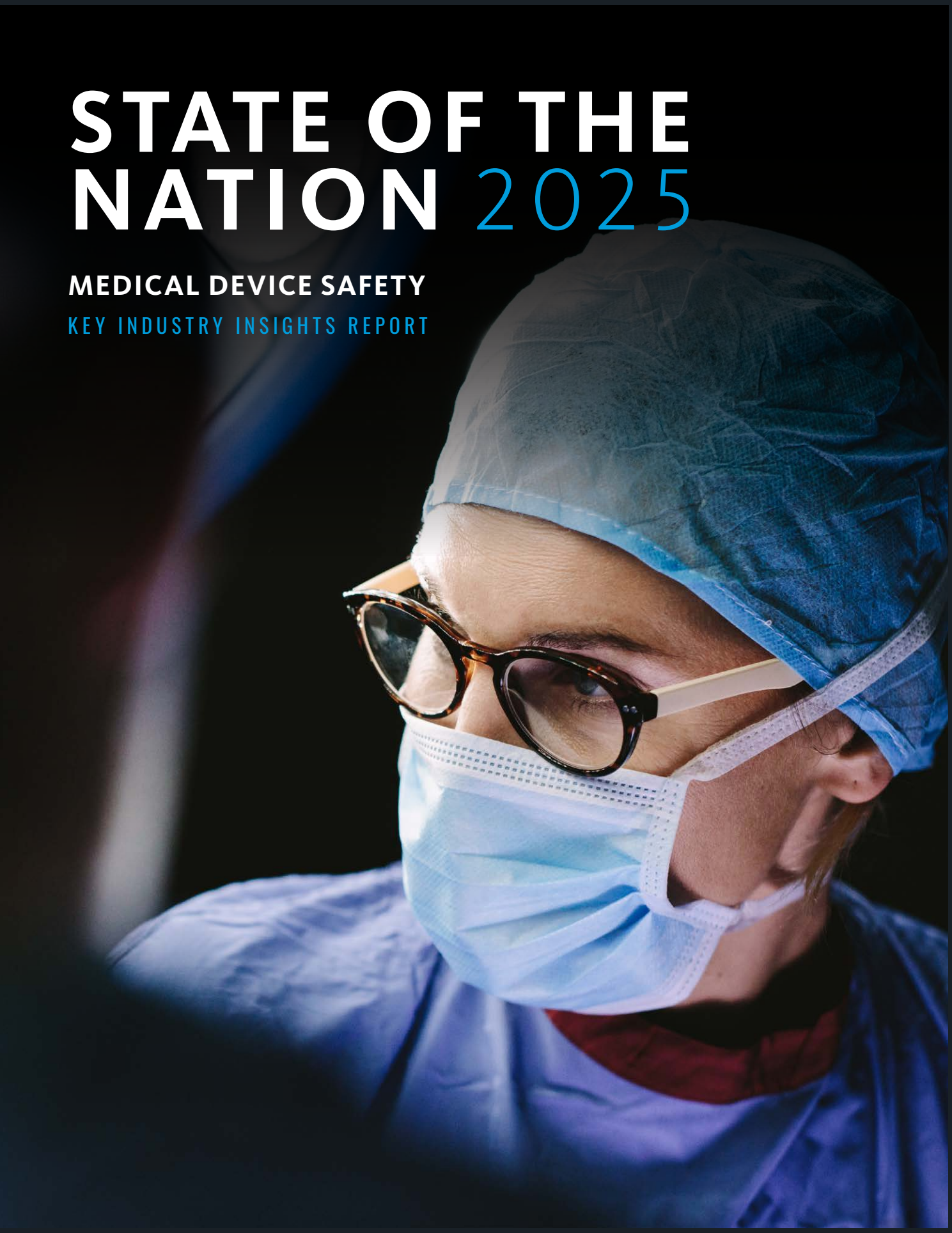
STATE OF THE NATION 2025

MEDICAL DEVICE SAFETY

KEY INDUSTRY INSIGHTS REPORT



DATA, TRENDS & PREDICTIONS **FOR THE MEDICAL DEVICE SECTOR**

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THE RECALL INDEX REPORT

The Sedgwick brand protection Recall Index is the leading resource for manufacturers, suppliers, and retailers seeking an unbiased, informed perspective on past and present trends, as well as predictions about what's next in global product safety and product recalls. It reviews five product categories: Automotive, Consumer Products, Food and Drink, Pharmaceutical, and Medical Device.

This report is focused solely on the medical device sector, with data from the U.S. Food and Drug Administration (FDA), UK's Medicines and Healthcare products Regulatory Agency (MHRA), regulators in the European Union including the European Medicines Agency (EMA) and European Commission, and Australia's Therapeutic Goods Administration (TGA). These exclusive insights are designed to help medical device manufacturers and distributors safguard their brands against operational risk and reputational damage.

This special edition of the Recall Index looks at recall actions and regulatory changes impacting medical devices from all of 2024 as complied in our 2025 State of the Nation Recall Index reports for the U.S., Europe, and Australia. It also includes perspectives from some of our strategic partners at global law firms, insurance companies, and regulatory and safety organizations to help stakeholders across the medical device industry navigate regulatory complexities.

You can access the full 2025 State of the Nation Recall Index report for any of the three jurisdictions. Each edition presents recall data from relevant regulatory agencies, along with expert analysis on product safety and regulatory changes from a national perspective. To complement these reports, we also host webinars featuring our product safety experts, offering additional insights and commentary. Use the links below to access each edition:

- **U.S. edition available here:** click here
- **European edition available here:** click here
- **Australian edition available here:** click here

HOW RECALL READY ARE YOU?

Thousands of recall events impact the medical device industry each year, and even those manufacturers with robust recall plans often encounter unexpected hurdles when it comes to facing a live event.

Whether you're well versed in recall management or new to the process, take our short online audit and receive a comprehensive report featuring personalized insights and strategic recommendations tailored to your unique risk profile and needs.

Don't wait until a recall strikes. Safeguard your brand and your bottom-line.

Click on the below to begin

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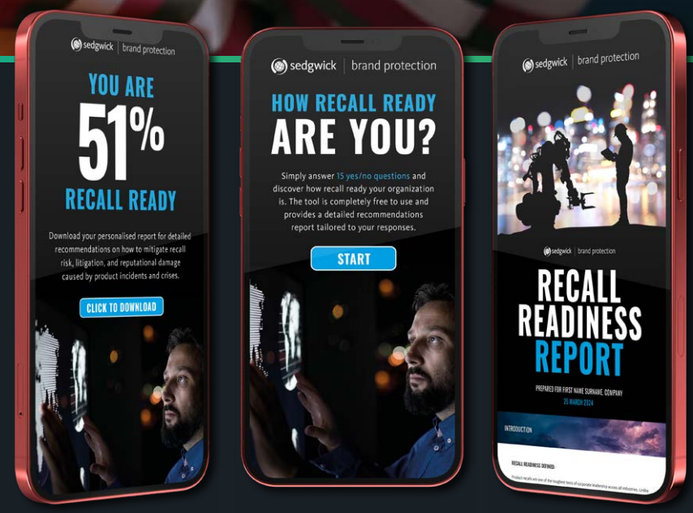

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UNITED STATES SUMMARY

The U.S. medical device sector recorded 1,059 recalls in all of 2024, a four-year high. The number of units recalled rose from 283.44 million units in 2023 to 440.41 million in 2024, an increase of 55.38%

A key theme in the U.S. in 2024 was litigation. This applies to lawsuits being brought against government agencies, as well as regulators pursuing criminal actions against companies and individuals around recall and product safety issues.

The FDA was sued twice over its final rule regulating laboratory-developed tests (LDTs). Previously, most LDTs did not require FDA approval. Under a new rule that took effect in July 2024, oversight of these tests shifted from the Center for Medicare and Medicaid Services (CMS) to the FDA. The regulation also classified the tests as in vitro diagnostics (IVDs).

The agency claims the rule will ensure the tests are safe and effective. Opponents of the measure say the new oversight places considerably more requirements on LDT manufacturers and will make it harder for patients to access essential care.

Other noteworthy litigation in 2024 included significant settlements from the Department of Justice (DOJ) concerning medical device manufacturers. A manufacturer of continuous positive airway pressure (CPAP) machines, bi-level positive airway pressure (BiPAP) machines, and mechanical ventilators was ordered to stop manufacturing most sleep and respiratory devices at three U.S. facilities and stop distributing these devices produced at those locations. The DOJ mandated that the company implement specific measures to increase the safety of its devices and ensure they comply with the requirements in the Federal Food, Drug, & Cosmetic Act (FD&C Act) before production and distribution could resume.

In another criminal case, the DOJ found a medical device manufacturer had concealed a device malfunction that resulted in inaccurately low readings for lead tests. According to the settlement, the company pled guilty to violations of the FD&C Act and will pay a $21.8 million fine, $10.9 million in forfeiture, and a minimum of $9.3 million to compensate patient victims. There is also a deferred prosecution agreement to resolve felony conspiracy fraud charges against the company as part of the ruling.

Another potentially burdensome regulation for medical device companies that was approved in 2024 is a final rule on Quality Management System Regulation (QMSR), which is designed to more closely align U.S. processes with the ISO standard used in many other countries. The FDA acknowledged that there will be costs associated with retraining staff and modifying existing internal processes but claims the harmonization with international standards will result in annualized net cost savings of up to $554 million across the medical device industry.

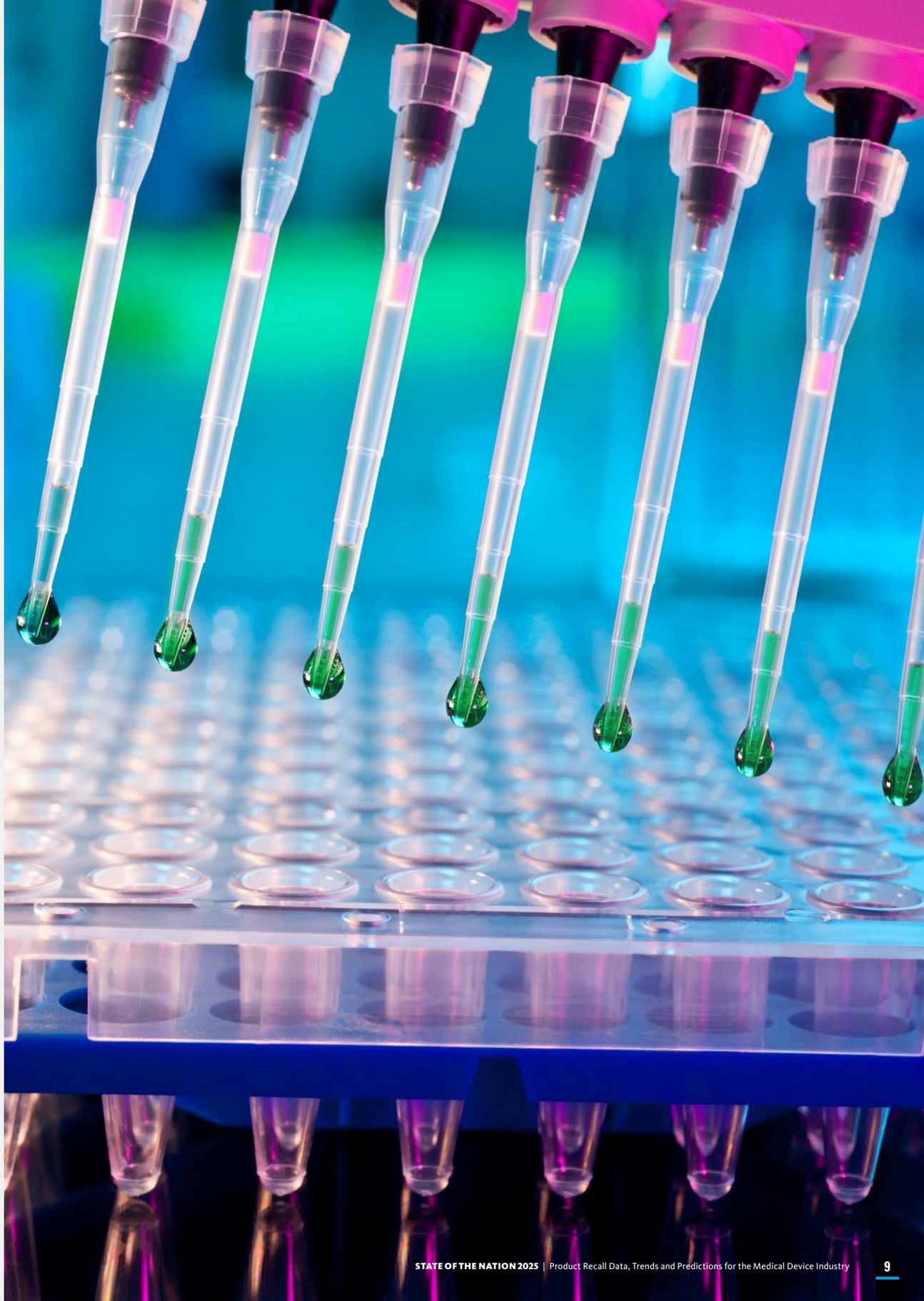
Prompted by feedback from a Patient Engagement Advisory Committee (PEAC) meeting, the FDA launched a pilot program to expedite public notification of “high-risk” Class I medical device recalls. This comes as the percentage of Class I designations has been rising. In 2022, 7.7% of all events were Class I. That figure increased to 8.7% in 2023 and rose to 10.8% in 2024. The exact details of the program are still being developed, but it reflects the FDA’s desire to be more responsive to patients and care providers.

The FSA is also focused on regulating devices that use AI. In November 2024, the agency issued its final guidance for predetermined change control plans (PCCPs) tailored to AI-enabled medical devices. The goal is to allow some flexibility for manufacturers without sacrificing patient safety.

Another final guidance issued in Q4 2024 focuses on conducting decentralized clinical trials (DCTs). These types of trials allow research to be done away from one central clinical site. This flexibility may allow sponsors to include more diverse or historically underrepresented participants through the use of telehealth and in-home visits or digital health technologies (DHTs) and other activities. More widespread adoption of this type of clinical trial could also increase the use of a variety of DHTs.

It is clear that the FDA is working to leverage the benefits of new innovations such as AI and telehealth. The agency wants to give medical device manufacturers some flexibility with the use of PCCPs and DCT, but will take aggressive action if it feels companies are not being responsible or are threatening patient safety.

For a more in-depth analysis of the U.S. medical device industry click here.



EUROPE SUMMARY

European medical device recalls increased 11.1% year-over-year, from 3,311 in 2023 to 3,679 in 2024. This marks a new annual record for the sector. Software concerns were the leading cause of medical device recalls in 2024.

The primary themes for regulators overall in 2024 were fair competition and trade, greener practices, and consumer protection. In the medical device sector, EU and UK regulators are working on comprehensive changes to their regulatory frameworks. Lawmakers have shared plans and issued consultations throughout the year to keep stakeholders informed and to garner feedback.

In April 2024, the European Parliament approved a proposal to give in vitro medical device (IVD) manufacturers an additional two years to transition to the In Vitro Diagnostic Medical Device Regulation (IVDR), moving the implementation date to December 2029 for certain classes of devices.

These ongoing delays for the IVDR and Medical Device Regulation (MDR) rules are causing frustration and potentially harming patients. In October 2024, the European Parliament instructed the European Commission to amend the draft regulations to address key issues and quickly move forward to implement the rules.

One of the biggest challenges in implementing the IVDR and MDR has been the lack of notified bodies to perform the required conformity assessments. There is a growing gap between the number of assessment applications submitted by manufacturers and the number of certificates of conformity that have been granted.

So far, the plans for the UK's regime seem to be going more smoothly. The UK's Medicines and Healthcare products Regulatory Agency (MHRA) updated stakeholders on its plans to reform the UK Medical Device Regulations 2002. Its new roadmap is built around four key areas. New regulations under the strategy are expected to take effect in 2025.

In May, the MHRA announced it was planning a new International Recognition Procedure (IRP) to streamline the authorisation of medical devices for use on the UK market that have already been approved by regulators in four other countries. This is similar to a program the agency has already implemented for pharmaceuticals.

The European Medicines Agency (EMA) is trying to encourage medical device manufacturers to develop orphan medical devices, which are products that target diseases or conditions that affect fewer than 12,000 individuals in the EU per year. The agency launched a pilot programme in 2024 to provide manufacturers and notified bodies free advice from a panel of experts to help them navigate the clinical approval and certification process for this class of devices.

Programs to promote more environmentally friendly and sustainable practices are priorities for UK and EU regulators. Several publications were issued in Q4 2024 with ways for medical device and life sciences companies to improve their environmental footprint, including a proposal to reduce the number of single-use products.

Stakeholders across the medical device industry are waiting for final implementation of the long-awaited changes to the medical device regulatory schemes in both the EU and UK. Medical device companies will have more obligation under the new scheme and there will likely be new challenges that emerge.

For a more in-depth analysis of the European medical device industry, click here.

AUSTRALIA SUMMARY

The Australian medical device sector recorded a total of 626 recall notifications in 2024. This includes product recalls, defect corrections, defect alerts, and hazard alerts. Medical device recall actions in Australia have been consistently increasing the past several years, with 519 in 2022 and 598 in 2023.

Throughout 2024, sustainability was a top priority for regulators in Australia. There were also big changes for the medical device and pharmaceutical sectors as the Therapeutic Goods Administration (TGA) works to implement a series of medical device reforms. These changes include amendments to the Essential Principles for medical devices.

Regulators are also monitoring entries into the Australian Register of Therapeutic Goods (ARTG). The Federal Court of Australia fined a major medical device manufacturer $22 million in penalties for selling a medical device that was not properly registered. The court ruled that the device company had sold more than 16,000 units of a product that was not registered properly.

After several years of transition, medical device companies must now comply with the new classifications for software-based medical devices when listing them in the ARTG. The new system assesses product use and potential risk to patients to determine the risk classification for the product. The new definitions align more closely with EU rules.

In addition, the TGA continues to roll out its updated Uniform Recall Procedure for Therapeutic Goods. The new version emphasises quickly disseminating information about defective products to the public.

Medical device companies will need to closely monitor the TGA's updates and guidance as more changes are on the way.

For a more in-depth analysis of the Australian medical device industry, click here.

> *Prompted by PEAC feedback, and a rise in their frequency from 7.7% in 2022 to 10.8% in 2024, the FDA is launching a pilot program to improve public notification of Class I device recalls."*

MEDICAL DEVICE

UNITED STATES PERSPECTIVE

Over the past year, the Federal Trade Commission (FTC) has challenged more than 300 patents listed in the U.S. Food and Drug Administration's (FDA's) Orange Book. The agency claims that companies are providing inaccurate information to keep generic products off the market and inflate prices for brand name devices.

In December, a U.S. Court of Appeals for the Federal Circuit affirmed a district court's order to delist five patents listed in the Orange Book that belong to a major pharmaceutical company relating to certain medical devices. The original complaint was made by a competing pharmaceutical company and not the FTC. This decision could lead to more challenges by competitors related to patents for medical devices and products.

Prompted by feedback from a Patient Engagement Advisory Committee (PEAC) meeting, the FDA is launching a pilot program to ensure the public is notified quickly when there is a "high-risk" recall for medical devices, designated as a Class I event. This comes as the percentage of medical device recalls that are categorized as Class I has been rising. In 2022, 7.7% of all events were Class I. That figure increased to 8.7% in 2023 and then subsequently rose to 10.8% in 2024. The exact details of the program are still being developed, but it reflects the FDA's desire to be more responsive to patients and care providers.

The agency is also focused on regulating medical devices that use artificial intelligence (AI). In November, the FDA issued its final guidance for predetermined change control plans (PCCPs) tailored to AI-enabled medical devices. The goal is to allow some flexibility for manufacturers without sacrificing patient safety.

Another final guidance issued in Q4 focuses on conducting decentralized clinical trials (DCTs). These types of trials allow research to be conducted away from one central clinical site. This flexibility may allow sponsors to include more diverse or historically underrepresented participants through the use of telehealth and in-home visits or digital health technologies (DHTs) and other activities.

It is clear that the FDA is working to leverage the benefits of new innovations such as AI and telehealth. Stakeholders will need to look for opportunities to provide input as regulations move forward.

Pilot program to improve “high-risk” recall communications

In November, the U.S. Food and Drug Administration’s (FDA) Center for Devices and Radiological Health (CDRH) announced a pilot program to improve the timeliness of communications about corrective actions being taken by companies that the FDA believes are likely to be high-risk recalls.

These actions may involve removing products from the market, addressing product defects, or updating usage instructions to mitigate significant safety risks. The FDA aims to enhance transparency and shorten the time between its initial awareness of high-risk medical device removals or corrections and its communication of these actions to healthcare providers and the public.

The first phase of the program will focus on early alerts of potentially high-risk device removals or corrections related to cardiovascular, gastrorenal, general hospital, obstetrics and gynecology, and urology. The agency stated that no other recall process or recall communication timelines will change for these areas during the pilot.

Attorneys with Akin Gump Strauss Hauer & Feld LLP noted that the FDA’s announcement did not clarify how these early alerts will be communicated. Furthermore, since the program focuses on product recalls, it is unclear how the agency will determine whether a company’s corrective action is a recall, a device enhancement, or other corrective measures unless the company itself voluntarily labels it as a recall. The lawyers also said that classifying a product recall as Class I, the highest risk category, typically occurs after the FDA evaluates information submitted by the company.

This initiative was developed following recommendations from the October 6, 2021, Patient Engagement Advisory Committee (PEAC) meeting on how CDRH can improve its medical device recall program to better address the needs of patients. Based on stakeholder feedback, the agency highlighted the need for quicker and clearer communication about certain potentially high-risk device issues. This step is part of a broader effort to incorporate more patient input into regulatory efforts.

FDA explores regulations for AI-enabled devices

According to U.S. Food and Drug Administration (FDA) officials, the agency’s first approval of a medical device partially enabled with artificial intelligence (AI) was in 1995. Since then, approximately 1,000 AI-enabled medical devices have been authorized by the FDA, with numbers continuing to rise. The FDA understands the need to regulate the use of AI in product development in a way that is flexible enough to allow for innovation but strict enough to protect patient wellbeing.

In November, the agency issued its final guidance for predetermined change control plans (PCCPs) tailored to AI-enabled medical devices, including parts of device-led combination products that are reviewed through the 510(k), De Novo, and Premarket Approval (PMA) pathways. The recommendations allow improvements to devices without creating overly burdensome processes for manufacturers, while maintaining assurances of device safety and effectiveness.

The guidelines provide best practices for sharing anticipated device modifications, detailing how to communicate plans to develop, validate, and implement those modifications, and the methodology to assess how the changes will impact device safety and efficacy. AI-enabled devices that include a PCCP as part of their marketing submission may be able to avoid additional marketing submissions when they implement an update described in the PCCP.

The FDA also held the first public advisory committee meeting of its newly formed Digital Health Advisory Committee (DHAC) in November to discuss total product lifecycle considerations for Generative AI-enabled devices. In its executive summary from the meeting, the DHAC noted that not all GenAI-enabled products would be under the FDA’s regulatory purview. There will be some GenAI-enabled products that may not meet the definition of a device and other products that may meet the definition of a device, but for which the FDA will exercise enforcement discretion.

The FDA intends to focus its regulatory oversight on GenAI-enabled products that perform patient-specific analysis, provide specific outputs or directives, and are used by health care professionals to diagnose, treat, mitigate, cure, or prevent a disease or condition. Also covered are products that "perform patient-specific analysis and provide patient-specific diagnosis or treatment recommendations to patients, caregivers, or other users."

The publication also addresses the two broad categories of challenges the FDA faces when regulating GenAI in medical devices. First, there are issues associated with using a risk-based approach to classification and determining regulatory requirements for GenAI-enabled devices. The second concern is how to determine the types of valid scientific evidence needed to evaluate the safety and effectiveness of GenAI-enabled devices across the total product life cycle (TPLC).

It is clear that regulators are making efforts to adapt to the rapidly evolving technology of generative AI while maintaining their oversight responsibilities. Sponsors should aim to collaborate closely with the agency and prioritize transparency as they navigate the approval process.

Decentralized clinical trial guidance issued

In September, the U.S. Food and Drug Administration (FDA) issued its final guidance for sponsors, investigators, and other interested parties related to conducting decentralized clinical trials (DCTs). The December 2022 Food and Drug Omnibus Reform Act (FDORA) required the FDA to issue a draft guidance on DCTs.

The agency defines a DCT as a clinical trial that includes decentralized elements such as telehealth visits with trial personnel, in-home visits with remote trial personnel, or visits with local health care providers. It may also include the use of telehealth and digital health technologies (DHTs) such as activity trackers, smart watches, and glucose monitors to remotely acquire data.

According to the FDA, many clinical trials already include decentralized elements. Incorporating these types of provisions allows trial-related activities to occur remotely at locations convenient for trial participants as opposed to traditional clinical trial sites.

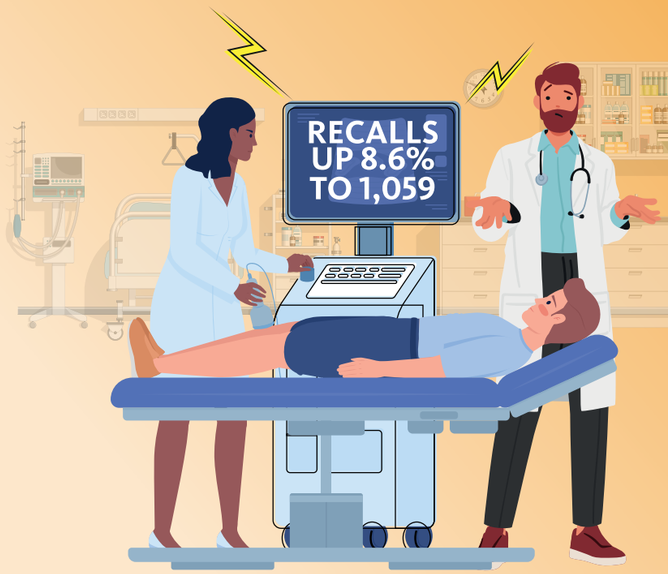
Potential benefits of DCTs include enhancing convenience for trial participants, lessening the burden on caregivers, and making it easier to research rare diseases and diseases affecting populations with limited mobility or limited access to traditional clinical trial sites. The end results could be increased trial participant engagement, recruitment, enrollment, and retention with a more representative trial participant population. In turn, that would strengthen the evidence produced by the trial and help sponsors meet new requirements for increasing enrollment of underrepresented populations in clinical trials.

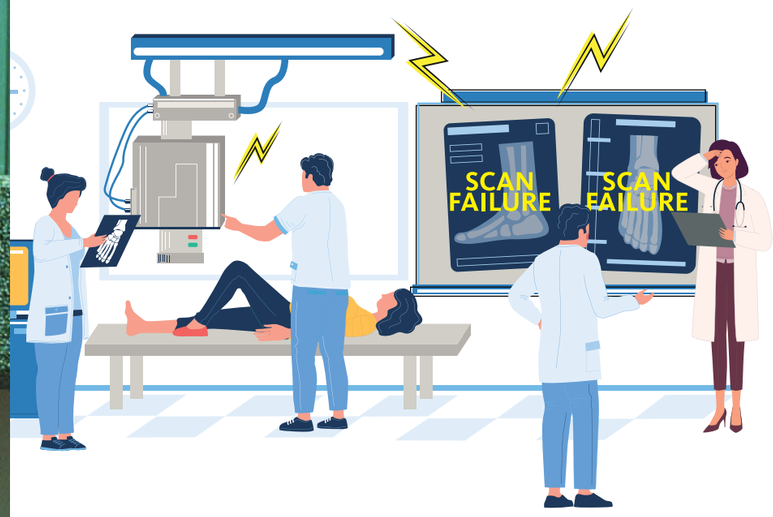
Attorneys with McGuireWoods LLP note that while some stakeholders may be able to delegate certain responsibilities to third parties using DCT elements, any such transfer must be "consistent with regulatory requirements, agreed upon by all interested parties, and carefully documented." The legal experts also advise that if a decentralized element raises novel or nuanced regulatory issues, sponsors should coordinate with the appropriate FDA review division for help identifying and addressing any concerns early in the process.

> *"If a DCT element raises novel or nuanced regulatory issues, sponsors should coordinate with the appropriate FDA review division for help identifying and addressing any concerns early in the process."*

Medical device recall events increased 8.6% in 2024, from 975 (in 2023) to 1,059.

With this increase, U.S. medical device recalls are currently at a 3-year high. Furthermore, those of a Class I severity are at a 15-year high.





Accounting for 118 events (11.1%), **Device failure was the leading cause** of recall activity in 2024.

This marks the highest failure rate in over 5 years, and the first time this has been the leading cause.

Total impacted units surged 55.4%, from 283.4M in 2023, to 440.4M in 2024.

With this increase, impacted units are at their highest rate in 3 years.

UNITED STATES - MEDICAL DEVICE
2024 BY THE NUMBERS

In Q4 2024, medical device recalls saw a marginal decline of 1.1% compared to Q3, dropping from 262 to 259. However, the number of impacted units experienced a much steeper decrease, falling 79.8% from 158.73 million in Q3 to 32.11 million in Q4—marking the second-lowest quarterly total in a decade. Correspondingly, the average recall size dropped sharply, from 605,855 units in Q3 to 123,992 units in Q4.

Despite lower numbers this quarter, for the full year, 2024 recorded more medical device recalls and more impacted units compared to 2023. There were 1,059 recalls in 2024, the highest total in the past four years. This is an 8.6% increase from the 975 recalls in 2023. There were 440.41 million units recalled in 2024 compared to 283.44 million in 2023.

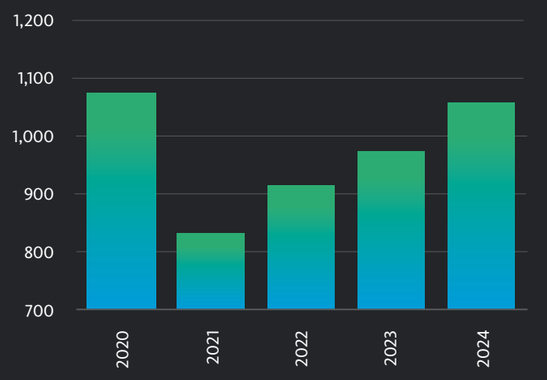
For Q4, device failure was the leading cause of medical device recalls, accounting for 44 events. Software was the second-most common concern with 31 events, followed by mislabeling and manufacturing defects with 27 recalls each.

Safety concerns were responsible for the most units recalled this quarter with 5.36 million, primarily linked to a recall of 5.32 million dental aligners. The second-most common reason for medical device recalls by volume was parts issues, with 5.34 million units impacted, including 4.44 million transfer sets used in dialysis. Leakage was tied to the third-highest number of units recalled, with 5.31 million units impacted.

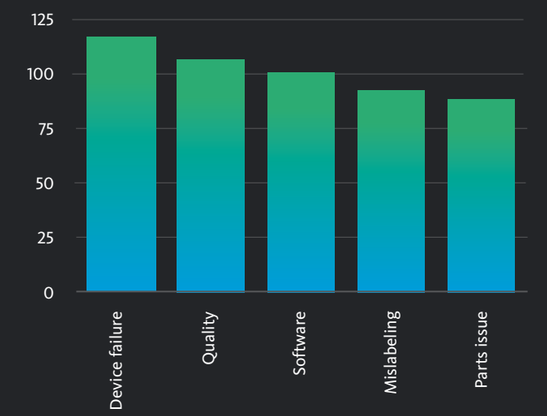
While the number of Class III recalls increased from five to eight in Q4, Class II and Class I recalls experienced notable decreases, dropping from 231 to 226 (a reduction of 78.9%) and from 26 to 25 (a reduction of 86.4%), respectively. The number of impacted units declined across all three categories compared to Q3, with Class III units experiencing the steepest drop at 98.6%. Class I and Class II units also fell significantly, by 86.4% and 78.99%, respectively.

Despite this quarterly drop, from an annual perspective, Class I medical device recalls reached their highest level in over 15 years.

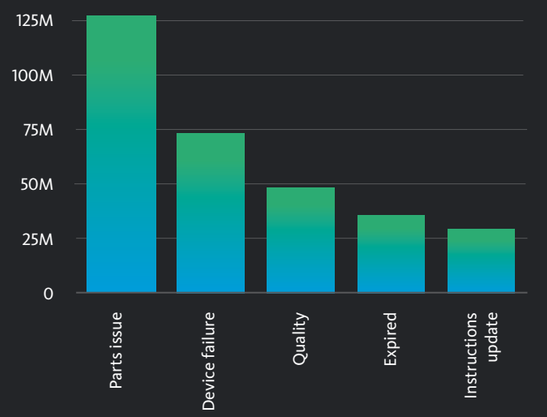
NUMBER OF RECALL EVENTS BY YEAR



2024 TOP 5 CAUSES BY RECALL EVENTS



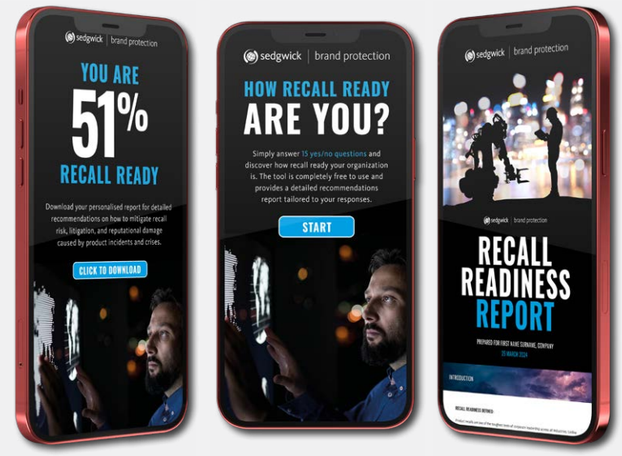
2024 TOP 5 CAUSES BY UNITS RECALLED



HOW RECALL READY ARE YOU?

As regulatory pressures intensify, it is crucial for medical device manufacturers and supply chain partners to assess how prepared they are to withstand a product incident or crisis. Sedgwick brand protection can help with its interactive **Recall Readiness audit.**

Simply answer 15 quick questions and you'll receive a personalized "recall readiness score" and a detailed report featuring tailored recommendations based on your responses. **Protect your brand and bottom line today, visit: www.recall-ready.app**



SEAN K. BURKE, PARTNER,
DUANE MORRIS

MEDICAL DEVICE RECALLS—WHAT'S AHEAD IN 2025?

The medical device industry had an eventful year in 2024. Not only were there nearly 100 Class I FDA recalls issued related to medical devices, but scrutiny regarding FDA recall protocols and responsiveness also sparked a new pilot program, which debuted with a flurry in November.

In addition to the resources needed to conduct a product recall, the incidents can also increase the risk of product liability litigation for medical device companies. The preemption doctrine continues to be a viable defense against certain legal claims for medical devices approved under the FDA premarket approval (PMA) process. However, its application depends on how courts interpret the rule, and that can vary greatly from court to court and case to case.

Early Alert Pilot Program

Dating back to one major manufacturer's 2021 recall of more than 15 million respiratory machines, criticism of the FDA's recall process has grown significantly. This culminated in January 2024 when the Government Accountability Office, a federal watchdog, accepted a request from two U.S. senators to review the Center for Devices and Radiological Health's (CDRH's) recall process.

Responding to criticism of how long it takes the FDA to notify the public of a product recall, the CDRH announced a pilot program in November 2024 to shorten the time between when the FDA first learns of a potential corrective action for a "high risk" recall and when such action is reported to the public. Per the program announcement, the relevant corrective actions may include the removal of the product from the market, product corrections, or updates to product use. The pilot is focused on devices within the areas of cardiovascular, gastrorenal, general hospital, obstetrics and gynecology, and urology. Other device areas—such as those used in orthopedics—are not impacted by the program at this stage.

There are only limited details on the exact boundaries and intended implementation of the program. One glaring uncertainty is how the CDRH will determine which potential corrective actions qualify as "high risk" and warrant immediate public notice. Typically, the FDA determines whether something amounts to a Class I recall, its highest risk category, after careful consideration of information provided as part of a company's voluntary recall of a product.

Under the pilot program, the FDA can issue an early alert before any voluntary recall is made by the company and potentially before the FDA has access to critical information. This means that the FDA could issue early alerts for products that it later determines do not rise to the level of a Class I recall after reviewing all pertinent information. Of course, patient safety and providing the public with information of potential risks are highly important. However, it is also critical to balance those considerations with the dangers of raising public alarm based on incomplete information, something the FDA has long sought to avoid.

While many of these issues and questions remain unanswered, the end of 2024 did provide some examples as to how the CDRH may seek to use this program. The year ended with a burst of six early alerts, with five occurring in the eight-day period between December 23 and December 31.

The notifications ranged from product-wide "do not use" recommendations to updates regarding previous warnings and instructions. The number and range of injuries reported also varied. For example, one manufacturer recommended that customers stop using an endoscope accessory associated with infection and 120 reported injuries, including one death. Another company recommended users discontinue use of a blood circuit device that would suddenly terminate a therapy session, but was associated with only three injuries to date. A third manufacturer was subject to an early alert after revising its instructions for use of an endoscope sheath after it was used for an incorrect purpose that was associated with one patient death.

From these examples, it is difficult to ascertain any pattern and potential thresholds that may trigger the FDA to consider an early alert. Obviously, each of these examples poses a risk for substantial bodily injury. However, it is hard to gauge at what point the FDA deems it necessary to provide a faster public alert. There were nearly 120 injuries and one death associated with the endoscope accessory before the alert was issued. A similar FDA action and recommendation were directed at the manufacturer of the blood circuit device, despite that product having a much smaller number of injuries reported and no associated death.

This potential uncertainty in application underscores some of the concerns raised about the program not yet having defined parameters. This lack of clarity leaves manufacturers in a difficult position of trying to investigate sudden reports of injuries to identify and address the actual issue while simultaneously working with the FDA on an early product alert. It will be interesting to see whether the pilot program continues to be used with frequency in the first quarter of 2025 and whether additional direction and guidelines are provided by the FDA.

The Preemption Doctrine for Recalled Products

Recalls—while often necessary—are expensive. In addition to the costs of carrying out a recall, there is also an increase in exposure to product liability lawsuits filed by patients alleging harm from the product. While the early alert pilot program could result in an increase in recalls and liability exposure for manufacturers, a federal court in Alabama provided a positive reinforcement earlier in 2024.

Federal law provides certain protections for medical device manufacturers if their device has been authorized by the FDA. This provision is rooted in a desire to promote innovation and to avoid juries and judges questioning the decisions of FDA scientists. Specifically, federal law 21 U.S.C. Sec. 360k(a), as confirmed by the U.S. Supreme Court, provides express preemption of state law-based claims where the device at issue received premarket approval (PMA) through the FDA.

SEAN K. BURKE, PARTNER,
DUANE MORRIS

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As a result, many common state law claims filed by injured plaintiffs against authorized medical devices are dismissed because they conflict with FDA compliance. However, device manufacturers commonly ask, "Does the preemption defense survive if the product is recalled?" The general answer to that question is yes, though with some caveats. From a regulatory perspective, the existence of a recall does not mandate that the PMA no longer has effect or has been withdrawn.

Rather, the withdrawal of a PMA is a separate process set forth under regulation 21 CFR Sec. 814.46. Without following those separate procedures for withdrawing a PMA, the PMA remains in place, regardless of a recall. This means that manufacturers may still argue for preemption in defense of a personal injury claim based on state law claims.

In order to defeat preemption, a plaintiff must assert a "parallel claim." This type of assertion says that the state law claim allegedly violated is no different than a violation of some federal law requirement. In other words, plaintiffs must allege a specific violation of an FDA requirement and present facts that establish a link between the manufacturer's violation of that requirement and the alleged bodily injury. Courts have routinely held that a recall itself does not automatically mean that any FDA requirements have been violated.

To that end, a court in Alabama confirmed this tenant of law in March 2024. The matter involved claims filed against a large manufacturer's recall of a PMA defibrillator due to battery depletion. Despite the recall, the court confirmed that the patient's claims were preempted by federal law because the patient's suggestion that a federal law was violated by the mere fact of a recall was insufficient.

This matter confirms that manufacturers undertaking a recall of a PMA device can be assured that the recall alone will not invalidate their PMA or otherwise strip them of a potential preemption defense.

We will continue to watch the evolution of the early alert pilot program in 2025 while also continuing to monitor growing attempts by organized plaintiff attorneys to circumvent the preemption defense.

MEDICAL DEVICE

EUROPEAN PERSPECTIVE

Programmes to promote more environmentally friendly and sustainable practices are priorities for UK and EU regulators. Several publications were issued in Q4 outlining strategies for medical device and life sciences companies to improve their environmental footprint.

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) updated stakeholders on its plans to reform the current UK Medical Device Regulations 2002. Its new roadmap focused on four key areas, with some new regulations expected to take effect in 2025.

The EU is also making extensive changes to its medical device and in vitro diagnostic medical device regimes. In October, the European Parliament issued a resolution calling on the European Commission to make changes to the draft regulations and move forward its efforts to implement the planned changes.

Stakeholders across the industry are waiting for final implementation of the long-awaited changes to the medical device regulatory schemes in both jurisdictions.

> *"The efforts in the EU & UK show just how far-reaching sustainabiliy goals are. Medical device manufacturers should review their current operations against the recommendations ahead of any new mandatory regulations."*

Push for greener practices in medical device sector

In November, MedTech Europe published a position paper with recommendations for implementing the EU Green Deal in healthcare. The European trade association for the medical technology industry said the report was in response to the European Commission's Sustainable Prosperity and Competitiveness Plan.

The suggestions include accelerating the rollout of renewable energies and smart clean energy infrastructures and leveraging the common goals of the green and digital agendas to increase overall system efficiencies. The association also recommended creating the right structure to foster collaboration and partnerships among all healthcare stakeholders to drive systemic change and continuous improvement across the social, environmental, and economic performance of healthcare systems.

MedTech Europe also expressed a need for genuine harmonisation of rules to fully complete the European single market. They called for steps to strengthen a sustainable finance framework that supports research and innovation in developing and utilising alternative materials, sustainable packaging, and circular products.

Other recommendations from the association include removing regulatory, financial, and administrative barriers to sustainability in existing legislation and to develop realistic, patient-centric, and economically viable transition pathways. These pathways should ensure that patients and practitioners have reliable, uninterrupted access to medical technologies during the transition to net-zero.

The report also mentions measures to enable circularity of medical technologies as part of the future Circular Economy Act and proposes simplifying chemical assessment processes to ensure there are safe and sustainable design policies for the transition to sustainable chemicals and materials.

Attorneys with Osborne Clarke highlight other considerations from the Commission's competitiveness plan that medical device companies need to consider. To comply with the Green Deal provisions, medtech and in vitro diagnostic medical device (IVD) companies will need to reduce their environmental footprint by implementing greener manufacturing processes, reducing waste, and minimising energy consumption. Other options include steps to use fewer hazardous materials in medical devices, making them easier to recycle at the end of their life cycles.

UK regulators are looking at similar challenges. In October, the Department of Health and Social Care (DHSC) published its "Design for Life" roadmap to build a circular economy for the medical technology sector. The goal is to increase resilience, drive growth, reduce costs, and improve sustainability.

Where possible, the government wants to transition away from single-use medical technology products and implement a functioning circular system that maximises reuse, remanufacture, and recycling by 2045.

The roadmap outlines 30 actions to achieve this vision, including initiatives to encourage positive behavioural change, new commercial incentives to provide circular medtech, and the creation of new standards to enable innovative products and services. The strategy also involves planning for a future decontamination and recycling infrastructure and establishing new collaborations to accelerate the emergence of transformative science.

The efforts in the EU and UK show just how far-reaching goals for sustainability are. Medical device manufacturers should review their current operations against the recommendations to see if there are improvements they can make ahead of any new mandatory regulations.

MHRA advances device post-market surveillance rules

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) published a revised roadmap for reforms to the UK Medical Device Regulations 2002. The updated plan reflects progress made in 2024 and offers additional clarity on the target dates to complete consultations, deliver legislation, and implement subsequent reforms to the regulatory framework for medical devices and in vitro diagnostic medical devices (IVDs) in Great Britain (GB).

Attorneys with Hogan Lovells outlined the four core tranches of work included in the roadmap. The first is new regulations for post-market surveillance. The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 (PSMR) were introduced before the UK Parliament in October 2024 and signed into law on 16 December 2024. The new requirements are expected to come into force in summer 2025.

The second area involves new regulations for pre-market requirements. In November, the MHRA published a consultation seeking input on four matters related to these provisions: a proposed international reliance scheme, the use of UKCA marking, classification and market access for IVDs, and a proposal to remove the current 26 May 2025 revocation date for four key pieces of retained EU legislation that are still included in the GB regulatory framework.

A third focus of the plan is policy development. Between now and Q3 2025, the MHRA intends to develop and publish guidance on several regulatory areas, such as exceptional use authorisations to supply a non-compliant medical device on humanitarian grounds; a policy intent statement on early access and innovation; and the publication of a specific IVD roadmap.

The final work area is software, AI, and digital mental health products. The agency plans to publish a series of guidances related to software as a medical device. Specific topic areas include Good Machine Learning Principles published in collaboration with the FDA and Health Canada, the use of AI as a medical device, cybersecurity, and digital mental health tech.

Significant work still lies ahead for both manufacturers and regulators. While the MHRA is working to offer guidance and updated plans, many questions will undoubtedly arise as the new regime is implemented.

More revisions ahead for EU medical device regulations

In October, the European Parliament (EP) passed a resolution calling on the European Commission (EC) to make additional changes to the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR).

While the EU's plans to overhaul the regulatory system for medical devices were ambitious, and some might say overdue, the transition has not been easy. The two regulations entered into force in May 2017 but are still not being enforced. There have been multiple adjustments and extensions over the past several years in response to demands from patient organisations, public health bodies, and the pharmaceutical and medtech industries. However, the EP feels the changes have not gone far enough or been enacted quickly enough.

The Parliament said that there have been significant challenges in implementing the MDR and IVDR, resulting in failures to achieve certification and approval of medical devices and IVDs. These shortcomings have impacted small and medium-sized enterprises (SMEs) in particular, as well as caused device shortages that have restricted patient access to life-saving therapeutic and diagnostic technologies.

The regulator also stated that many stakeholders, especially SMEs, notified bodies, and healthcare providers, have reported difficulties in navigating the complex regulatory procedures under the current MDR and IVDR framework. These challenges have the potential to impact the continuous availability of life-saving medical devices and critical IVD tests in the EU.

> *“With the revised EU PLD now in effect, there are increased risks for pharmaceutical companies. Based on an analysis of case law, lawyers state that 67% of product liability decisions by the CJEU concern pharmaceutical products and medical devices.”*

Attorneys with Bristows outlined some of the key demands from the EP, including adopting multiple implementing acts to address the most pressing challenges generated by the MDR and IVDR by the end of Q1 2025; undertaking a systematic revision of the two regulations; and resolving divergent interpretations that have arisen over the years.

The Parliament has also told the Commission it must urgently and fully implement the European database on medical devices (EUDAMED), calling the system a crucial but significantly delayed cornerstone of the MDR/IVDR framework. Additionally, the EP wants the Commission to eliminate unnecessary re-certification of products, stating that an entire product re-certification is not required for certain product updates or adjustments.

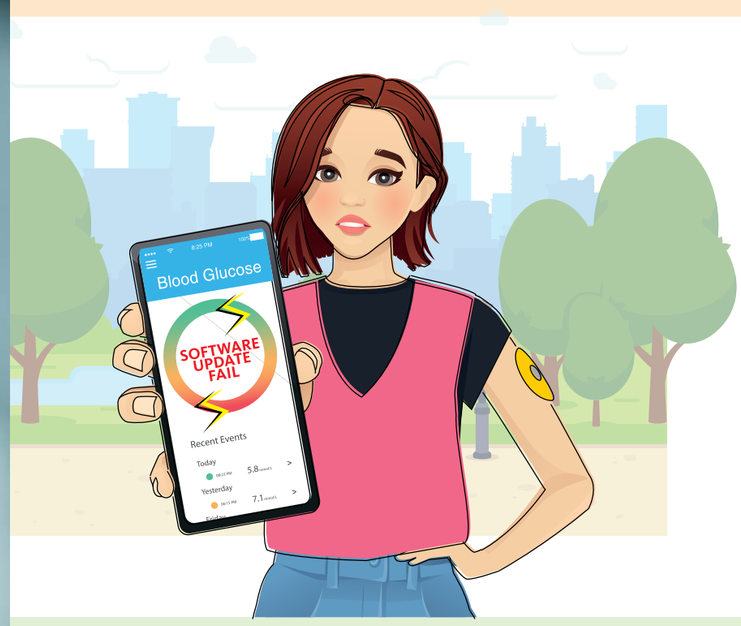
Furthermore, Parliament wants improvements in the performance, transparency, and accountability of notified bodies, including binding timelines to ensure the timely CE marking of medical devices and IVDs. Delays and backlogs have been an ongoing concern.

According to the legal experts, the EP has instructed the Commission to introduce special rules to expedite access to orphan and paediatric devices and to fast-track approval pathways for innovative technologies to address unmet medical needs and health emergencies.

To respond to Parliament’s demands, the Commission launched a consultation in December to assess the performance of the MDR and the IVDR. The comment period ends on 21 March 2025. From there, the Commission will have a lot of work to do, and Parliament and the industry will be watching.

European medical device recalls increased 11.1% in 2024, marking a 10-year high for the sector.

The 3,679 recalls set a new record, surpassing the previous high of 3,311 in 2023.

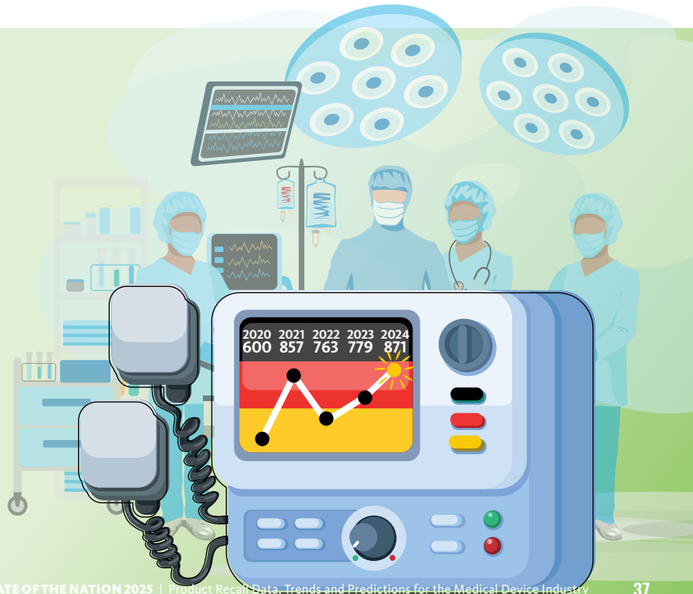


Software accounted for 504 events, making it the leading cause of recalls in 2024.

This marks the highest level of annual activity for any cause in the past three years.

Germany was the leading notifier of recall activity in 2024 with 871 events.

This marks the highest of number of annual alerts submitted by any country in the past 5 years.



EUROPE - MEDICAL DEVICE
2024 BY THE NUMBERS

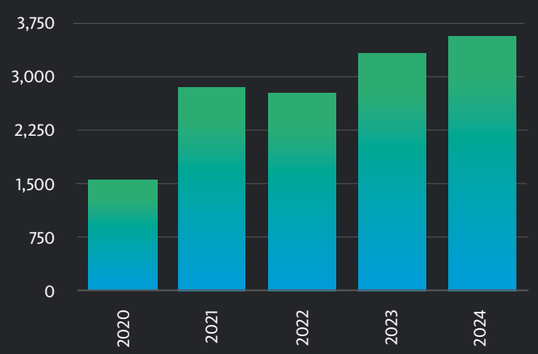
There were 893 EU and UK medical device recalls in Q4 2024, down 6.8% from the five-year quarterly high of 958 that was set in Q3. For the year, 2024 had 3,679 medical device recalls, setting a new annual record. The total is 11.1% higher than the record set just last year of 3,311 recalls.

Device failure was the leading cause of European medical device recalls in Q4 2024 with 121 events. This is 18.8% lower than the 149 recalls in Q3 2024. Software concerns were the second-most cited issue, accounting for 119 recalls, down from 144 last quarter.

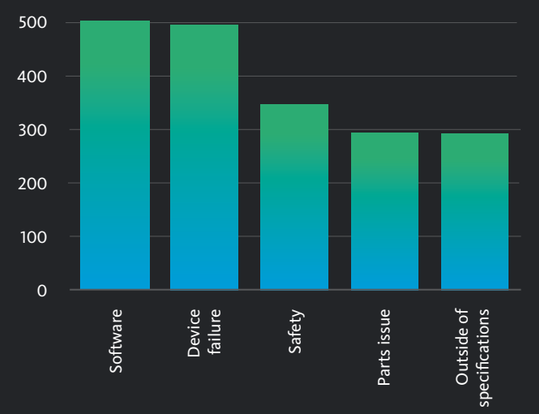
Software was also the top risk for medical devices in all of 2024. In Q4, there were 83 medical device recalls attributed to concerns about products being outside of specifications, making it the third-most common cause of recalls.

The same three countries have issued the most medical device recall alerts for both Q4 and all of 2024. France led with 217 notifications in Q4 2024. Germany issued 201 alerts this quarter, down from 227 in Q3. Italy was third with 153 notifications, a slight increase from 151 in Q3. The UK issued 110 notifications this quarter, putting it in fourth place in terms of alerts.

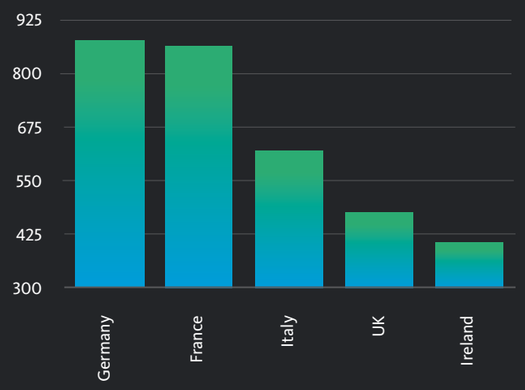
NUMBER OF RECALL EVENTS BY YEAR



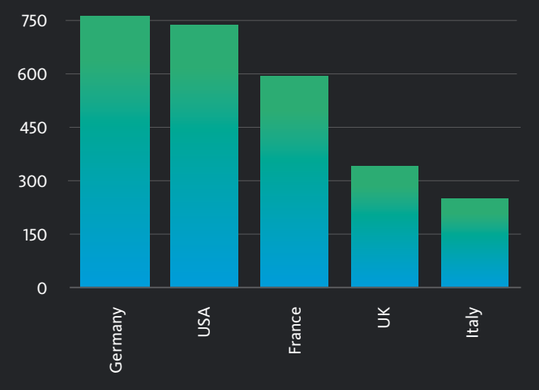
2024 TOP 5 CAUSES BY RECALL EVENT



2024 TOP 5 NOTIFYING COUNTRIES BY EVENT



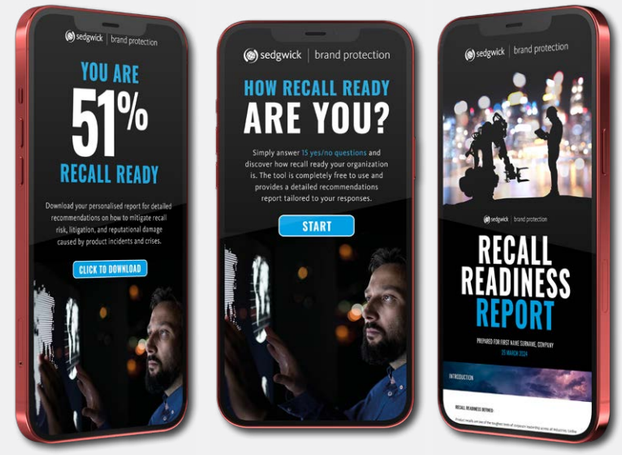
2024 TOP 5 COUNTRIES OF ORIGIN BY EVENT



HOW RECALL READY ARE YOU?

As regulatory pressures intensify, it's crucial for medical device manufacturers to assess how prepared they are to withstand a product incident or crisis. Sedgwick brand protection is proud to introduce its new interactive **Recall Readiness audit.**

Simply answer 15 quick questions and you'll receive a personalised "recall readiness score" and a detailed report featuring tailored recommendations based on your responses. **Protect your brand and bottom line today, visit: www.recall-ready.app**



MIRAN BAHRA, ASSOCIATE**, THOMAS PANTER,** SENIOR ASSOCIATE, **AND**
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UPDATES ON THE EU AND UK MEDICAL DEVICE REGULATORY LANDSCAPE

Both the EU and UK are making substantial updates to their frameworks for regulating medical devices. The changes will impact stakeholders across the industry by adding more robust reporting requirements and increasing post-market obligations.

Challenges to the EU Medical Device Regulatory Framework

On 23 October 2024, the European Parliament adopted a resolution calling on the European Commission to propose delegated and implementing acts to the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR). Parliament set a deadline of the first quarter of 2025 for these measures.

Regulators have been working on revisions to the existing regulatory framework for medical devices and in vitro diagnostic medical devices (IVDs) for several years. The updates were prompted by several high-profile scandals involving allegedly unsafe medical equipment. The changes are an attempt to bring about higher standards of safety, transparency, and clinical performance while not hindering innovation.

The MDR and IVDR introduced more robust requirements for post-market surveillance, vigilance reporting, and clinical evaluations. However, there were significant implementation challenges due to the complex regulatory requirements coupled with a shortage of notified bodies to certify devices under the new regime. These factors resulted in delays and failures to achieve certification and approval of medical devices, ultimately restricting patient access to devices.

Parliament's resolution calls for transparent and binding timelines, including clock stops for procedural steps in conformity assessment by notified bodies. Parliament also wants to eliminate re-certification of products, stating that certain product updates or adjustments should not necessarily lead to an entire re-certification of the device. The resolution also calls on the Commission to consider fast-track and prioritisation pathways for the approval of innovative technologies in areas of unmet medical need.

The Commission launched a targeted evaluation of the MDR and IVDR on 12 December 2024 to take stock and assess whether the rules are effective, efficient, and proportionate and meet both current and emerging needs. The consultation remains open until 21 March 2025.

Future Regulatory Framework for UK Medical Devices

Reform of the UK medical device regime remains at the top of the agenda for UK policymakers. Whilst the seeds of this reform reach back as far as the 2021 consultation and the resulting government response, momentum gathered in January 2024 with the Medicines and Healthcare Products Regulatory Agency (MHRA) publishing a roadmap towards the future regulatory framework for medical devices.

In a post-election update on the planned Med Tech regulatory changes, the MHRA confirmed that the "shape" of the roadmap would remain the same, apart from some of the details and timings. On 11 December 2024, the agency published a revised plan with a further update on the intended timelines for implementing the new regulations.

The medical device regulatory roadmap, which is a living document, focuses on four areas: new regulations for post-market surveillance, new regulations for pre-market requirements, policy development, and software, including AI and digital mental health products.

Post-market surveillance

A draft post-market surveillance (PMS) statutory instrument (SI) for medical devices was laid before the UK Parliament on 21 October 2024. The objective of the SI is to introduce more stringent and clearer post-market surveillance requirements that are risk proportionate with improved regulatory oversight. The measures were signed into law before the end of 2024 with a six-month transition period and will enter into force on 16 June 2025.

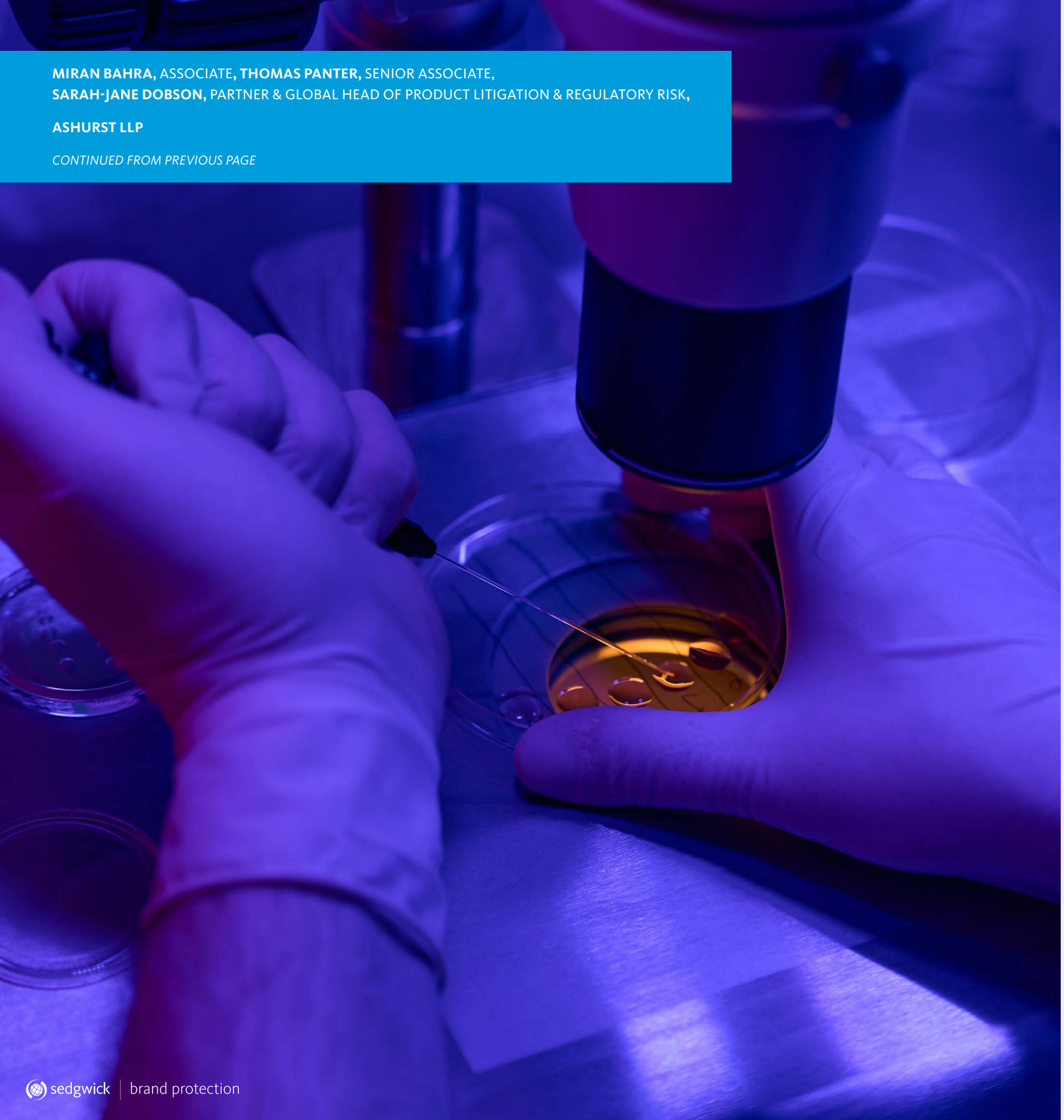
The regulations expand the scope of medical devices that must comply with post-market surveillance requirements in Great Britain, setting out in more detail what must be included as part of a PMS system and increasing obligations around reporting serious incidents. In contrast to the previous regime that existed under the 2002 Medical Device Regulations, these regulations are designed to provide a more clearly defined system which will better safeguard public health and patient safety through more stringent PMS requirements.

The MHRA has put in place comprehensive guidance documents on post-market surveillance to assist medical devices manufacturers in complying with the new rules.

Pre-market requirements

A public consultation on proposed updates to the UK regulatory framework for medical devices closed on 5 January 2025. The consultation focused on routes to market for medical devices and IVDs. It sought views on four key areas: market access for IVDs, UKCA marking, international reliance, and assimilated EU law. The updated roadmap foresees new pre-market legislation being in force in early 2026. This means 2025 will be an active year in terms of consultation on these measures.

The pre-market regulations are anticipated to introduce improvements for implantable medical devices, including up-classifying them, which will result in more stringent requirements for manufacturers.



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CONTINUED FROM PREVIOUS PAGE

The new rules are also likely to align IVD classifications with those of the International Medical Device Regulatory Forum and change the classification of several types of devices, in particular, increasing the class of certain Software as a Medical Device (SaMD) products.

Other expected revisions include ensuring devices have a unique device identifier (UDI), stronger requirements for technical documentation, new mandates for custom-made devices, and new rules regarding the claims manufacturers can make about their devices.

The proposed reforms will also look at introducing a framework for international recognition to enable swifter access for devices already approved by comparable regulators and greater alignment of essential requirements for medical devices with those of the EU. The UK introduced similar measures in 2024 for pharmaceutical products.

The MHRA's hope is that these pre-market regulations will enable greater international collaboration combined with more patient-focused and proportionate requirements for medical devices.

Policy development

As part of general policy development, the UK is considering creating and publishing an exceptional use authorisation (EUA) guidance, an IVD roadmap, and a policy intent statement for early access and innovation. Regulators are also refining policy on the guidance on health institution exemption (HIE) to align with the government strategy. The aim is to have these initiatives completed by September 2025.

Conclusion

The aims of these wide-spread reforms for regulating medical devices, both in the EU and the UK, remain unchanged—to improve and protect patient safety. To this end, additional regulatory burdens on device manufacturers, importers, and distributors are being imposed across the board.

As always, the challenge for, and the source of criticism from, the medical device industry is whether such stringent and increased obligations strike the right balance and do not impose a barrier to the supply of medical devices, patient care, and innovation in this important field.

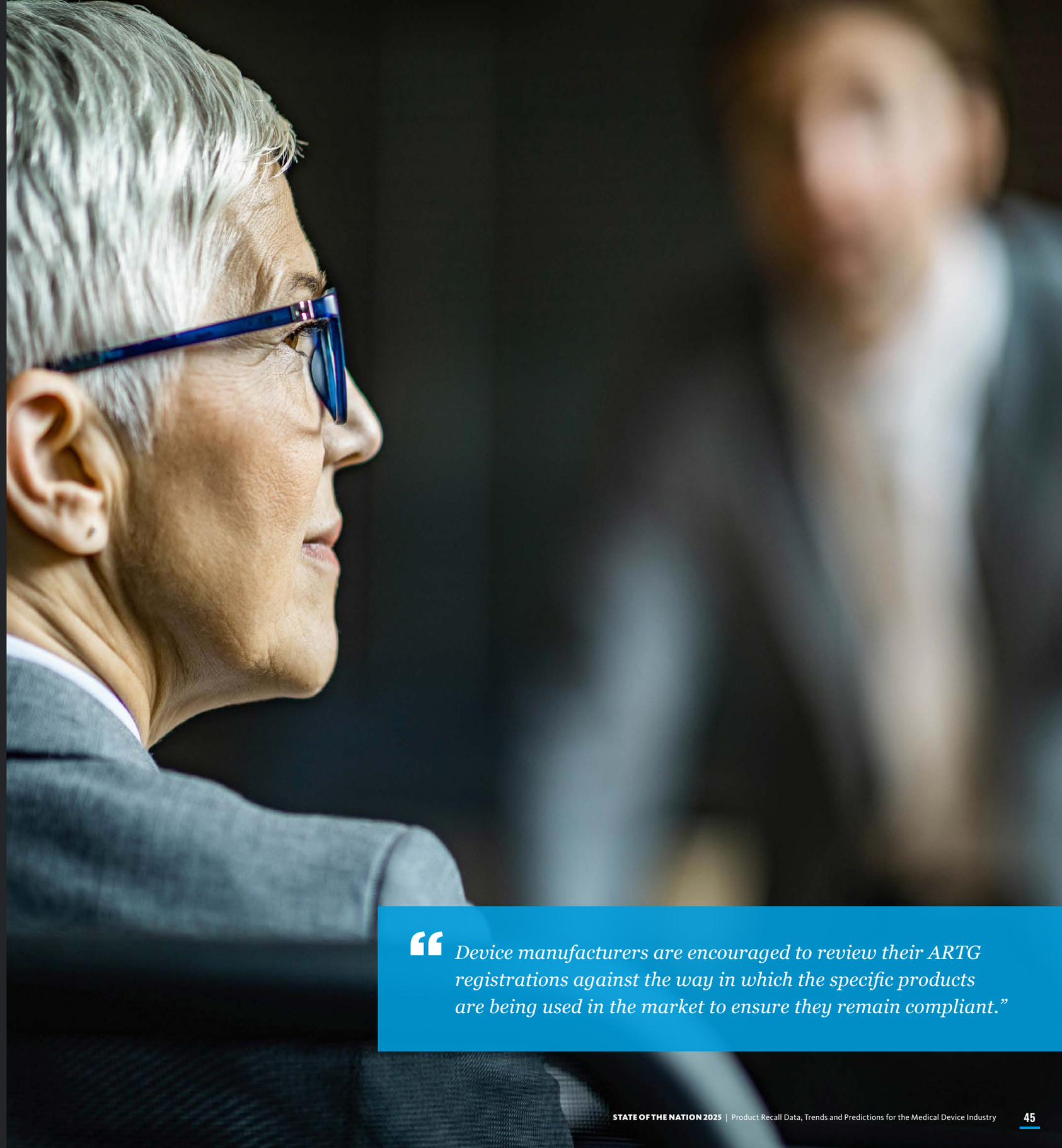
MEDICAL DEVICE

AUSTRALIAN PERSPECTIVE

The Federal Court of Australia fined a major medical device manufacturer $22 million in penalties for breaching the Therapeutic Goods Act. The court ruled that the device company had sold more than 16,000 units of a product that was not properly registered in the Australian Register of Therapeutic Goods (ARTG).

After several years of transition, medical device companies must now comply with the new classifications for software-based medical devices when listing them in the ARTG. The new system assesses product use and potential risk to patients to determine the risk classification for the product. The new definitions align more closely with EU rules.

The Therapeutic Goods Administration continues to refine medical device regulations to ensure that they are keeping up with changes to technology and patient care.



> *"Device manufacturers are encouraged to review their ARTG registrations against the way in which the specific products are being used in the market to ensure they remain compliant."*

Court issues largest Therapeutic Goods Act penalty

In September, the Federal Court of Australia ordered a major medical device manufacturer to pay $22 million in penalties for breaching the Therapeutic Goods Act. The court ruled that the company unlawfully supplied 16,267 units of a bone graft kit to more than 100 hospitals across Australia between 1 September 2015 and 31 January 2020. This fine is the largest ever imposed for non-compliance with the Act.

While the fine is significant, it was much less than it could have been. If the court had determined that each of the 16,267 units was a separate breach, rather than considering the matter as one single course of conduct, the maximum penalty could have been $162 billion. The Court also ordered the company to make a $1 million contribution to the Therapeutic Goods Administration (TGA) for legal costs incurred by the agency in pursuing the matter.

Most therapeutic goods must be entered in the Australian Register of Therapeutic Goods (ARTG) before they can be lawfully supplied in Australia. Though the manufacturer did enter the device in the ARTG, it was listed as a composite product with two separately packaged parts—a spinal cage and a bone graft kit. However, the company saw "significant clinical demand" for the kit on its own, even though it was not authorised to supply the single component as a standalone product.

Professor Anthony Lawler, Deputy Secretary of the Department of Health and Aged Care and head of the TGA, called the large penalty, "a reminder to sponsors and others in the therapeutic goods industry to take their obligations seriously."

Attorneys with Gadens recommend that therapeutic goods manufacturers and suppliers take steps to ensure that their internal processes support compliance with their goods' specific ARTG entries. Suggested actions include conducting regular quality control audits and compliance reviews that specifically consider ARTG entries.

In addition, the legal experts counsel companies to review and consider their ARTG registrations against the way in which the specific products are actually being used in the market to ensure that the current ARTG registrations cover that use. Ideally, this assessment should be done frequently as part of ongoing compliance reviews and quality control audits.

Software-based medical device regulations in effect

The Therapeutic Goods Administration (TGA) implemented major reforms to Australia's regulations related to software-based medical devices, including software that functions as a medical device.

The amended regulations took effect on 25 February 2021 and the transition period ended on 1 November 2024. All new applications for inclusion in the ARTG must now meet the revised classification rules to be legally supplied in Australia.

The updates classify software-based medical devices according to their potential to cause harm if they provide incorrect information. The new classifications more closely align with the updated European Union Medical Devices Regulations that are currently being adopted.

The changes apply to devices that perform certain functions such as providing a diagnosis or screening for a disease or condition; monitoring the state or progression of a disease or condition or the parameters of a person with a disease or condition; specifying or recommending a treatment or intervention; or providing therapy through the provision of information.

The factors used to calculate risk vary by product use. For example, software intended to specify or recommend a treatment or intervention is considered a Class III device if the absence of the treatment or intervention, or where the treatment or intervention itself poses a high risk to public health or lead to a serious deterioration in a person's health or death. In comparison, software intended to provide information to a relevant health professional to assist in making a decision about treatment or intervention that has the potential to cause the same adverse outcomes is considered a Class IIb device.

Several types of software products are exempt from the new classifications. These include certain clinical decision support systems, which are still considered a medical device but are not subject to all regulatory requirements.

Other medical software products have been excluded and are not subject to any TGA regulatory requirements. These include consumer health products, software that helps digitise other processes, population-based analytics tools, Laboratory Information Management Systems (LIMS), and technology that enables telehealth, healthcare, or dispensing.

Device manufacturers were required to notify the TGA that they had an eligible inclusion for the ARTG, obtain the appropriate evidence of conformity assessment, and apply for their medical device to be included in the ARTG under the new classification rules before 1 November 2024.

Manufacturers who did not submit their completed application by the deadline were instructed to cease supply on or before this date and cancel their inclusion in the ARTG.

The reforms also included amendments to the Essential Principles (EPs) for medical devices to clarify existing requirements for software-based products. The EPs are the safety and performance requirements for medical devices, including in vitro diagnostic devices (IVDs).

The updates clarified the existing requirements for cybersecurity and the management of data and information, as well as rules relating to development, production, and maintenance included in Essential Principle 12.1. They also expanded Essential Principle 13.2(3) to allow information to be provided electronically rather than on a leaflet.

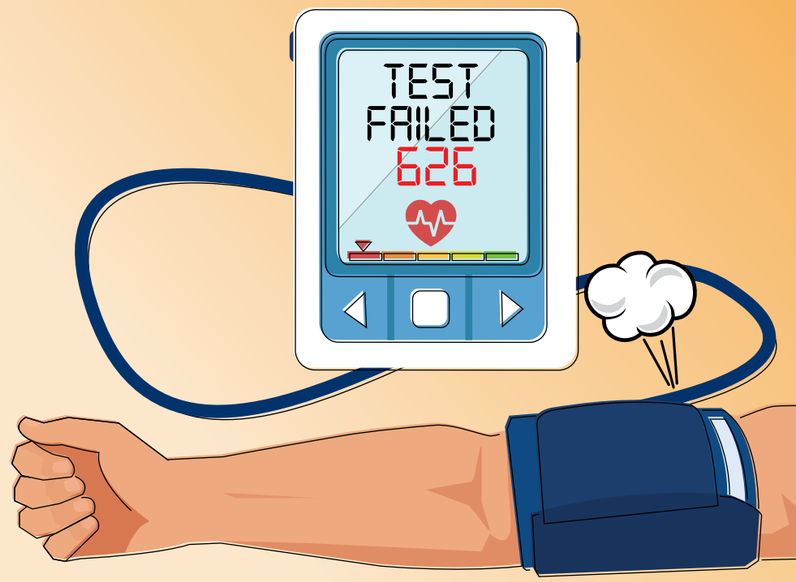
In addition, a new principle, Essential Principle 13B, was added that requires the current version and build number for the software to be made accessible and identifiable to users of software-based medical devices. Information must be in English, but it can also be displayed in other languages. This new EP took effect on 1 November 2024, alongside the other changes.

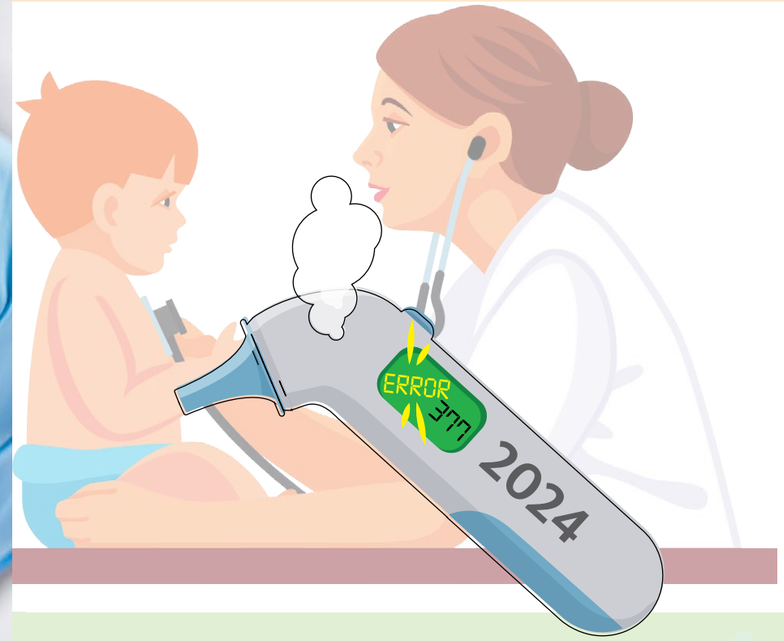
Software-based medical device companies looking to enter the Australian market must ensure they are aligned with the new product classifications. Similarities with the EU market may facilitate compliance for companies operating in both markets.

> *"Software-based medical device companies looking to enter the Australian market must ensure they are aligned with new product classifications. Similarities with the EU market may facilitate compliance."*

There were a **total of 626 medical device safety actions** recorded in 2024.

This marks an increase of 4.7% from the 598 actions recorded in 2023.





Of all product safety actions issued, **defect corrections accounted for 60.2%** (equating to 377 events).

This was followed by product recall with 208 events, product defect alert (27), and hazard alert (14).

Software was the leading cause of medical device recalls in 2024 with 100 events.

Device failure was the second most common cause with 93 recalls, followed by manufacturing defects with 59.

AUSTRALIA - MEDICAL DEVICE
2024 BY THE NUMBERS

In the second half of 2024 (H2 2024), the TGA had 326 product safety actions across the medical device sector. These included 115 product recalls, 196 defect corrections, 12 defect alerts, and three hazard alerts. This is an increase from the 300 safety actions in H1 2024, which included 15 defect alerts, 181 defect corrections, 93 product recalls, and 11 hazard alerts.

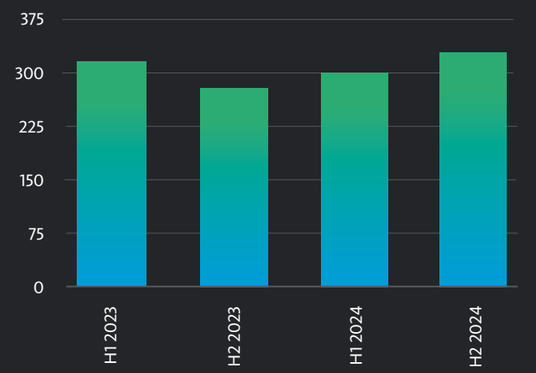
For all of 2024, there were 626 product safety actions. Medical device safety actions have been increasing steadily over the past several years, with 519 events in 2022 and 598 in 2023.

Software concerns and device failure resulted in 49 safety actions each, more than any other hazard categories in H2 2024. Software issues were also the topic risk for all of 2024. Manufacturing defects were second with 33 events in H2 2024, up from 26 actions in H1 2024. False results were the third-most common risk in H2 2024 with 27 recall events.

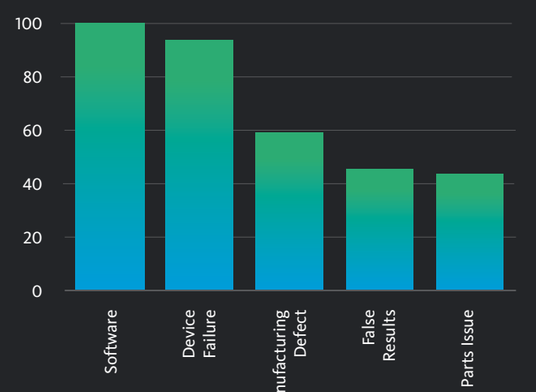
The majority of medical device safety actions occurred at the hospital level in terms of distribution into the market. There were 298 events in this category, up from 259 in H1 2024. There were 14 safety actions at the consumer level and 10 at the retail level. In addition, three actions took place at the wholesale level and one at the sponsor level.

In H2 2024, there were 37 medical device recall actions categorised as Class I, up slightly from 36 events in H1 2024. There were 241 events deemed Class II events, compared to 223 in the first half of 2024. There were 48 Class III actions in H2.

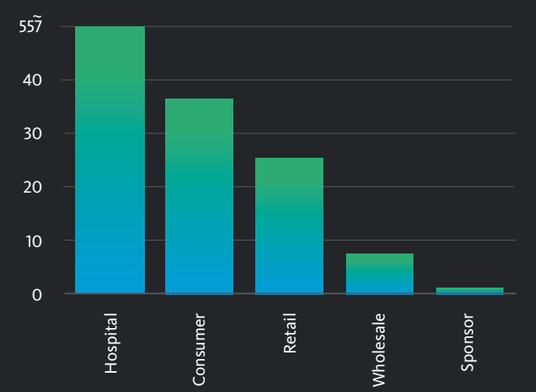
NUMBER OF SAFETY EVENTS BY HALF YEAR

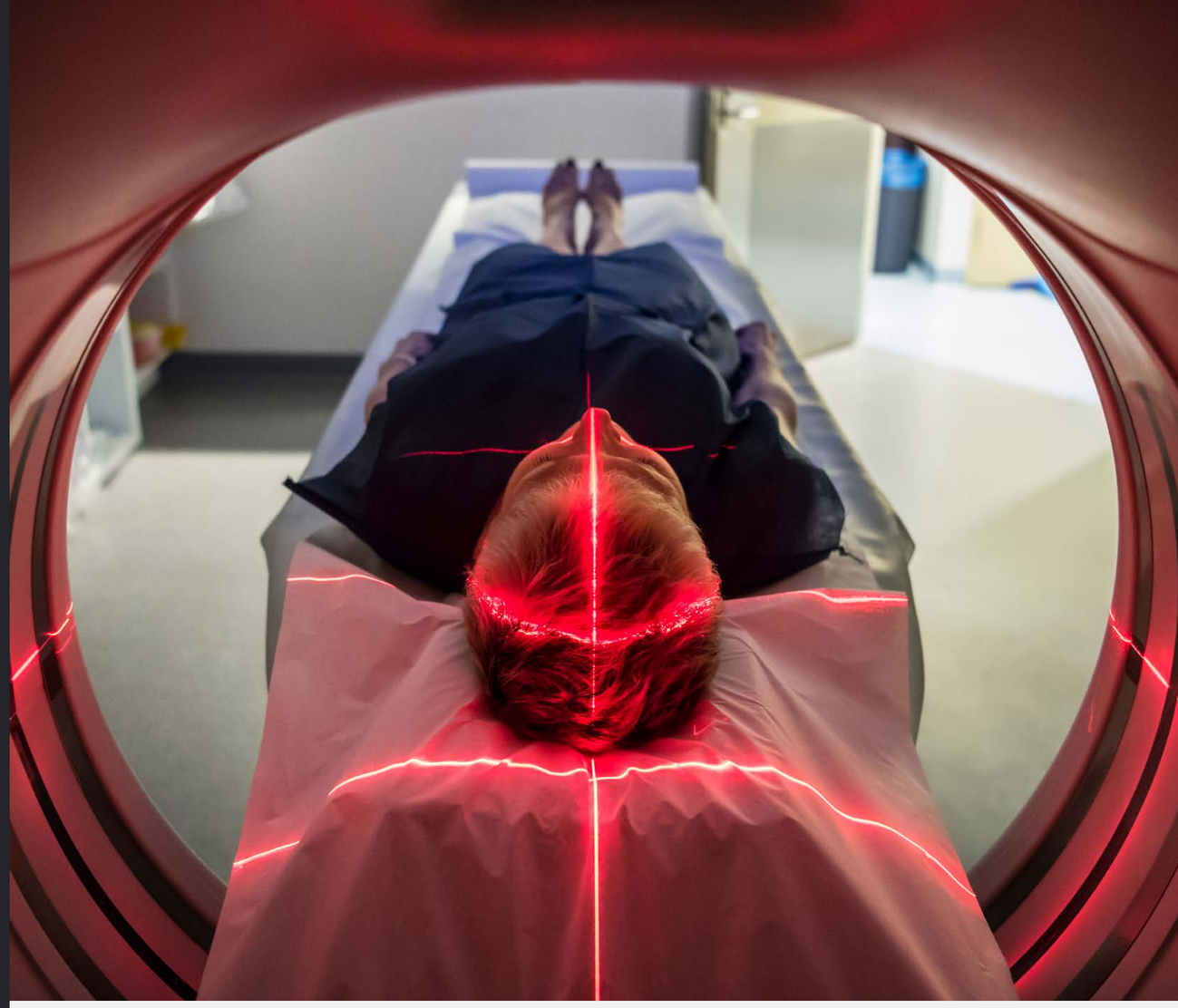


2024 TOP 5 CAUSES OF SAFETY EVENT



2024 TOP 5 DISTRIBUTION CHANNELS BY EVENT





HOW RECALL READY ARE YOU?

As regulatory pressures intensify, it's crucial for medical device manufacturers to assess how prepared they are to withstand a product incident or crisis. Sedgwick brand protection is proud to introduce its new interactive **Recall Readiness audit.**

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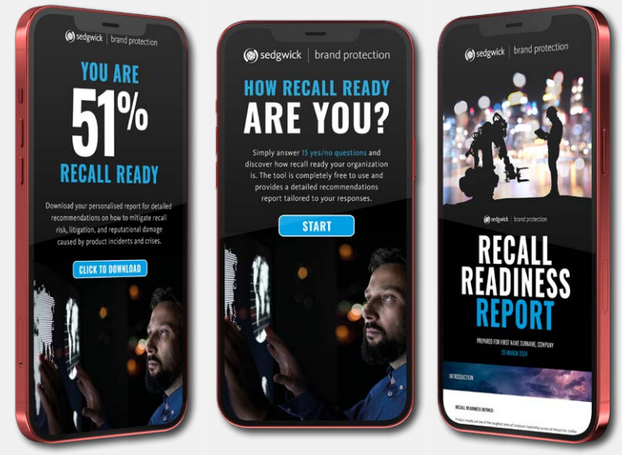

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BIG CHANGES IN MEDICAL DEVICE SAFETY REGULATIONS

As a testament to the volume and pace of change happening in the medical device sector, there have been several key product safety regulation developments between late 2024 and early 2025 for the Australian market. These changes primarily relate to enhanced product safety standards, increased regulation, and mandatory obligations, particularly around regulatory reporting.

International harmonisation is another theme addressed in these latest updates. The Therapeutic Goods Administration (TGA) is one of several regimes and practices in Australia are now deferring to or recognising international counterparts as part of their everyday and accepted functions.

In addition, certain popular and higher-risk product categories that are prevalent in modern day society have been targeted for regulatory change. These include more invasive medical devices and medical software.

These trends are mirrored globally. Australia's focus on these topics ensures the country's continued prominence as a market leader in medical device regulation. Local and international businesses alike should take an interest in these legal trends and developments.

Increased Mandatory Regulatory Reporting - Adverse Event Reporting

New mandatory adverse event reporting requirements for medical devices take effect on 22 March 2025 . The regulation follows a lengthy legislative process. In 2021, the TGA issued a public consultation to garner feedback on a discussion paper, "Potential Mandatory Reporting of medical device events by healthcare facilities in Australia." The publication explored important topics such as the feasibility of the new obligation, the scope of its application in terms of what types of medical devices and facilities were included, potential issues with duplication, and accountability of the system as a whole.

The feedback obtained formed the basis of the Therapeutic Goods Amendment (2022 Measures No. 1) Bill 2022, which was passed into law on 21 March 2023. This legislation makes it mandatory for all public and private hospitals, as well as any other healthcare facilities, to report on adverse events.

This reporting practice is aimed at greatly increasing the likely reportable events in Australia as a way to improve patient safety standards. The data collected during these reports and the post-market surveillance activities carried out thereafter will help stakeholders more quickly detect device-related issues.

In that regard, the TGA continues to collaborate with the Australian Commission on Safety and Quality in Health Care (ACSQHC) and Australian hospitals, peak bodies, and state and territory governments to improve and increase rapid information sharing about medical device safety and effectiveness.

Medical device companies should be cognisant of these new obligations within the supply chain since entities other than the device sponsor may have their own obligations to report. Stakeholders should employ a joined-up product safety approach to ensure consistency, coordination, streamlined actions, and positioning with the TGA when an obligation is triggered by one or several actors.

Traceability Requirements - Unique Device Identification

The TGA remains focused on the roll-out of its unique device identification (UDI) system, the first system of its kind in Australia. The aim is for the system to be adopted throughout the healthcare system and supply chains to allow improved tracking and tracing of medical devices. The system is positioned to assist with earlier and quicker notification to healthcare facilities, healthcare professionals, and patients if there is a medical device safety issue.

The revised regulations introduce requirements for pre-market traceability and post-market monitoring of medical devices. It will better align Australia's regulatory framework with global standards.

To bring about the UDI system, the TGA consulted extensively with sponsors, manufacturers, and healthcare communities throughout the supply chain and collaborated with the ACSQHC. The agency also made amendments to the Therapeutic Goods Act 1989 and the Medical Device Regulations 2002, established the Australian UDI Database (AusUDID), and ran state-based healthcare pilot sites to inform use and adoption of UDI in healthcare organisations.

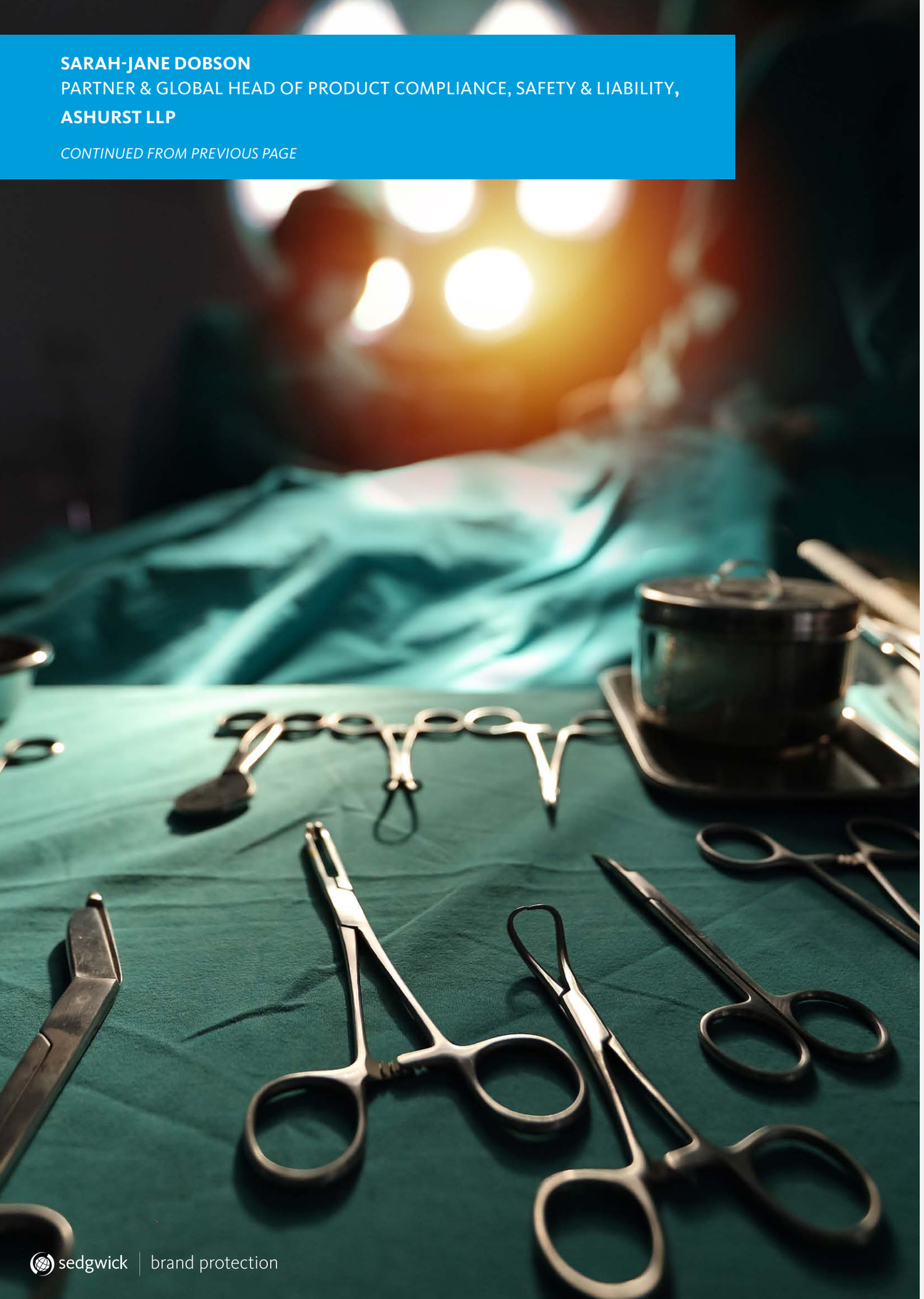
The TGA continues to take practical steps to fully launch the system. On 29 November 2024, the agency implemented significant enhancements to the AusUDID system, including changes where there are multiple sponsors for the same medical device consultation, database structure updates, fixes to system issues, the removal of all existing data, and updates to a bulk upload template to allow a structured way to standardize the input of large amounts of data.

On 12 December 2024, the TGA published draft guidance to help sponsors and manufacturers of medical devices comply with the newly introduced UDI obligations. Included in the guidance are the types of medical devices and in vitro diagnostic (IVD) medical devices for which the UDI regulations are applicable, labelling requirements, data submission requirements, specific device requirements, processes to get and apply a UDI, and how to submit and maintain UDI data in the AusUDID.

Medical device manufacturers should move towards early implementation of these obligations, which are aimed at improving traceability in the event of product safety issues. Lack of traceability often leads to recalls that are broader in scope. Having the ability to better identify products will be a benefit for manufacturers.

Acceptance of Global Safety Practices – FDA Approvals

On 18 October 2024, the Therapeutic Goods—Medical Devices Information Amendment Determination No. 2 2024 introduced flexibility to the Australian Register of Therapeutic Goods (ARTG) process for certain medical devices based on an expanded recognition of U.S. Food and Drug Administration (FDA) approvals. The ARTG is the public database of therapeutic goods that can be legally supplied in Australia.



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In particular, Class IIa devices, which are exempt from FDA 510(k) requirements, can now utilise a Medical Device Single Audit Program (MDSAP) certificate to be included in the ARTG. Class III medical devices with clearance under FDA 510(K) can similarly make use of a MDSAP certificate for entry into the register.

However, in an attempt to continue to ensure high levels of patient safety, devices supported by 510(k) clearances must undergo a mandatory TGA application audit before being included in the ARTG. This is an additional requirement for these U.S. FDA-approved devices.

Based on this development, companies with an existing presence in the U.S. may be able to better leverage and streamline their compliance practices with careful and considered product launch planning.

Regulation of Exempt Medical Devices

The TGA is currently assessing feedback from a public consultation conducted between April and June 2024 which sought comments on proposals to improve the regulation of exempt medical devices and Other Therapeutic Goods (OTGs).

Currently, exempt medical devices and OTGs may include custom-made medical devices, patient-matched or low-volume devices, devices used only for an individual or an immediate family member, and clinical decision support software that meet specific criteria.

The main purpose of the consultation was to enhance transparency, identification, and awareness of these products, and support prompt action if safety issues arise. The results of the consultation will likely lead to regulatory changes in 2025 that are aimed primarily at enhancing transparency, identification, and awareness of exempt medical devices to improve post-market surveillance and ultimately patient safety.

These developments will complement the raft of legislative changes already in place, which the medical device industry should continue to track and implement in a timely fashion. Companies impacted by these matters should also consider early participation in consultation schemes to try and influence the appropriateness of the final legislation introduced wherever possible.

Commentary

The wide-sweeping reforms taking place in Australia reflect the growth and dynamism of Australia's medical device industry. The developments continue to secure Australia as a world-leader in this space. Companies should consider how they can apply Australia's increasingly stringent requirements as part of a global product portfolio.

In particular, the introduction of incident-based triggers for regulatory reporting in the context of healthcare facilities and adverse events mirrors a growing trend throughout the world. The EU in its general product safety regime and the UK in its draft general product safety regime are both moving away from the historic preference of a risk-based approach to this incident-based approach. Australia's increased obligations in respect to incident reporting is in keeping with this global trend.

The emphasis on product traceability and identification requirements is a well-recognised and necessary precursor to successful product safety actions. Whilst potentially a large uplift at the outset, in the long run it has helped companies more accurately determine the scope of any product corrective actions and minimise the cost and possible reputational harm.

The recognition of international compliance practices is slightly against the global trend of regulatory divergence. It speaks to an international mindset that many modern-day companies are likely to appreciate.

Rapid changes around product safety issues in the medical device industry are likely to continue in Australia. Companies are encouraged to not only track but also proactively seek out these developments to ensure forward-thinking in product development matters and general compliance practices.

CONCLUSION

Across jurisdictions, regulators advanced a series of measures to balance implementing new innovations like AI and telehealth with the need to protect consumers in 2024. There were serious repercussions for companies who did not take action quickly enough or weren't transparent about product safety issues.

Fairness and transparency were also important themes. Regulators want to be sure that consumers have access to truthful information when making purchasing decisions and that companies have equal opportunities, especially in rapidly changing markets like AI.

For the medical device industry, manufacturers and distributors are facing major regulatory changes in multiple jurisdictions. While some, including the EU's MDR and IVDR have been pending for years, actual implementation and enforcement will still cause challenges.

In the U.S., the political climate is increasingly rocky. The Republican party is in control of both houses of Congress and the White House. The new administration has already introduced a number of tariffs which could impact the medical device industry and cut funding for health campaigns and medical device research, both domestically and abroad. In addition, the new Secretary of Health and Human Services, whose agency controls the FDA, is expected to break with tradition around many policy decisions.

With all the unknowns, companies need to plan for risks across a variety of areas, including:

- Business interruptions
- Supply chain challenges
- Regulatory and legislative changes
- Financial impacts
- Product updates, upgrades, and warranty work
- Product recalls and market withdrawals
- Data privacy and cybersecurity issues
- Innovation and advancements in technology
- Dynamic consumer demand
- Customer and partner apprehension

Unfortunately, product recalls in today's business environment are inevitable. Many regulatory agencies recommend, even mandate, that companies have recall, remediation, and/or risk management plans in place as part of their standard business processes. Advance planning means better protection for your customers, brand, and bottom line when the inevitable product issue does occur.

As regulatory pressures intensify, it's crucial for manufacturers and supply chain partners to assess how prepared they are to withstand a product incident or crisis. Sedgwick brand protection is proud to introduce its new interactive Recall Readiness audit.

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Whether planning for or actively managing a product safety crisis, leveraging the experience and insights of an external partner can save millions of dollars in regulatory and litigation costs, as well as time and stress on other internal resources. In addition, their expertise will help you honor your commitments to customers, supply chain partners, industry groups, and regulators, while protecting your reputation among the stakeholders that matter most.

ABOUT SEDGWICK BRAND PROTECTION

We are in-market risk experts. We are problem solvers. We protect businesses, their customers, and our environment through best practice product recall and remediation solutions.

Since 1995 we've worked with the world's leading medical device brands to help manage the risks and minimize the impacts of in-market business and product crises. When your reputation is on the line, we put our three decades of global experience on 7,000+ recalls affecting 500MM+ units to work for you. No one knows more about the recall and regulatory process than we do.

Through that lens, we've seen the sector evolve based on changing legislation, advancements in technology, shifting healthcare needs, and the growing complexities brought about by the transformation of supply chains.

We haven't just watched this evolution. We've been part of it. We've helped mecical device manufacturers around the world prepare for and adapt during some of the most challenging events in their history.

While this Index report outlines the changes on the horizon, our experience ensures that no challenge is unfamiliar or uncharted. In fact, these events—though they may feel overwhelming for the companies facing them—can become pivotal moments to reinforce trust and strengthen brand reputation when handled effectively.

Sedgwick's extensive brand protection resources, combined with our unmatched experience handling thousands of recall events, gives us a unique perspective on the risks, challenges, and often overlooked opportunities associated with the reputational threats you face every day.

In an increasingly-complex and regulated world, being prepared for risks is essential. Having the capabilities to act quickly and effectively is critical. Let us leverage our capabilities for you.

To find out more about our product recall capabilities, contact us today.

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