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Greenwheel Insights

What if this is an unsafe product? Assessing the effectiveness of product recalls for medical devices

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Executive Summary

Medical devices play a critical role in improving quality of life and extending life expectancy. As the global population ages, the demand for medical devices will continue to grow. With the surge in the number and types of medical devices in the market, it is not surprising to see an increase in the number of product recalls.

All medical devices carry inherent risks. Safety risks may occur due to errors in design, assembly, clinical application, or consumer use. Businesses are responsible for implementing robust risk management systems, and should errors arise, corrections and/or corrective actions are taken. Product recall is a vital component in a wider system on product safety.

Businesses face many challenges in carrying out product recalls. The definition of good product recall can vary by jurisdiction. Product safety data and reasons for recalls for medical devices are not collected globally. Clinical and patient data on device safety are not fed back to manufacturers. Manufacturers operate in a complex value chain through many intermediaries before reaching the end-users or consumers.

To help investors assess the effectiveness of product recall for medical devices, Greenwheel developed an investor checklist based on the best practices identified by international organisations, regulatory bodies, academic research, and industry research.

The Checklist consists of three key steps in the recall cycle. Within each step, Greenwheel highlights the actions businesses can take:

(1) **Prevent a product recall**: build good governance; maintain a quality management system; ensure product traceability; develop a recall strategy; develop a communication strategy; adopt a post-market surveillance plan; conduct mock product recalls; and, establish a complaint mechanism

(2) **Implement a product recall**: adopt a corrective and preventive action plan; communicate to external stakeholders; remediate adverse impacts; remove products sustainably; and, write a status report

(3) **Monitor and learn**: monitor recall effectiveness and commit to continuous learning and improvement

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The Investor Need

As a professional investor, sometimes you spend as much time trying to work out what could go wrong for a company as what could go right. Investee companies having defective products in the marketplace should be a concern for all investors, but it is especially concerning if the defective product reaches a patient.

I commissioned this piece of research from our internal research team, Greenwheel, because medical devices make up 38% of all products recalled that fall under the US Food and Drug Administration's remit. This piece lays out practical steps investors can take to assess the robustness of a company's product safety policies and its attitudes towards patient safety. We are already applying this research in an ongoing engagement with an investee company to assess a historical product recall and ongoing issues with its corrective and preventive action plan identified by the FDA. We aim to make investments in companies providing solutions with life changing results for patients, often this means investing in leading-edge medical devices, which could be at higher risk of product recalls due to the novelty of their technology, I believe this makes it even more important that we have a robust framework for assessing a company's recall readiness.

Peter Hughes

Life Changing Treatments Strategy

Defining product recall

Product recall is an important corrective action taken by businesses to mitigate the risks posed by unsafe products.[1] The main objectives of a product recall are to locate unsafe products across the value chain (i.e. from suppliers to consumers), communicate risks and hazards in an accessible way to consumers, and offer remedies for affected persons. Recalls should be differentiated from other types of corrective actions such as corrections (repairing, modifying, or other rectification without physically removing the product) or withdrawals (preventing a product from being made available on the market).[2] Product recalls can be voluntarily initiated by businesses or mandated by regulatory bodies.[3]

Over the last decade, the number of product recalls is growing.[4] This growth is attributed to a variety of factors (Figure 1). Product recalls are increasingly complex, as products span across markets globally and across different jurisdictions. A single recall can involve numerous manufacturers, reaching millions of consumers in multiple countries.

Figure 1: Factors driving the increase in product recalls globally

Source: OECD, 2018; created by Greenwheel.

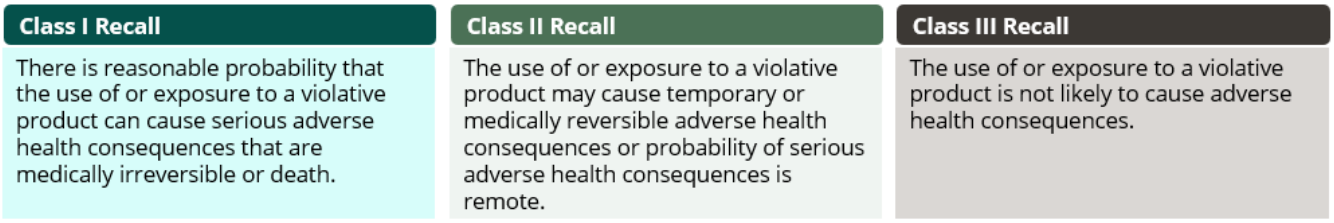
The recall of medical devices

There are more than two million medical devices in the world. Medical devices are categorised into more than 7000 generic devices groups, including but not limited to devices that diagnose illnesses, monitor treatments, assist persons with disabilities, and treat acute and chronic illnesses.[5]

Faulty medical devices can have serious adverse impacts on people, affecting their right to health, and in severe cases, the right to life.[6] While issues posed by faulty medical devices such as diagnostics machines can be resolved through retesting patients, some unsafe products can cause irreversible damage. For example, where implantable devices cannot be explanted, a patient may require long-term modifications to the clinical management of their condition.

Product recalls need to involve an understanding of the risks and hazards posed to consumers followed by identifying the most effective remedy for affected persons. The United States' Food and Drug Administration has developed a classification system to understand the harm that can be caused by unsafe medical devices (Figure 2).

Figure 2: Class I, II, and II Recalls in the United States



Source: US FDA, 2024a; created by Greenwheel.

Currently, there are no global figures on the number of medical devices recalled as fewer than 20% of countries have publicly available information on safety alerts and recall information.[7] However, existing studies based on available data provide insights on the drivers of medical devices recalls as well as how recalls are implemented. It should be noted that most studies are based in developed markets, particularly the United States and the European Union due to the maturity of their medical devices recall systems and the number of devices in these markets.

While the number of recalls has increased over time, this is not because of decreasing quality but due to the demand for devices (Box 1).[8] Additionally, the length of devices staying inside patients is a contributing factor. The number of recalled devices increased between 2016 and 2021 due to problems with devices implanted decades ago, where metal ions are released into the body the longer the implants stay.[9]

Box 1: An ageing world and the demand for medical devices

Medical devices play an important role in improving quality of life and extending life expectancy. The demand for medical devices is likely to grow, as the world is experiencing both a growth in the size and proportion of older persons. The population aged 60 years and older is expected to increase from 1 billion in 2020 to 1.4 billion in 2030. By 2030, one in six people will be over the age of 60. The World Health Organisation (WHO) expects the population of people aged 60 years and older will double to 2.1 million by 2050. Between 2020 and 2050, the number of people aged 80 years or older will triple to 426 million.

Though developed economies are first to experience the shift towards an ageing population, emerging markets, particularly low- and middle-income countries, will begin experiencing significant changes. An estimated two-thirds of the world's over-60 population will live in emerging markets by 2050.

While the initial growth in demand for medical devices is in developed economies, over time, it is expected that will shift towards emerging markets. This trend is particularly noticeable in Asia. Across the continent, the medical devices market grew from approximately $67.5 billion USD in 2016 to $88.6 billion USD in 2020; it is expected that the market will reach 3.7 billion by 2028. Within the region, Japan is a leading innovator and consumer of medical devices due to an ageing population and the unmet need for elderly care. As China's elderly population grows, with more

than one in five persons over the age of 60 (approximately 280 million persons) by the end of 2023, the growing demand for medical devices will likely accelerate.

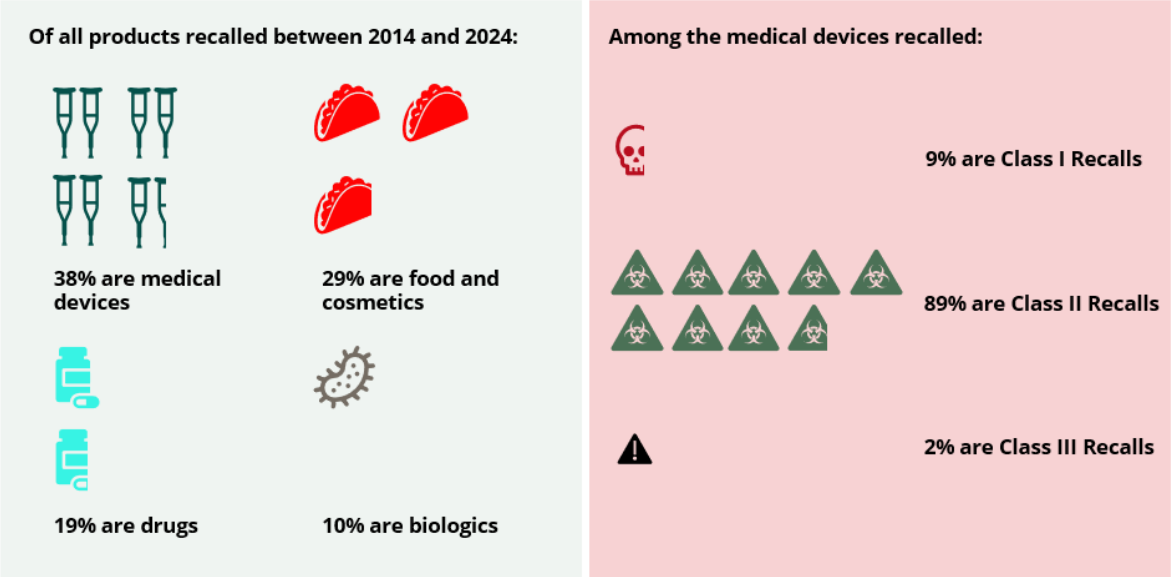
Across the region in the "younger" countries, the demand for home-based monitoring devices is expected to increase due to the size of the nursing and physician workforce, cost containment and avoidence of inpatient care, and weakening traditional roles in elderly care by family members and low fertility rates.

Source: Fidelity International, 2024, McKinsey, 2023, Wang et al., 2022, World Health Organisation, 2022 , Jakovljevic et al, 2021.

In the United States, medical devices make up the highest proportion of products recalled (Figure 3). Most medical devices recalls are Class II whereas only a small share of recalls is Class I.

Data from 2018 and 2022 showed that the primary reasons for recalls are device design (55%), manufacturing error (13%), and processing error (12%).[10] Breaking down the recalled devices by medical specialty, cardiovascular devices make up the most recalls (34%), followed by anesthesiology (21%), and general hospital devices (17%).[11] 66% of the products were recalled multiple times.[12]

Figure 3: Products recalled in the United States (2014 – 2024)



Source: US FDA, 2024a; created by Greenwheel.

A study on osteosynthesis implants and joint replacement implants from 2011 to 2021 across four countries showed that **the reasons for recalls differ across geographies and by the type of implant** (Figure 4). Overall, **four companies are responsible for 70% of the total recalls**.[13]

Figure 4: Drivers of product recalls for osteosynthesis implants and joint replacement implants in Australia, Canada, China, and the United States (2011 – 2021)

Note: The definitions for the recalls are explained by the authors Wang et al. as follows**:** clinical application (defects due to delayed or failed operation, recurrence or reoperation increased); device design (technology does not meet requirements of the product, the product does not achieve therapeutic effective in clinical application); mislabelling (content on label is incorrect, label and product are mismatched, missing label); non-conforming part (unqualified or components used); packaging process control (packing error, poorly sealed product, sterile barrier broken); process control (errors in production leading to assembly error, unqualified or missing component). **Source:** Wang et al., 2022; created by Greenwheel. The information shown above is for illustrative purposes.

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For osteosynthesis implants, one in four recalls in the United States are due to device design whereas in China, almost a quarter of all cases are due to mislabelling. Whereas mislabelling is main driver for product recalls in China for joint implants, the leading causes for recalls differ in the United States and Australia for the two types of implants. The major cause for recalls in osteosynthesis implants in Australia is due to packaging errors while the key recall factor for joint implants is related to clinical application. In the United States, errors in the packaging process are more likely to cause recalls.[14]

In addition to poor quality control and errors attributed to manufacturers, **regulatory loopholes can also contribute to recalls**. Compared to pharmaceutical products that require substantial evidence of safety and efficacy through clinical trials and post-market surveillance, medical devices are not required to demonstrate the same level of evidence or process controls.[15]

In the United States, only high-risk devices (e.g., life-saving or life-supporting) are required to submit clinical data to prove safety and efficacy for "pre-market approval". For other products, the 501(k) pathway allows devices that are essentially equivalent to devices already on the market or "predicates" to be approved through a "fast track". Through the 501(k) pathway, manufacturers need to demonstrate that new devices have the same intended use as predicate devices and have the same technical and safety characteristics and effectiveness.[16]

In theory, manufacturers cannot use predicates that are undergoing a mandatory recall; in practice, manufacturers can use predicates that are voluntarily recalled by manufacturer, which is the preferred and typical approach for medical devices. In some cases, Class I recalls are still active when new devices are authorised, and consequently, descendants may be cleared for using predicates even when safety concerns are known but not resolved. **There are no effective guardrails to prevent devices subject to Class I recalls being used as predicates**. As such, 501k clearance is not a signifier that a device is safe (Box 2).[17]

By contrast, **in the European Union, the equivalence pathway is more stringent than the 501k**. The European Union requires manufacturers to demonstrate equivalency based on technical, biological, and clinical characteristics. Additionally, market approvals in the United States do not have a time limit compared to the limited validity of the "CE marking" in the European Union (i.e., devices will undergo a conformity assessment approximately every five years).

Unlike the United States, the regulation of medical devices is highly decentralised in the European Union, and manufacturers can "self-attest" for non-high-risk products. Whereas the US FDA is responsible for regulating medical devices and in mandating recalls, the European Union devolves responsibility to Notified Bodies, which leads to risks of differences in interpreting the legal requirements (Figure 5).[18]

Figure 5: How medical devices are regulated in the European Union and the United States

	European Union	United States
Regulation	Medical Devices Regulation (2017), replacing the Medical Device Directive (1993) and the Active Implantable Medical Device Directive (1990)	Medical Devices Amendment (1976) Safe Medical Devices Act (1990) 21st Century Cures Act (2016)
Implementation	EU single countries responsible for market surveillance; Notified Bodies in charge of conformity assessment of high-risk products	The US FDA is responsible for approvals and market surveillance of medical devices.
Classification	Low to high-risk system. Class I is low risk, Class II is moderate risk, and Class III as highest risk. Class I is disaggregated into measure products (Class Im), reusable surgical products (Class Ir), and sterile products (Class Is). Though manufacturers are responsible for classifying their products, notified bodies and competent authorities can verify or challenge.	Low to high-risk system. Class I is low risk, Class II is moderate risk, and Class III are products are highest risk. The FDA can adjust the classification based on market data.
Approval process	All devices require a CE mark before it is placed on the market. Manufacturers can self-attest compliance of devices (e.g., simple class I). For Class Im, Ir, Is, manufacturers need to go through a conformity assessment performed by a Notified Body. Notified bodies will intervene for high-risk devices. If a device is similar to a well-established technology, a manufacturer can use data from a lower evidence level to demonstrate conformity based on pre-clinical, post-market data, data from similar devices, and/or data from state-of-the-art devices to show conformity. Equivalence is determined based on technological, biological, and clinical characteristics with existing devices with a CE marking. For novel devices, a clinical investigation is required for all implantable and class III devices to receive the initial CE mark.	FDA approval is required before a device is rolled out on the market. A Pre-market notification or the 501(k) is allows manufacturers to gain clearance for devices that are equivalent to existing or "predicate devices" that the FDA already cleared. To qualify as such, the device must have the same intended use as a predicate and has the same technological characteristics; the device must have the same intended use; the device cannot raise different questions of safety and effectiveness; and, the information provided to the FDA shows that the device is as safe and effective as the predicate. For novel devices that are not Class III, manufacturers do not need a Pre-Market Approval. Manufacturers need to demonstrate that the device is safe and effective with clinical data. Devices targeting rare medical conditions (<4000 individuals in the US) qualify as orphan medical devices, where no scientific evidence for performance is required due to low number of patients.
Post-market surveillance	Manufacturers are to conduct active and systematic post-market data collection, including a Periodic Safety Update Report annually or biennially based on the risk class. Implantable and Class III devices reports need to be submitted to the Notified Body for their assessment. Where long-term clinical data is not available, manufacturers are required to conduct post-market clinical follow-up activities (e.g., using existing registries, or conducting separate studies).	Manufacturers are required to carry out general post-market activities, for instance, collecting feedback from physicians or accessing the Manufacturer and User Facility Device Experience (MAUDE) database.

Source: Fink and Akra, 2023 and MD Lawj, 2023; created by Greenwheel.

Box 2: The dangers of the 501(k) pathway in the United States and the risks to consumer health

The 501(k) pathway was established to balance safety concerns with the need to innovate to create life saving devices. Compared to other routes to market approval (e.g., the PMA), 501(k) cleared devices are more likely to face recalls.

Currently, 99% of medical devices enter the market through the 501(k) pathway. A study on 156 medical devices subjected to Class I recalls between 2017 and 2021 found that 44% of authorised devices used predicates that are subject to Class I recalls. **Devices that are authorised through 501(k) using predicates that are subject to recalls are 6.4 times more likely to be subjected to a Class I recall than devices that use recall-free predicates**.

Manufacturers continue relying on the 501(k) pathway even though safety data can be limited. For instance, predicates were used despite the low rates of premarket clinical testing (4.4%) and despite safety concerns in the post-market setting (28.8%). Moreover, 15% of Class I recalls listing of 501(k) devices do not specify the reason for recall.

In response to the safety concerns, since 2012, approximately 1500 devices have been eliminated as predicates. There are now recommendations to push for all 501(k) devices to go through a Safety and Performance Based Pathway.

Source: Kadakia et al., 2023 and Pisac and Wilson, 2021.

The importance of managing product recalls for businesses and investors

Based on a review of the medical devices recall landscape, Greenwheel has identified three key takeaways for businesses and investors:

- **New risks may emerge**: As the global population ages, the demand for medical devices will continue to increase. New risks may arise due to the plethora of devices and through the development of new devices that are not tested with sufficient real-world data (i.e., consumers using the products over time). In addition, as devices are used for longer periods of time.

- **Data is not consistent or readily available**: There are clear data gaps in tracking the recall of medical devices globally due to the absence of centralised and readily accessible public information on product safety. Even in advanced regulatory regimes such as the United States or the European Union, safety and recall data is neither transparent nor fully accessible.

- **Compliance is not an indication of safety**: Ultimately, Governments are responsible for consumer safety through establishing a regulatory framework to guide and advise medical devices manufacturers. Yet, the practical implementation of the 501(k) in the United States show that compliance is not sufficient to ensure consumer safety.

What does good product recall look like?

Product recall should be viewed as one part of a wider risk management system on consumer product safety. In 2020, the OECD adopted a Recommendation on Consumer Product Safety, which lays out the core principles that guide regulatory and business action. The Recommendation provides key actions to take as part of good business practices, effective protection, information disclosures, product risk assessment and management, and product recalls or other correction actions (i.e. remediation) (Figure 6).[19]

As the World Health Organisation highlights, **all medical devices carry inherent risks, which further stresses the importance of having a robust risk managements system**. Risks should be acceptable to stakeholders (e.g., patients, medical care providers), wherein risks are outweighed by the anticipated benefits. For instance, stakeholders may be more accepting of high risks in life-saving devices than devices that improve the quality of life.[20]

Ultimately, **good product recall requires businesses to show that they have taken the adequate steps proportional to the risks posed by their product to reduce potential harm to consumers**. Where harm is caused because of a manufacturing, clinical, or user error, businesses have a responsibility to provide remediation through corrective action. As part of the corrective action, businesses are expected to demonstrate a commitment to continuous improvement. This process should be well-documented, transparent, and clear to external stakeholders, from regulators to consumers.

Figure 6: Guiding principles on consumer product safety

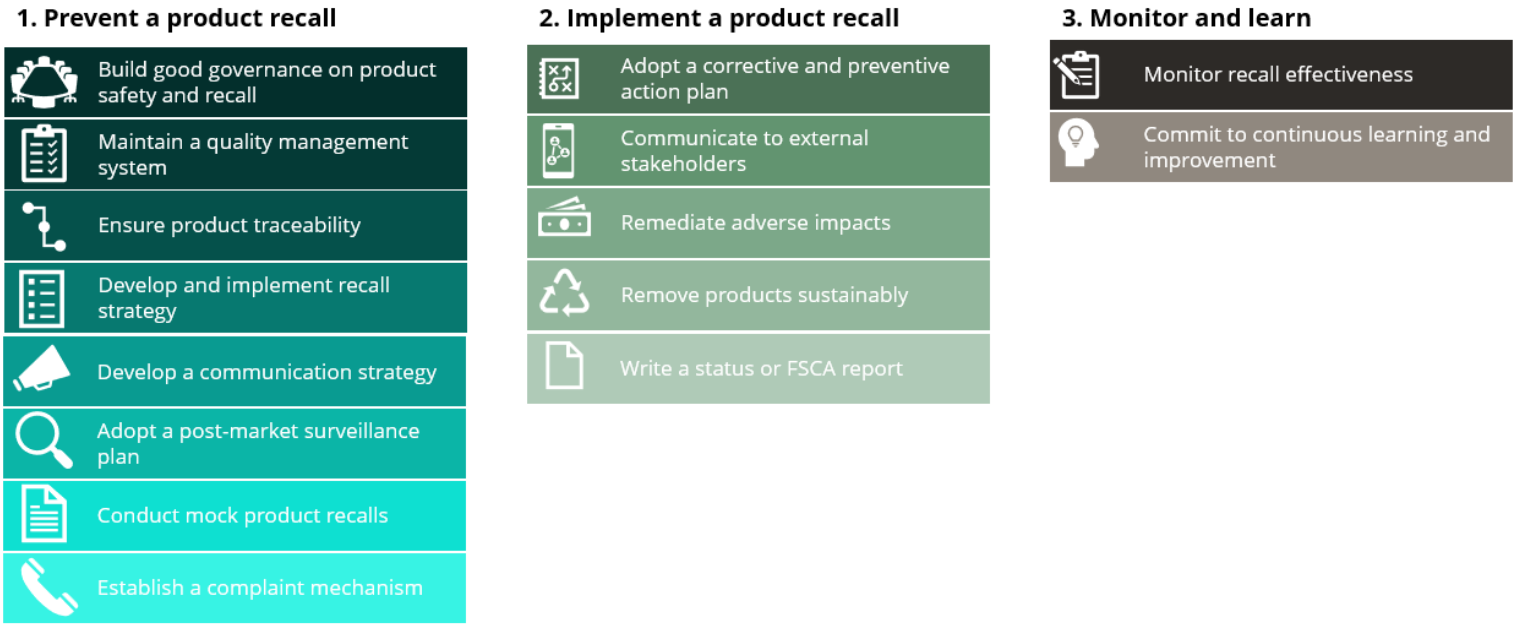
Source: OECD, 2024; created by Greenwheel.

A Greenwheel Investor Checklist on Effective Product Recall for Medical Devices

To help investors assess the effectiveness of product recall for medical devices carried out by portfolio companies, Greenwheel developed an investor checklist based on the best practices identified by international organisations (World Health Organisation, United Nations Trade and Development, the OECD), regulatory bodies, academic research, and industry research. Greenwheel notes that although the requirements can differ based on regulatory requirements, this Checklist provides what "good" should look like regardless of where businesses operate.

The **Greenwheel Investor Checklist on Effective Product Recall for Medical Devices consists of three key steps in the recall cycle** (Figure 7). Within each step, there are key actions that businesses can take.

Figure 7: The key steps in the product recall cycle



Source: Created by Greenwheel.

1. Preventing a product recall

Build good governance on product safety and recall

The structure of CEO incentives can affect the timely implementation of recalls, which can magnify or reduce public health risks. A 2% increase in the percentage of shares owned by the CEO is associated with a 26-day delay in recall initiation. As such, CEO stock ownership may allow unsafe and potentially dangerous medical devices to linger on the market.[21] Investors may consider assessing performance metrics for CEOs and senior leadership that encourage the prioritisation of patient safety in the event of a product recall.

An autonomous corrective action team should be established to oversee product recalls. The team should consist of management representative, production, product manager, technical officers (IT, engineers), quality assurance or quality control, risk management, marketing or public relations experts, and customer services. Where businesses do not have internal capabilities, they should seek support from external experts.[22]

Senior leadership and the corrective action team should be adequately trained to carry out their responsibilities. In addition, these **internal stakeholders should be trained on judgment bias**, as evidence show that businesses can under- and over-react based on product nature or characteristics:

- **Recency bias**: Businesses tend to under-react when risks are associated with older products and over-react for newer products.

- **Perceived risk bias**: Responsible personnel may under-react to risks associated with "low-risk" products related to dental, ear-nose-throat, and physical medicine. They may over-react with "high-risk" products such as cardiovascular, surgical, and hospital devices.

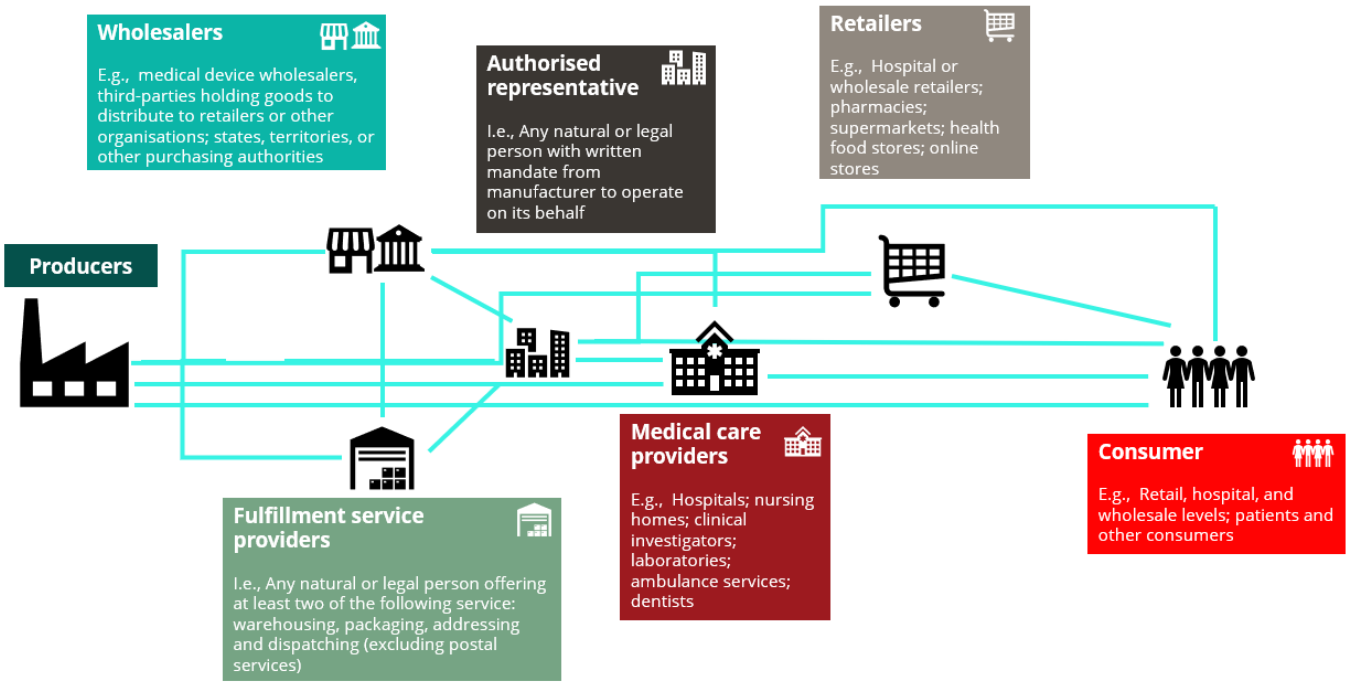
Maintain a quality management system

A **quality management system (QMS) can help businesses promote safety across the product lifecycle**: design and development, production, storage and distribution, installation, servicing, and associated activities (e.g., technical support).

The International Organization for Standardization established a dedicated industry standard on quality management systems for medical devices through the ISO 13485.[23] In addition to this standardised approach, investors should be aware that quality management systems requirements may differ across jurisdictions.

Ensure product traceability

Figure 8: The challenges in tracing products downstream



Source: Australian Government Therapeutic Goods Administration, 2024 and European Commission, 2020; created by Greenwheel.

The medical devices value chain is complex, which makes it difficult to trace products downstream (Figure 8). Oftentimes, medical devices go through many economic operators or intermediaries before reaching the consumers. There are many tools that businesses can adopt to promote traceability across the value chain, from upstream suppliers to end-users, for instance, using manufacturer/producer identification and general identifiers (serial numbers, batch reference, manufacturing date or bar code). These are tools that are not unique to the medical devices industry.[24]

Specifically for medical devices, the use of Unique Device Identification (UDIs) is recommended by expert organisations such as the World Health Organisation and the OECD; increasingly, UDIs are mandatory under some jurisdictions.[25] UDIs are numeric or alphanumeric codes that consists of two components: a device identifier and a production identifier. UDIs facilitate an unambiguous tracing of medical devices.[26] Since 2013, medical devices manufacturers have been using UDIs in conjunction with other health databases; for instance, when used in

conjunction with electronic health records for device implants in patients, adverse event reporting, and recall notifications, UDIs can facilitate post-market surveillance for safety risks.[27]

Develop a recall strategy

A recall strategy or plan is put in place in case an error necessitates a recall. **An effective recall strategy should contain six key components** (Figure 9). A recall strategy should be scaled based on the severity of the potential recall. For higher risk products, a strategy should be more extensive and detailed.[28]

Figure 9: Key components in a product recall strategy

Source: European Commission, 2020; created by Greenwheel.

Develop a communication strategy

Recall communication requires coordination of internal stakeholders and a dedicated plan to engage external stakeholders. The strategy should take all necessary precautions to avoid potentially harm patients as a result of miscommunication and/or misinformation.[29]

A comprehensive communication strategy details internal communications, communications with regulatory authorities, customers, and the broader public. The strategy should ensure that the appropriate communication channels are selected for the intended audience. There is no single effective channel of communication, especially for companies with a large global footprint. As a good practice, businesses should use multiple channels, both online and offline, to reach consumers.[30]

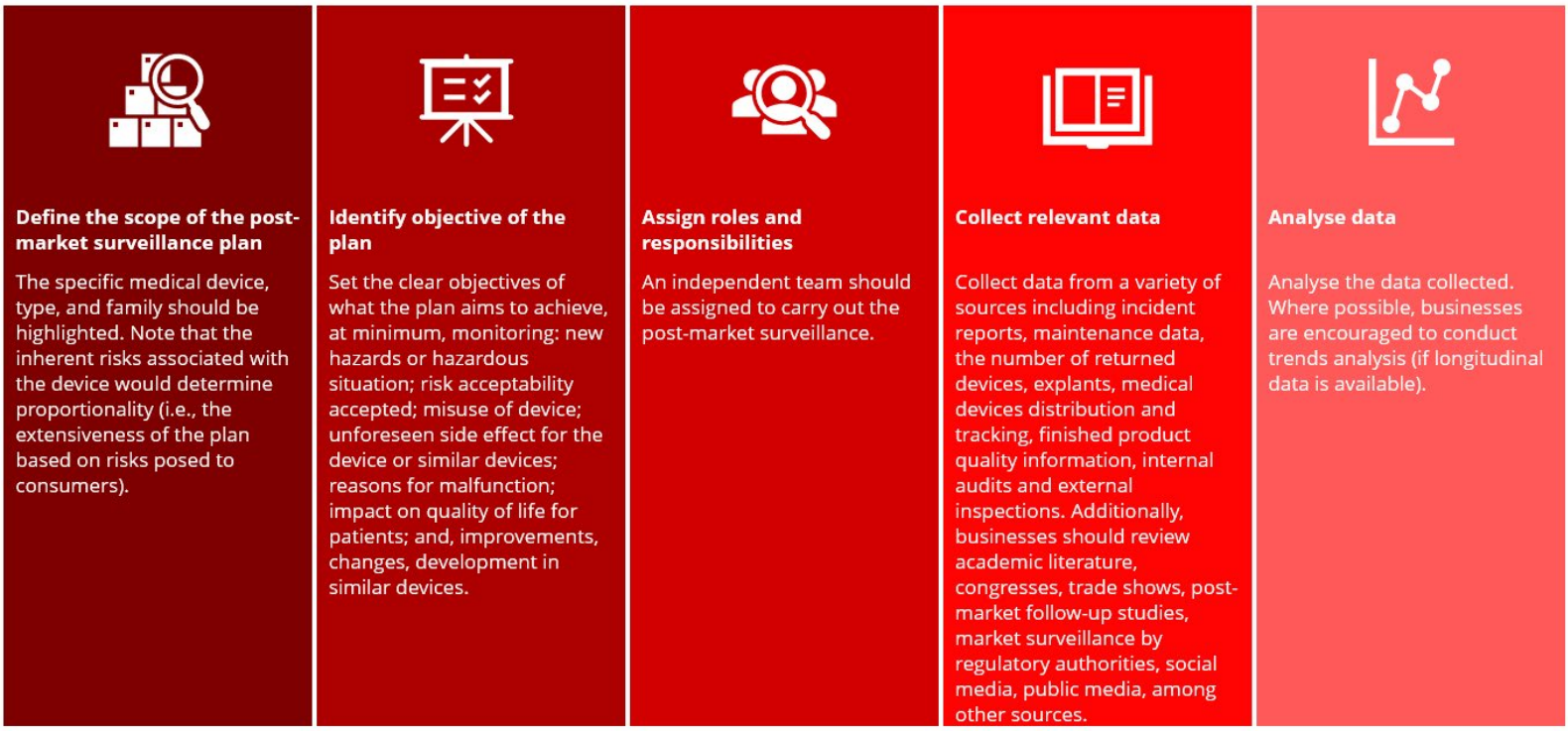
Information should be made accessible to consumers. In practice, this may include working through intermediaries such as medical care professionals, hospitals, governments, consumer interest groups, and other organisations to maximise reach.[31] Information about the potentially affected products, risks and hazards, and next steps should be presented factually and concisely. **Special measures should be taken to ensure the needs of different groups are taken into account** (e.g., age, income, disability, literacy, language).[32]

Businesses should prevent "recall fatigue" by avoiding bombarding the public with too much communication which can impact consumer participation in recalls. Businesses are also advised to accurately depict the risks and hazards so to avoid under- or over-reaction.[33]

Adopt a post-market surveillance plan

Post-market surveillance is a critical tool to ensure medical devices continue to be safe and well-performing. Even where the proper quality management systems are in place, there are residual risks; as such, **market surveillance allows businesses to identify problems, including unforeseen problems such as environment, user interaction, and other unexpected failure or misuse.** A post-market surveillance plan should contain five steps (Figure 10).[34]

Figure 10: Ingredients of a post-market surveillance plan



Source: created by Greenwheel.

Box 3: Practical challenges in conducting post-market surveillance

Product safety issues and errors may occur months or years after devices are in service. Particularly in the case of implanted medical devices, there is no centralised or systematic data collection on patient outcomes from adverse impacts of medical device events. In some countries, physicians voluntarily report data.

A Canadian study on barriers to reporting for physicians revealed three factors preventing medical professionals from reporting device safety issues:

- **Behavioural factors**: Some physicians may not see reporting device safety concerns as their formal responsibility. Depending on the structure of medical systems, providers responsible for implants may be monitor the "recovery" phase and but not beyond. There is also a belief held amongst medical professionals that errors and adverse impacts are inevitable and "expected" as part of medical practice, especially

for life-saving devices. Instead of reporting, physicians are choosing to clinically address adverse medical devices events or discontinue the use.

- **Institutional factors:** There is an absence of local, national, and international policies and processes to promote the reporting of medical devices adverse events. Patient records may not contain relevant information on the implant of medical devices. Consequently, it may be difficult to track patients in case of recalls.

- **Value chain factors:** There is no feedback loop between medical practitioners and industry representatives, distributors (e.g., wholesalers, authorised representatives, fulfilment service providers), and manufacturers.

Given the constraints for businesses in gathering data as part of their post-market surveillance, additional measures should be taken to actively monitor the safety performance of their devices (e.g., academic literature, congresses, post-market follow-up studies).

Sources: Pisac and Wilson, 2021 and Gagliardi et al., 2018

Conduct mock product recalls

Mock recalls simulate a scenario where an unsafe or harmful product is identified (Figure 11)**.** Typically, participants are not told in advance that it is a mock scenario.[35] Mock recalls help companies test recall procedures and ensure employees understand their responsibilities as well as the requirements for timely and effective outcome. Mock recalls can help assess an organisation's recall readiness and identify potential gaps in implementation. Mock recalls should not be a one-off exercise.[36]

Figure 11: Steps to a mock recall

Source: FTI, 2024; created by Greenwheel.

There is no formal guidance on the frequency of mock recalls. While existing recommendations vary widely (from quarterly to every 18 months), the typical frequency is at least annually if not semi-annually.[37] For companies operating in multiple markets, it is good practice to carry out mock recalls in different country and cultural contexts.

Establish a complaint mechanism

An anonymous whistleblowing mechanism allows employees, suppliers, consumers, and other downstream economic operators (e.g., medical services providers, retailers) to share concerns about product safety. An anonymous system allows stakeholders to share concerns without the fear of retaliation.[38]

A complaints mechanism should be made available to consumers who are adversely impacted by unsafe or harmful products. This mechanism should be accessible, expeditious, fair, inexpensive, and transparent without transferring any costs to participate to consumers.[39]

2. Implementing a product recall

Adopt a corrective and preventive action plan

A corrective and preventive action (CAPA) plan is a quality process that helps businesses eliminate product defects and non-conformities. CAPA consists of assessing the risks and hazards to consumers, identifying the root causes of defects, and implementing the appropriate remedial and preventive actions (Figure 12).[40]

Figure 12: A corrective and preventive action plan in the context of medical devices recalls

Source: Croft, 2024 and European Commission, 2020; Created by Greenwheel.

Communicate to external stakeholders

A company should consult relevant authorities as soon as possible after a risk of injury or actual injury occurs. Although the timeframe can differ by jurisdiction, the World Health Organisation recommends that manufacturers should report serious public health threats immediately but no later than 48 hours. For devices that lead to death or a serious deterioration in health of a user, users should be contacted as soon as possible but no later than 10 calendar days. For devices that may have caused a death or serious health deterioration of a user, manufacturers should report no later than 30 calendar days.[41]

Alongside regulators, businesses should coordinate and communicate clearly with up and downstream economic operators. These operators can be leveraged to help businesses communicate to consumers as part of the recall.

With consumers, businesses should communicate promptly, accurately, and openly with the aim of minimising adverse impacts. This can also help businesses contain litigation risks.

Remediate adverse impacts

Remedies should aim to restore the rights of affected stakeholders or to an equivalent state. Depending on the nature of the product faults, remediation may include corrections or corrective action. Corrections involve repairing, modifying, adjusting, relabelling, destroying, inspecting devices. It can also entail retraining practitioners, retesting, and seeking additional clinical reviews.[42]

By contrast, corrective action is recommended in instances where one or more incidents pose an unacceptable increase in risk through malfunctions, deterioration in safety, quality or performance, or undesirable side-effects. As part of corrective action, the product should be returned to the manufacturer or representative. This can include device modification (software upgrade, retrofitting parts of the device), device exchange, device destruction, or modification of clinical management (especially in cases where implants cannot be explanted).[43]

For user errors that are foreseeable (e.g., inserting the test strip backwards on a glucose monitor), businesses can report this to reduce the chances of other users from making the same mistakes and issue a user warning. Whereas for abnormal user error (e.g., using a product beyond its expiry date), there is no expectation for businesses to report.[44]

Remove products sustainably

Businesses should strive to remove products from the market in a sustainable way. Businesses are encouraged to balance safety, ethical, and environmental considerations. Where feasible and not at the expense of safety considerations, businesses should repair, rework, or recycle the product. If the recall contains hazardous chemicals, then product needs to be destroyed but in a way that does not create further harm.[45]

For transparency, businesses should document the products collected and provide evidence on how they carried out the recall in a sustainable way.[46]

Write a status or field safety corrective action (FSCA) report

A field safety corrective action (FSCA) or status report contains the final assessment of the root causes, proposed corrective actions, progress on implementation, and outcome of remediation and reconciliation.[47] National requirements may differ on the contents required in

such reports. For instance, the US FDA provides clear guidance on the required information in a status report (Figure 13).[48]

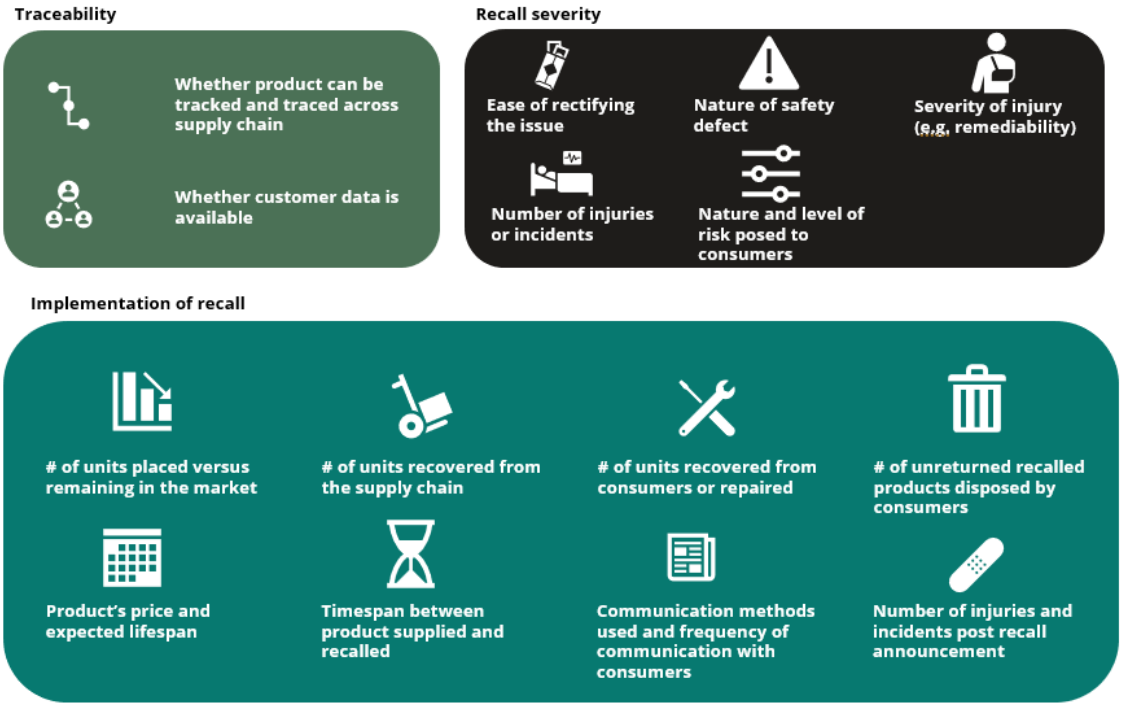
Figure 13: Information to include in a FSCA or status report

Source: US FDA, 2020; created by Greenwheel.

3. Monitor and learn

Monitor recall effectiveness

Figure 14: Assessing the effectiveness of a product recall



Source: OECD, 2019; created by Greenwheel.

The OECD provides a set of metrics to help measure the effectiveness of a recall (Figure 14); it should be noted that this is not a recommendation specific to medical devices. Consequently, the OECD does not provide concrete recommendations, for instance, on what "good" or "good enough" looks like in terms of the number of units recovered from the supply chain or the timing of the recall.

The United States' Title 21 of the Code of Federal Regulations for the FDA provides guidance on recall effectiveness for medical devices based on the number of consignees contacted. The effectiveness is ranked from Level A to E, where 100% of consignees are contacted for Level A and no effectiveness checks for Level E (i.e., no verification on whether consignees are contacted).[49] **This is proportional to the risks posed to consumers as a result of the error or fault** (e.g., for life-threatening or irreversible medical harm, businesses should aim for Level A).

Commit to continuous learning and improvement

One key metric as part of responsible business conduct is continuous improvement. Based on the experience carrying out a product recall, businesses should demonstrate that they have learned from their experiences. For example, the product recall experience should inform the review of working practices, including but not limited to safe designs, production, the procurement of materials and components, packaging, storage, shipping, clinical management.[50]

References

[1] OECD, 2019.
[2] European Commission, 2020.
[3] OECD, 2018.
[4] Ibid.
[5] World Health Organisation, 2024.
[6] Wampler, 2021
[7] International Medical Devices Database, 2018.
[8] Ibid.
[9] Based on observations in Australia, Canada, China, and the United States. Wang et al., 2022 and Maurer-Ertl et al., 2017.
[10] Mooghali et al, 2023.
[11] Ibid.
[12] Note that due to data availability for products undergoing the pre-market approval (PMA) or 501(k), those numbers are excluded from the determination of multiple recalls.
[13] Wang et al., 2022.
[14] Ibid.
[15] Wampler, 2021 and Pisac and Wilson, 2021.
[16] Pisac and Wilson, 2021.
[17] Kadakia et al., 2023.
[18] Fink and Akra, 2023.
[19] OECD, 2024.
[20] World Health Organisation, 2020
[21] Mukherjee, 2023 and Mukherjee et al., 2018.
[22] European Commission, 2020 and ASQ, 2024.
[23] ISO, 2016.
[24] European Commission, 2020.
[25] US FDA, 2023 and European Commission, 2024. #
[26] World Health Organisation, 2020.
[27] Pisac and Wilson, 2021.
[28] European Commission, 2020.
[29] Morgenthaler, et al., 2022.
[30] OECD, 2019.
[31] Ibid.
[32] OECD, 2022.
[33] OECD, 2019.
[34] World Health Organisation, 2020.
[35] Sage, 2023.
[36] Ibid.
[37] Quality Assurance and Food Safety, 2011 and Sedgwick, 2022.
[38] USDOL, 2021.
[39] UNCTAD, 2016.
[40] Qualio, 2021.
[41] World Health Organisation, 2020.
[42] Ibid.
[43] Ibid.
[44] Ibid.
[45] European Commission, 2020.
[46] Ibid.
[47] World Health Organisation, 2020.
[48] US FDA, 2020.
[49] US Code of Federation Regulations, 2024.
[50] European Commission, 2020.

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