indicate a systematic defect. For an implantable product such as DES, traceability is particularly valuable because a defect may affect multiple patients before the underlying problem is recognized.

India's framework is also connected with broader medical-device quality requirements, including quality-management systems and international standards such as ISO 13485. The source document notes that regulatory oversight is intended to maintain safety and performance throughout the product lifecycle rather than ending at initial authorization.^[15]

Regulatory Framework and Post-Market Surveillance in Japan

Japan regulates medical devices under the Pharmaceuticals and Medical Devices Act. The Ministry of Health, Labour and Welfare is the principal administrative authority, while the Pharmaceuticals and Medical Devices Agency performs scientific and technical reviews, quality-system assessments, consultations and post-market safety activities. The source document describes Japan's risk classification as Classes I through IV and identifies DES as high-risk Class IV devices requiring stringent regulatory control.^[8,10,11]

For high-risk DES, the source document describes the Shonin pre-market approval pathway and a regulatory evaluation that considers both the physical stent and the drug/polymer component. Foreign manufacturers must establish an appropriate Japan-based regulatory structure, including a Marketing Authorization Holder or Designated Marketing Authorization Holder, and overseas manufacturing sites are subject to Foreign Manufacturer Registration requirements. Quality-system oversight is linked to MHLW Ordinance No. 169, while Good Vigilance Practice provides a formal structure for ongoing safety monitoring.^[10,11]

GVP, GPSP and re-examination

Japan's post-market framework is distinguished in the source document by the combination of Good Vigilance Practice and Good Post-Marketing Study Practice. GVP supports continuous collection, assessment and management of safety information. GPSP governs planned post-marketing studies intended to generate longer-term real-world safety and effectiveness evidence. The source document also identifies database-driven approaches and the use of real-world data as increasingly important components of Japanese surveillance.^[8,10]

The re-examination system is another major feature. For selected products, the marketing authorization holder must accumulate post-market evidence over a defined period and submit the resulting information for regulatory assessment. The source document describes periods of 4–6, 8 and 10 years for different categories and notes that regulatory authorities may modify labeling, require additional studies, restrict use or withdraw approval if substantial safety or effectiveness concerns emerge. For DES and other high-risk devices, the practical value of this approach lies in forcing the post-market evidence base to remain connected to the original benefit-risk assessment.^[8-10]

Adverse-event communication and corrective action

The source document describes reporting timelines to PMDA that distinguish serious/unanticipated events, serious anticipated events and non-serious/unanticipated events, with 15-day and 30-day categories. It also describes Yellow Letters for urgent, life-threatening risks and Blue Letters for risks requiring rapid and widespread attention. For medical devices, field safety corrective actions and traceability are linked with quality-system oversight. These mechanisms provide routes from signal detection to communication and action.^[8]

Lifecycle Regulatory Considerations Manufacturing

DES manufacturing is a high-precision process involving device geometry, metallic tubing, laser cutting, cleaning, heat treatment, electropolishing, inspection, drug/polymer coating, drying or curing, crimping onto the delivery system, sterilization, quality control and packaging. The source document presents this sequence as a controlled chain in which failures at any stage can affect clinical performance.^[3,4]

In India, the source document describes central licensing and submission of manufacturing and product information, including manufacturing-site details, quality certifications, manufacturing processes, device specifications, intended use, testing procedures, stability, clinical information where applicable and labeling. In Japan, manufacturing is described within the PMD Act framework and Japanese QMS requirements, with particular emphasis on ISO 13485-aligned systems, risk management, validation and PMDA review.^[7,9,15]

Importation and local representation

For India, the source document describes CDSCO control of DES imports and the requirement for an Authorized Indian Agent for foreign manufacturers. Applications are submitted through the SUGAM system, and the source identifies Form MD-14 and Form MD-15 in the import licensing pathway. It also describes post-import obligations involving labeling, batch information, complaint monitoring and materiovigilance.^[7,16]

In Japan, a foreign manufacturer must work through a Japan-based MAH or DMAH and complete the relevant foreign-manufacturer and quality-system requirements. The source document describes a staged pathway involving local representation, Foreign Manufacturer Registration, PMDA consultation, submission of a technical dossier, QMS inspection, scientific review, MHLW approval, reimbursement/pricing procedures and customs clearance.^[10,11,16]

Commercial environment

The commercial environments also influence how DES reach patients. In India, the source document describes a hospital-centered supply and consignment model and emphasizes government price regulation through the National Pharmaceutical Pricing Authority. The document reports a ceiling price of ₹39,186 per DES at the time of its preparation and identifies affordability as an important policy consideration. In Japan, the source emphasizes the role of National Health Insurance reimbursement and a strong market for advanced technologies, including imaging-guided intervention.^[17]

These commercial differences matter for PMS because access, device selection, patient mix and adoption patterns can influence the real-world evidence base. A surveillance system therefore benefits from collecting not only adverse-event reports but also exposure denominators, device type, lesion characteristics, procedural context and clinically relevant outcomes.

Recent DES Advances Relevant to Surveillance

The source document describes several contemporary DES developments in India, including ultrathin-strut designs, biodegradable polymers, polymer-free systems, improved drug-delivery technologies, improved deliverability and increasing domestic manufacturing. It also notes the expanding use of drug-coated balloons for selected indications. These innovations can reduce restenosis or improve procedural performance, but each introduces device-specific questions that should be reflected in surveillance plans.^[4,12]

In Japan, the source document highlights biodegradable-polymer DES, thin-strut cobalt- and platinum-chromium platforms, improved delivery systems, widespread intracoronary imaging, shorter dual-antiplatelet regimens, polymer-free platforms and long-term registry evidence in complex lesions. It also identifies research into bioresorbable magnesium scaffolds, nitric-oxide-eluting surfaces and automated optical-coherence-tomography applications. From a regulatory perspective, rapid innovation increases the need for device-specific endpoints, robust traceability and post-market evidence capable of distinguishing device-related events from patient- or procedure-related factors.^[10,12]

Post-Marketing Clinical Evidence Summarized in the Source

The source document includes clinical findings intended to illustrate how PMS data can support assessment of DES safety and effectiveness. These findings are not a new dataset for this article; they are summarized from the submitted project.

Japanese evidence

A Japanese PMS study of a cobalt-chromium everolimus-eluting stent included 2,010 patients and reported three-year clinical outcomes. The source document reports major adverse cardiovascular events in 6.8% of patients, including cardiac death in 1.7%, myocardial infarction in 1.5% and clinically driven target-lesion revascularization in 4.2%. It also reports no very late stent thrombosis between one and three years. Together, these findings were interpreted in the source as supportive of the safety of DES in routine Japanese practice.^[18]

The source also summarizes a separate Japanese post-market study involving drug-coated balloons for DES-related in-stent restenosis. A 12-month target-lesion revascularization rate of 17.6% was reported, and DES-related in-stent restenosis was identified as a strong risk factor, with an odds ratio of 5.77. These observations demonstrate why surveillance should consider the clinical context in which a device is used and should not treat every post-procedure event as a homogeneous endpoint.^[19]

Indian evidence

The source document summarizes a prospective multicenter Maharashtra Government study comparing DES with bare-metal stents. It reports one-year unadjusted mortality of 3.8% for DES versus 5.0% for BMS, with a reported p value of 0.185. DES use was associated with significantly lower rehospitalization ($p < 0.001$) and lower recurrence of unstable angina in the study summary. Total stent length and number of stents were described as important survival predictors, followed by age and employment status.^[20]

The source further reports that increased DES use after 2015, following price-control interventions, was associated with a reduction in the hazard ratio from 0.94 to 0.58. The source interprets this as suggesting that cost had previously limited access to DES among higher-risk patients. These findings illustrate a feature of real-world surveillance in India: regulatory and economic policy can influence which patients receive DES and therefore shape the outcomes observed after market introduction.^[17,20]

Comparative Regulatory Analysis

Table no 1: Comparative Regulatory Analysis.

Parameter	India	Japan
Primary authorities	CDSCO / MoHFW; DCGI and Central Licensing Authority	MHLW and PMDA
Primary legal framework	Drugs and Cosmetics Act, 1940; Medical Devices Rules, 2017	Pharmaceuticals and Medical Devices Act
High-risk classification described in source	Class D	Class IV
Local representation for foreign manufacturers	Authorized Indian Agent	Japan-based MAH/DMAH
Import pathway described	SUGAM; MD-14 application and MD-15 licence	FMR, Shonin approval and MAH/DMAH structure
Post-market surveillance	MvPI, complaint handling, periodic safety information and FSQA	GVP, GPSP, re-examination, adverse-event reporting and FSQA
Quality system	ISO 13485-related QMS requirements	MHLW QMS Ordinance No. 169, aligned with ISO 13485
Safety communication	Recalls, FSQA and regulatory notices	Yellow Letters and Blue Letters plus corrective actions
Clinical evidence highlighted in source	Maharashtra multicenter DES/BMS real-world study	2,010-patient CoCr-EES PMS study
Commercial emphasis	Affordability, hospital-centered supply and NPPA price regulation	NHI reimbursement and advanced-device adoption

The comparison indicates that the two countries share several fundamental principles: high-risk devices require stronger regulatory oversight; manufacturers must maintain quality systems; adverse events must be collected and assessed; and significant safety signals can trigger corrective action or recall. The major distinction in the source document is the maturity and structure of longitudinal evidence generation. Japan's framework explicitly integrates vigilance, planned post-marketing studies and re-examination, thereby creating a formal mechanism for reassessing the benefit-risk profile after commercial exposure.^[7,8]

India has established the essential components of a modern medical-device surveillance system, particularly through CDSCO and MvPI, but the source document identifies a need for stronger national registries, broader long-term follow-up and more consistent real-world evidence generation. The Indian clinical evidence summarized in the project also demonstrates the importance of socioeconomic variables and pricing policy. Thus, strengthening PMS in India does not require simply copying the Japanese framework; rather, it requires adapting structured longitudinal surveillance to India's healthcare delivery system and large, heterogeneous patient population.^[6-8]

DISCUSSION AND IMPLICATIONS

DES surveillance should be understood as a continuous lifecycle process linking pre-market evidence to routine clinical experience. The evolution of DES illustrates this principle clearly. First-generation devices produced major reductions in restenosis but later generated concern regarding late thrombosis and polymer-related healing. Subsequent generations responded through thinner struts, improved polymers and different drug platforms. Each technological improvement reduced some risks while creating new questions about long-term performance. Regulatory surveillance therefore provides the mechanism by which these questions can be evaluated after broad clinical adoption.^[1,5,8]

The Indian framework has several strengths. The Medical Devices Rules provide a dedicated risk-based regulatory structure, and central oversight of high-risk implantable devices provides a clear regulatory pathway. MvPI creates a specific platform for medical-device adverse-event reporting rather than relying exclusively on pharmaceutical pharmacovigilance. Complaint handling, root-cause investigation and FSCA provide additional layers of protection. The growth of domestic DES manufacturing may also improve access and create opportunities for locally generated clinical evidence.^[6,7,15]

At the same time, the source document identifies important limitations. Underreporting can reduce the sensitivity of spontaneous surveillance, particularly when clinicians and hospitals are uncertain about reporting responsibilities or when events are attributed to patient or procedural factors. Limited registry coverage makes it difficult to calculate reliable event rates because a numerator without a well-defined exposure denominator can be misleading. Variability in follow-up may also obscure late events. For an implanted device, these limitations are especially important because some clinically relevant complications may emerge months or years after implantation.^[5,6]

Japan's approach addresses several of these problems by combining spontaneous safety monitoring with planned post-marketing studies and re-examination. GVP creates an organizational responsibility for safety surveillance, while GPSP provides a framework for structured evidence generation. Re-examination creates a formal regulatory checkpoint at which accumulated real-world evidence can be reviewed. The use of databases and registries can also improve denominator information and permit analysis across larger populations.^[8,10]

However, the Japanese system should not be regarded as universally superior in every respect. Regulatory requirements must be evaluated within national healthcare structures, resource availability, reimbursement mechanisms and device markets. Japan's mature health-information infrastructure and established regulatory institutions support intensive longitudinal surveillance. India's much larger and more heterogeneous healthcare environment may require scalable approaches that combine national coordination with hospital-level reporting and registry networks.

One practical priority for India is the development of stronger DES-specific registries. A useful registry could link patient characteristics, lesion complexity, device model and lot, procedural details, antiplatelet treatment, imaging findings, revascularization outcomes, myocardial infarction, stent thrombosis and mortality. Linking registry information with adverse-event reporting would allow regulators to move from passive detection toward risk-based active surveillance. Such a system could also support post-market evaluation of new ultrathin-strut, biodegradable-polymer and polymer-free devices.^[6-8]

Another priority is device traceability. A high-risk implant must be traceable from manufacturer to hospital and, where possible, to the individual patient. Traceability improves the speed and precision of recalls and permits targeted assessment when a specific batch or model develops a safety signal. Japan's emphasis on systematic tracking provides a useful conceptual model, although implementation in India should be aligned with existing national digital-health and medical-device infrastructure.^[7,8]

Adverse-event reporting should also become easier for clinicians. A surveillance system that depends on lengthy or complicated reporting forms may produce incomplete data. Reporting interfaces should encourage capture of essential information while allowing later regulatory investigation. Education of cardiologists, catheterization-laboratory staff, pharmacists, biomedical engineers and hospital quality teams can improve recognition of device-related events. Feedback to reporters is also important because clinicians are more likely to participate when they can see that reports lead to meaningful safety action.^[5,6]

The clinical findings summarized in the source demonstrate the value of surveillance evidence. The Japanese CoCr-EES study provides multi-year information on MACE, cardiac death, myocardial infarction, target-lesion revascularization and stent thrombosis. The Indian study provides evidence not only on clinical outcomes but also on hospitalization, unstable angina and socioeconomic influences on DES adoption. These different evidence profiles are complementary rather than mutually exclusive. Safety surveillance benefits from detailed clinical endpoints, while health-policy evaluation benefits from understanding affordability and access.^[18,20]

Future Indian PMS should therefore use a risk-based model. Devices with new materials, novel drug-delivery systems, substantially modified coatings or limited pre-market exposure could receive more intensive early surveillance. Established devices with extensive safety experience could move to less intensive routine monitoring. Risk-based surveillance can conserve resources while concentrating regulatory attention where uncertainty is greatest.^[4,12]

Finally, PMS data should be connected to regulatory decision-making. A surveillance system has limited value if reports are collected but not converted into action. Signal detection should lead to predefined processes for investigation, manufacturer response, risk communication, labeling or instructions-for-use changes, targeted recalls and, where necessary, restrictions on use. This lifecycle connection between data and action is one of the most important lessons from the comparative review.^[5,8]

Recommendations for India

- Develop a coordinated national DES registry with standardized definitions for device-related and clinical outcomes.^[6,7]
- Improve linkage between MvPI reports, hospital complaint systems, device identifiers and clinical follow-up records.^[6,7,14]
- Expand long-term follow-up beyond the immediate post-implantation period to detect late thrombosis, restenosis, repeat revascularization and other delayed outcomes.^[5,8,18]
- Adopt risk-based post-market plans that increase surveillance intensity for novel DES platforms and major design changes.^[5,8,12]
- Improve clinician and hospital staff training on recognition and reporting of medical-device adverse events.^[6,14]
- Strengthen batch and patient-level traceability to support rapid, targeted field safety corrective actions.^[7,8]
- Encourage multicenter real-world studies that include diverse Indian patient populations and complex coronary disease.^[20]

- Use standardized clinical endpoints such as MACE, stent thrombosis, TLR and TVR to improve comparison between studies.^[18,20]
- Integrate economic and access variables with clinical surveillance when evaluating technologies affected by pricing policy.^[17,20]
- Use accumulated PMS evidence to support periodic reassessment of device benefit-risk profiles and regulatory controls.^[5,8]

Limitations

This review is based primarily on the submitted project document and therefore inherits the scope, terminology and limitations of that source. Some regulatory statements in the source may reflect guidance or practices that can change over time, and the article does not independently verify every legal requirement against the latest government notification. Several market-size and commercial claims in the source are attributed to secondary market reports rather than primary regulatory datasets and are not central to the PMS comparison. The clinical findings are summarized as reported in the source and should not be interpreted as a pooled or comparative meta-analysis.

CONCLUSIONS

Drug-eluting stents require sustained post-marketing surveillance because long-term safety and performance cannot be fully established through pre-market studies alone. India and Japan both use risk-based regulation, quality-system controls, adverse-event monitoring and corrective-action mechanisms, but their post-market evidence-generation structures differ. India's CDSCO-MvPI framework provides an important foundation and is continuing to develop, while Japan's MHLW-PMDA system adds structured GVP/GPSP activities and re-examination to support longitudinal benefit-risk assessment. The source evidence indicates favorable real-world DES outcomes in both countries while highlighting different regulatory and healthcare priorities. For India, stronger national registries, improved reporting, traceability, long-term follow-up and risk-based surveillance could substantially strengthen the evidence base for DES safety and performance.^[1,6-8]

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