1 Executive Summary

Regulatory bodies expect manufacturers to have processes in place to ensure all promotional materials are thoroughly vetted before approval to prevent misleading claims from reaching the market. Making misleading claims about the intended purpose, safety, functionality or benefits of medical devices can result in legal actions, penalties, and product recalls.

This article proposes a cross-functional claims management process, beginning early in product development and extending through the entire product lifecycle. Such lifecycle approach supports marketing teams by allowing desired claims to be planned for and validated without delays, while also assisting compliance teams in reducing the risk of regulatory violations.

2 Introduction

Most regulatory frameworks explicitly prohibit misleading users and patients regarding the safety, intended use, and performance of medical devices. Violations can result in significant penalties, product recalls, and legal actions. Consequently, regulators expect companies to have processes in place to ensure that promotional materials and advertisements are reviewed by regulatory affairs professionals to confirm their alignment with the approvals granted by regulatory authorities.

Often the approval of promotional materials in a company is an increasingly complex task. With the rise of social media, the volume and variety of promotional content have increased, making it more and more challenging for Regulatory Affairs to approve every statement before use. This decreasing ability to conduct oversight and control what claims are made, raise the risk of non-compliance.

This article examines based on the regulations in EU and USA the current landscape of claims and introduces the concept of claims management through a cross-functional lifecycle process, that is integrated into the Quality Management System.

3 What is a Claim

Before diving into the details of claims, let's first define the term "claim" within the context of medical devices. After considering various definitions, I've settled on the following:

"A claim is any communication from the manufacturer or marketer of a medical device that describes its intended purpose, functionality, safety, benefits, or compares these aspects to available alternatives."

This definition begins with "any communication" to emphasize that claims can be conveyed through a variety of channels. The most obvious sources are labeling, instructions for use, marketing brochures, and advertisements. However, claims can also be made through company websites, social media, and

at exhibitions or congresses. For instance, the content of an exhibition booth or presentations at company-sponsored events featuring invited speakers may contain claims. It extends to verbal statements made by sales representatives on their social media or any other company personnel—these too can be considered claims.

It's also crucial to recognize that claims are not only made by the manufacturer. Anyone involved in marketing a device can make a claim. This includes distributors, key opinion leaders, local agents, and others promoting the device on behalf of the manufacturer. Therefore, it is vital for the manufacturer to be aware of all claims made by others, as the manufacturer remains legally responsible for any claims associated with their device.

Finally, also statements comparing intended purpose, functionality, safety, or benefits of device to available alternatives like alternative treatments, competitive products fall under the definition of a claim.

4 The Landscape of Claims

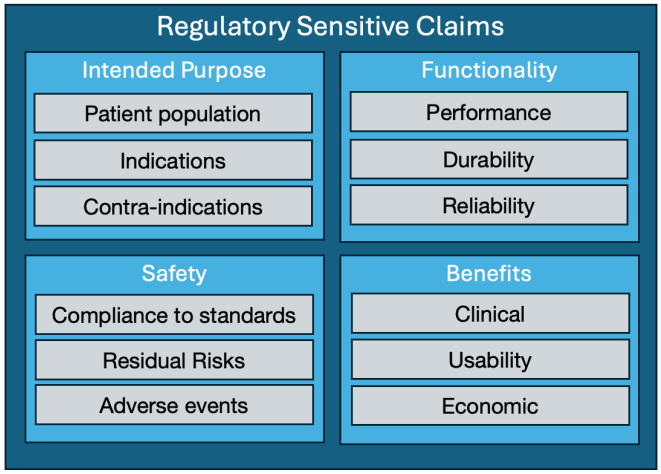

Figure 4.1: Four groups of claims that together form the set of regulatory sensitive claims.

In Figure 4.1 above I divided regulatory sensitive claims into four groups: claims around intended purpose, claims on functionality, claims on safety, and claims on benefits. Each of these groups are divided into three subgroups, which are explained in detailed in the paragraphs below.

4.1 Intended purpose

The MDR defines "Intended Purpose" as a combination of the intended use established in the clinical evaluation and the data on intended use provided by the manufacturer through any communication channel. The visual representation of this definition is given in Figure 4.2.

Claims regarding Intended Purpose must align with the clinical evaluation. These claims typically cover aspects such as the target patient population, intended users, indications and contraindications, anatomical sites for use, and the device's delivery or deployment methods. In essence, they provide all the necessary information to inform the user and patient about what the device is for, when, and how it should be used.

Since users and patients do not have access to the non-public Clinical Evaluation Report, they rely on the information provided by the manufacturer. While manufacturers may use various communication channels to convey this information, see Figure 4.2, the manufacturers are responsible for ensuring that all statements made by whoever markets a device on their behalf are consistent with the data approved in the Clinical Evaluation Report.

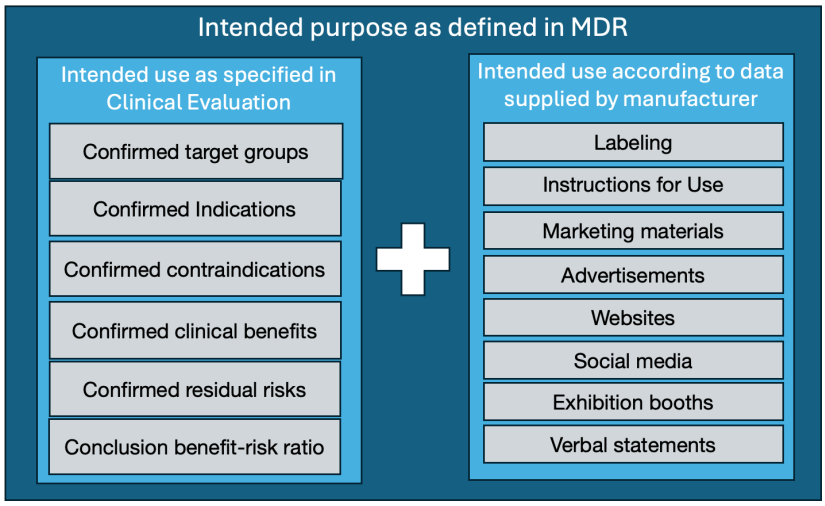

Figure 4.2: Graphical representation of the definition of 'Intended Purpose' per MDR.

4.2 Functionality

For this article functionality is defined as the combination of diagnostic, therapeutic, monitoring, and/or usability functions that allow the device to meet consistently and effectively its intended performance.

Claims related to functionality are typically straightforward, as they are based on the device's technical specifications. These may include claims about e.g. accuracy, measurement ranges, response times, or flow rates. Additionally, regulations require devices to have a defined lifetime, which may result in claims regarding durability and reliability.

4.3 Safety

According to ISO 14971 (2019) on Risk Management, safety is defined as the absence of unacceptable risks, meaning the benefit-risk ratio is favorable for both the user and patient once all risk mitigation measures have been implemented.

Technical safety is typically addressed through compliance with international standards, which are generally required for regulatory approval but are not commonly used for making claims as technical safety is usually not a commercial differentiator.

Instead, clinical safety claims have higher commercial value and may highlight e.g. a favorable lower number of complications or adverse events compared to literature or competitor data. Such clinical safety related claims are of special interest of regulators, and therefore must be substantiated by scientifically sound clinical data.

4.4 Benefits

Benefits can be categorized into clinical, usability, and economic benefits.

Clinical benefits refer to the positive impact a device has on patient health outcomes, as evidenced by measurable improvements in the patient's condition or quality of life. These could include reducing disease progression, minimizing the need for invasive procedures, or lowering the likelihood of adverse events during treatment. Clinical benefit claims are highly valuable because clinical outcomes are often the main factor in a patient or user's decision to select a device.

Usability benefits are most relevant to users, as they may shorten procedure times, reduce the likelihood of errors, and improve overall user experience. A positive usability profile can also translate into economic benefits.

4.4.1 Economic benefits are becoming increasingly significant as decision-making authority shifts from medical staff to purchasing groups within healthcare institutions. Claims related to operational costs or cost per procedure can be critical differentiators in a price sensitive market.

5 Regulatory requirements on claims

In the USA, FDA regulates claims under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Misleading or unsubstantiated claims can result in enforcement actions, including warnings or recalls. Paragraph 252 of 21 US Code focuses on misbranded drugs and devices. In summary any statement made on labeling or promotional material makes the device misbranded.

Similarly, the EU-MDR includes a provision in Article 7 regarding claims, which essentially prohibits misleading users or patients about the intended purpose, functionality, safety, or benefits of a medical device.

Upon closer examination, the obligations imposed by both regulators can be summarized into the following key requirements:

- Claims must be truthful and accurate.
- Claims must be substantiated by appropriate data.
- Claims must align with regulatory approvals.
- Communication regarding residual risks and benefits must be balanced.
- Only promotion of use within the approved intended purpose is permitted.

Legal manufacturers of medical devices are responsible for ensuring that all claims made on their behalf during promotional activities comply with these requirements. This requires a process for validating each claim against the device's regulatory approvals, ensuring supporting data is on file, and that the communication of risks versus benefits is balanced. Table 5.1 below provides examples of data sources that can be used to verify the validity of claims.

Claims group	Claims sub-group	Data sources to validate claim
Intended Purpose	Patient Population	• Clinical Evaluation Report • Regulatory approved IFU • Regulatory approved Labeling
	Indications for use	
	Contra-indications	
Functionality	Performance	• Customer specification • Design specifications • Verification and validation reports
	Durability	
	Reliability	
Safety	Compliance to standards	• Verification reports
	Residual risks	• Risk Management File • Clinical Evaluation Report
	Adverse events	• Clinical Evaluation Report • PMCF Reports[1)] • PSURs[1)]
Benefits	Clinical	• Clinical Evaluation Report • Clinical Investigation Reports • PMCF Reports[1)] • PSURs[1)]
	Usability	• Usability Study Report • Peer-reviewed publications[1)]
	Economic	• Health Economics Study Report[1)] • Peer-reviewed publications[1)]

[1)] Documents that are normally not available at the product launch and are created in the post-market phase.

Table 5.1: Mapping of likely data sources to validate a proposed claim.

Table 5.1 shows that the data to validate a claim is already created during the product development phase (except for economic benefit claims). Or in other words the design output determines already which claims you can make during launch, which emphasizes the importance of seeing desired claims as design input).

Claims on intended purpose and functionality will normally not change after market launch, only claims related to adverse events, clinical benefits, and economic benefits could be influenced by post-approval generated data.

6 Controlling claims using a Claims Management Process

As regulators require the review of promotional material your Quality Management System will likely already have a procedure or work instruction on how to conduct such review. Often such procedure describes the one-time review of a piece of marketing material that is developed by marketing. However, in my opinion a piece-by-piece review is not effective and a more holistic perspective on claims management as a lifecycle process brings significant benefits.

I apply in this section a standard lifecycle management process on claims. In figure 6.1 you see the concept that I will further explain in the following paragraphs.

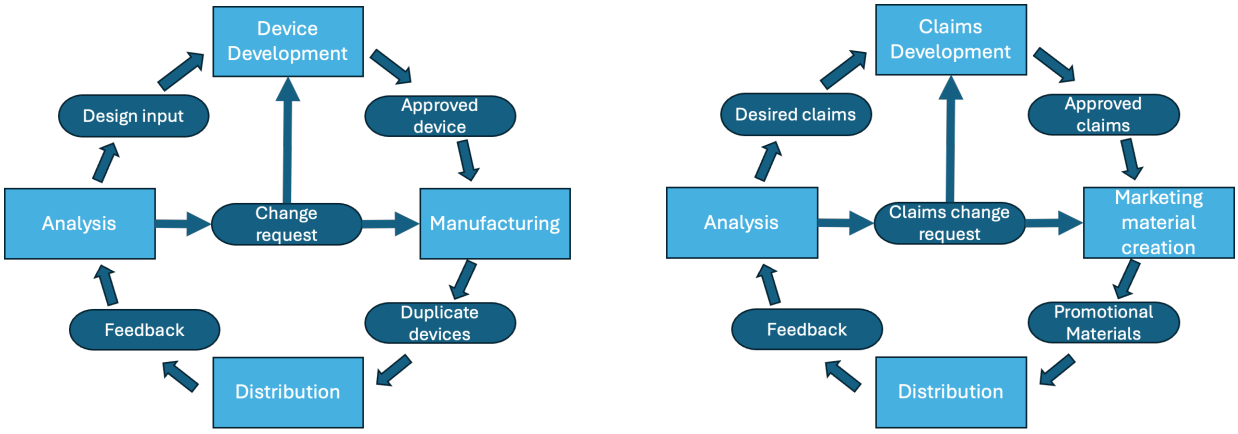

Figure 6.1: Typical life-cycle management process for a device (left) applied to claims management (right)

6.1 The similarities between device and claims development

It's never too early to start thinking about how a device will be marketed. Failing to address device claims in the begin of the development process can lead to costly delays or missed opportunities once the device reaches the market. As discussed in Section 5, the design output of the development process dictates which initial claims can be made. All others claims require additional post-launch investments and activities.

Therefore, the first question to ask the marketing team when customer specifications for a new device are provided should be: "What are the critical marketing claims this product must have at launch?" This should be followed by: "What additional claims are desirable post-launch to boost the product's commercial success?" Only when these desired claims are identified the design input is really complete.

Once customer specifications and the desired claims for a new or modified device are established, the development process can begin. It will deliver an approved device that meets customer specification, and the data required to substantiate claims.

The development team will define the product's technical specifications and identify testing methods to generate data that supports functionality claims. Meanwhile, the clinical team must determine what clinical data is necessary to support claims related to the product's intended use and benefits. Ideally, existing literature will provide the required data. If not, or if the available data is insufficient, clinical

data may need to be gathered through pre- or post-market clinical investigations. If there is insufficient time to collect this data before launch, certain clinical claims cannot be made until this data becomes available post-launch.

Claims regarding usability or economic benefits might require separate studies, which need to be completed before these claims can be made publicly. It is in such case whether such study is done pre-market or post-market.

Initiating early, cross-functional discussions about marketing's claim objectives ensures the company is better prepared to gather the necessary data and support those claims over time, reducing the risk of unexpected challenges down the line. It also helps to engage the marketing organization into the options and limitations regulations impose on medical device industry.

6.2 The similarities between product validation and claims validation

Just as the device must be validated at the end of the development process to ensure it meets customer specifications, the same applies to claims. It is essential to validate that the supporting evidence meets the criteria for substantiating the desired claims. Regulators expect that the validity of each claim is verified by the competent, trained personnel and gets a record of approval from Regulatory Affairs (RA) confirming that all claims have been properly assessed and authorized.

The requirements for a valid claim were provided in section 5:

- Claims must be truthful and accurate.
- Claims must be substantiated by appropriate data.
- Claims must align with regulatory approval.
- Communication regarding residual risks and benefits must be balanced.
- Only promotion of use within the approved intended purpose is permitted.

As the requirements do not define terms like ‘adequate’, ‘balanced’, ‘accurate’ the assessment will be subjective by design. To standardize assessments, I propose a classification system that helps to divide potential claims into four levels and also defines the depending on the level for what use the claims can be approved. This classification system and its related use is shown in table 6.3.1.

The distinction between Level 2 and Level 3 claims lies in the extent to which the claim is confirmed by independent sources. Level 2 claims are typically based on a limited dataset that may not be representative of the broader population. User testimonials and Key Opinion Leader (KOL) endorsements fall into this category, as you can quote individuals with their consent, but this does not guarantee that others will share the same views.

In contrast, Level 3 claims are backed by independent confirmations originating from different sources or can be independently reproduced by scientifically sound methods. These claims are considered reliable and can be even included in regulatory submissions.

Level 1 claims are more problematic because the supporting data may not be scientifically valid or accurate, meaning the conclusions drawn could be questionable. Ideally, Level 1 claims should be avoided, but if used, they should be limited to one-off instances and accompanied by a disclaimer that clearly outlines the data’s limitations.

Level 0 claims are not allowed and should be either discarded or thoroughly reworked with stronger supporting evidence.

The output of the claims development and validation process is a traceable record that includes references to the evidence used to substantiate each claim. This record also documents the assigned claim level. It serves as the foundation for ongoing claims management throughout the product’s lifecycle, as it will be updated when claim levels change or new claims are introduced.

Level	Use	Criteria
0	Not allowed	Any of the below criteria applies to the claim: • Non-verifiable data source, • Non-reproducible data, • No ability or permission to cite data source, • Not truthful or accurate, • Not covered by regulatory approval, • Promotion of off-label use, • Contradicts Clinical Evaluation Report • Unbalanced representation of benefits vs residual risk
1	Use not recommended, but if so, only during one-off occasions	Claim meets all following criteria: • Able and permitted to cite data source • Truthful • Covered by regulatory approval • Consistent with Clinical Evaluation Report • Residual risks are correctly represented. However, the data to substantiate claim may not be fully accurate or scientifically sound: • Clinical data from non-GCP studies • Clinical data from statistically underpowered study. • Data cannot be independently verified nor reproduced. • Source is non-peer reviewed publication • Data source lacks scientifically sound reputation
2	Marketing material	Claim meets all following criteria: • Able and permitted to cite data source • Truthful and accurate • Covered by regulatory approval • Consistent with Clinical Evaluation Report • Residual risks are correctly represented. However, the data to substantiate claim is based on a single, potentially biased source: • Single center GCP compliant study • Key Opinion Leader or user statement
3	Regulatory submissions	Claim meets all following criteria: • Able and permitted to cite data source • Truthful and accurate • Covered by regulatory approval • Consistent with Clinical Evaluation Report • Residual risks are correctly represented. • Confirmed by multiple, scientifically sound sources.

Table 6.3.1: Tiered level system used to determine the robustness of a proposed claim and its allowed used based on the robustness level.

6.3 How to use approved claims in the marketing process

Once each and every proposed claim has been assessed and have a assigned level of robustness, the approved Level 2 and 3 claims and their supporting reference documentation form collectively the 'Approved Claims List'. The list can serve as the reference guide for developing promotional materials in any format.

When only claims from the approved list are used to create new promotional content, it significantly simplifies the review process by regulatory affairs and the time needed to obtain approval as the claims on the Approved Claims List have already been validated. If the author of the promotional content indicates which claims from the Approved Claims List are used in the new material, it will be easy to for Regulatory Affairs to verify whether the claim is on the Approved Claims List and whether the references are correct.

In addition to streamlining the review process, an Approved Claims List also provides regulators with greater assurance that a controlled and compliant process is in place.

6.4 The similarities between making device related changes and changes in claims

After a device is launched, feedback from the market or manufacturing may lead to requests for changes in the device design, manufacturing process, or even to a request to the development a new device. The review and approval of such change requests typically involves a multidisciplinary team, and the process follows a pathway like the initial development process.

An equivalent change control process can be applied to claims. Feedback from the market, users, through publications, or from post-market clinical follow-up (PMCF) reports may prompt a review of existing Level 0, 1, or 2 claims. Additionally, there may be requests to add a new claims to the claims list, which would then need to be validated by Regulatory Affairs, potentially supported by newly generated internal data as part of the claims development process.

Once an updated or new claim is approved, the approved claims list is revised, and the new version replaces the previous one. This marks the next phase of the claims management lifecycle. This process continues until the last product is on the market, though the frequency of updates of the approved claims list generally slows down significantly a few years after market launch.

7 Conclusions and Recommendations

Global regulatory frameworks strictly control claims made about the intended purpose, functionality, safety, and benefits of medical devices. Making misleading claims can result in legal actions, penalties, and product recalls. Since manufacturers are accountable for all claims made on their behalf, including those from third parties like distributors or key opinion leaders, it is crucial to establish a rigorous process that ensures all promotional materials and communications are substantiated by adequate data and are approved by Regulatory Affairs.

This article recommends implementing a cross-functional claims management process, beginning early in product development and extending through the entire product lifecycle. This process should engage marketing, regulatory, clinical, and R&D teams to ensure adequate data is collected timely to support each potential claim. Regulatory Affairs should retain final authority on whether claims can be approved for use, require revision, or require collection of additional data.

To facilitate claim validation, a four-tiered system is proposed to categorize the robustness of claims. The highest level (Level 3) encompasses claims backed by multiple reliable sources, while the lowest level (Level 0) includes claims that are non-verifiable or conflict with regulatory approvals. This tier system ensures that claims used in marketing and regulatory submissions are supported by sufficient evidence and provides clear guidance on what actions are required to strengthen claims that cannot yet be approved.

A centralized, controlled list of approved claims is essential. Marketing teams and others involved in promoting the product must strictly adhere to this list when developing promotional materials or campaigns to prevent the use of non-approved claims.

It is recommended to approach claims management as a continuous lifecycle process, much like product lifecycle management. As certain claims—particularly those related to adverse events, clinical benefits, and economic factors—may evolve post-launch, manufacturers should regularly review and update approved claims list based on new clinical and market data. This approach ensures that promotional materials always reflect the most current and scientifically validated information.

Regulatory bodies expect manufacturers to have processes in place to ensure all promotional materials are thoroughly vetted before approval and to prevent misleading claims from reaching the market. The approach outlined in this article supports marketing teams by allowing claims to be planned and validated without delays, while also assisting compliance teams in reducing the risk of regulatory violations.

8 References

[1] Medical Device Regulation; (EU) 2017/745, May 5, 2017

[2] Federal Food, Drug, and Cosmetic Act (FD&C Act); 21 U.S.C. §§ 301-399h.

[3] Medical Devices – Application of risk management to medical devices, ISO14971 (2019)

Kees den Besten, 23 September 2024