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HOW TO
guide.

Medical device *marketing.*

LEGAL & REGULATORY COMPLIANCE CHECKLIST

Great healthcare products don't reach patients if they *don't know about them.*

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INTRODUCTION

This booklet is designed to serve as a practical guide for healthcare marketing professionals working with medical devices. In an industry where regulatory compliance is as critical as creative impact, this resource will help you navigate the complexities of medical device marketing regulations while maintaining creative excellence.

WHAT IS COMPLIANT CREATIVITY?

Compliant creativity is the art of developing innovative, impactful marketing materials that operate within regulatory boundaries. Rather than viewing compliance as a limitation, this approach integrates regulatory requirements into the creative process from the outset, removing compliance as an obstacle to creativity.

As the regulatory landscape continually evolves, so too must our approach to compliant creativity. This booklet provides a framework that is adaptable to these changes.

HOW TO USE THIS BOOKLET

Each section contains practical checklists that can be applied to different marketing channels and contexts. Use these as:

- Pre-launch verification tools.

- Training resources for team members.

- Quality assurance guides.

- Documentation for stakeholder approvals.

Remember that this booklet is not a substitute for professional legal advice but serves as a practical tool to guide your marketing efforts.

01

Understanding medical *device classification.*

Medical device classification directly impacts marketing requirements and claims substantiation. Understanding where your product fits is the first step in compliant marketing.

CLASSIFICATION OVERVIEW:

Classification	Risk Level	Examples	Marketing Implications
Class I	Low risk	Bandages, hand-held surgical instruments	Lower regulatory burden; still requires compliant claims
Class IIa	Medium-low risk	Hearing aids, dental fillings	More stringent evidence requirements
Class IIb	Medium-high risk	Ventilators, bone fixation plates	Significant constraints on claims, requires robust evidence
Class III	High risk	Implantable devices, heart valves	Highest level of scrutiny for all marketing materials
Class Is, Im, Ir	Class I with special requirements	Sterile devices, measuring function	Additional specific requirements

KEY REGULATORY TRANSITION DATES:

Medical device manufacturers must be aware of critical transition deadlines:

- **26 May 2024:** Deadline for manufacturers to implement quality management systems in accordance with MDR Article 10(9).
- **26 May 2024:** Deadline for manufacturers to lodge applications for conformity assessment for 'legacy devices'.
- **26 September 2024:** Deadline for manufacturers to sign agreements with notified bodies for conformity assessment.
- **31 December 2028:** End of transition period for medium and lower risk devices.

Classification Checklist

- Confirmed current device classification under relevant regulations.
- Verified transitions needed for legacy devices (MDD to MDR).
- Documented classification in marketing briefing documents.
- Ensured marketing team understands classification implications.
- Confirmed classification-specific marketing restrictions.

02

Claims *compliance.*

The distinction between standard claims and absolute claims is crucial in medical device marketing. Making unsubstantiated claims can lead to regulatory action, reputational damage and financial penalties.

STANDARD CLAIMS VS. ABSOLUTE CLAIMS:

Standard Claims:

- Assertions or statements about your product.
- Require substantiating evidence.
- Can include comparative language if properly qualified.
- Examples: “helps improve,” “designed to assist,” “contributes to”.

Absolute Claims:

- Unqualified statements without any caution or uncertainty.
- Require exceptionally robust, watertight evidence.
- No room for error or subjectivity.
- Examples: “the best,” “the most effective,” “vital,” “essential,” “completely safe”.

COMMON PROBLEMATIC TERMS:

Term	Why It’s Problematic	Possible Alternatives
"Best"	Absolute claim requiring market-wide comparison	"Effective," "Designed to optimize"
"Safest"	Suggests absolute safety superiority	"Designed with safety in mind"

COMMON PROBLEMATIC TERMS:

Term	Why It’s Problematic	Possible Alternatives
"Essential"	Implies necessity for all users	"Important," "Valuable"
"Vital"	Similar to "essential," implies absolute necessity	"Significant," "Notable"
"Completely eliminates"	Absolute claim about total effectiveness	"Helps reduce," "Designed to minimize"
"Revolutionary"	Implies radical superiority without specific context	"Innovative approach," "Advanced design"
"Eco-friendly"	Absolute environmental claim	"Designed with environmental considerations"

CASE STUDY:

THE WORD CHOICE THAT COST MILLIONS:

The Aqua Pura case demonstrates how even a simple phrase like “eco-friendly cap” constitutes an absolute claim requiring full substantiation throughout the product’s life cycle. The Advertising Standards Authority (ASA) ruled this claim was misleading because the company could not demonstrate the cap was not harmful to the environment at any point during its full life cycle. Similar scrutiny applies to medical device claims.

Classification Checklist

- Reviewed all marketing materials for absolute claims.
- Substantiated all claims with appropriate evidence.
- Ensured evidence is current and from credible sources.
- Qualified claims appropriately where needed.
- Verified claims relate to approved intended uses only.
- Documented the substantiation for each claim.
- Reviewed comparative claims for fairness and accuracy.
- Confirmed claim language aligns with classification requirements.

03 Channel-specific *checklists.*

The distinction between standard claims and absolute claims is crucial in medical device marketing. Making unsubstantiated claims can lead to regulatory action, reputational damage and financial penalties.

Print Materials (Brochures/Leaflets)

- Included device classification clearly.
- Listed intended uses accurately and completely.
- Included all required warnings and precautions.
- Added manufacturing information and CE/UKCA marking as required.
- Referenced clinical studies appropriately.
- Included clear disclaimers where needed.
- Verified all images accurately represent the device.
- Ensured all claims have substantiating references.
- Added appropriate legal copy in required font size.
- Included date of preparation/revision.
- Verified materials follow branding guidelines and compliance requirements.

Digital Marketing (Websites/Banners)

- Separated HCP and patient/public content where needed.
- Implemented appropriate access controls for HCP-only content.
- Included classification information on product pages. Added date of last update on medical content.
- Listed intended uses accurately and completely.
- Added required disclaimers prominently.
- Ensured all claims are substantiated with accessible references.
- Included clear contact information for adverse event reporting.
- Added T's & C's for website use.
- Implemented appropriate cookie and privacy notices.
- Ensured all downloadable materials are compliant.
- Verified website metadata doesn't contain unapproved claims.

Social Media

- Established monitoring process for adverse event reporting in comments.
- Created clear guidelines for responding to product questions.
- Ensured posts don't make claims beyond approved uses.
- Verified all shared images accurately represent the device.
- Included appropriate disclaimers on promotional posts
- Reviewed hashtags to ensure they don't constitute unapproved claims.
- Documented approval process for all social media content.
- Established guidelines for influencer/KOL partnerships.
- Created process for archiving all social media content.

Exhibitions and Events

- Created compliant stand graphics and materials.
- Prepared compliant handout materials.
- Trained booth staff on compliant product discussions.
- Created process for recording adverse events reported at events.
- Ensured demonstrations are consistent with approved uses.
- Verified all displayed marketing materials are approved.
- Separated HCP and public-facing materials if needed.
- Prepared compliant presentation materials.
- Created system for documenting unsolicited requests for off-label information.

Advertising (Including Google Ads)

- Verified compliance with country-specific advertising regulations.
- Ensured ads only promote approved uses.
- Included required disclaimers appropriately.
- Verified image usage rights and compliant presentation.
- Confirmed Google Ads compliance with healthcare policies.
- Ensured landing pages are fully compliant.
- Added appropriate qualifying statements where needed.
- Documented approval of all advertising materials.
- Confirmed compliance with platform-specific requirements.

04

Stakeholder *approval process.*

Effective stakeholder management is essential for ensuring compliant marketing materials and efficient workflows.

KEY STAKEHOLDERS MAP:

Stakeholder	Role in Approval Process	Typical Concerns
Regulatory Affairs	Ensures adherence to regulations	Classification, labeling, claims substantiation
Legal	Reviews legal compliance	Risk mitigation, claim substantiation, comparative claims
Medical Affairs	Validates clinical accuracy	Scientific accuracy, clinical evidence quality
Quality Assurance	Ensures quality system compliance	Documentation, process adherence
Marketing	Develops content	Messaging impact, brand alignment
Commercial Leadership	Strategic oversight	Market positioning, competitive strategy

STAKEHOLDER APPROVAL TEMPLATE:

[Use this template to track approvals for each marketing material].

Project Name:

Material Type:

Intended Audience:

Markets:

Stakeholder	Approved By	Date	Comments/ Changes Required	Resolved
Regulatory Affairs				
Legal				
Medical Affairs				
Quality Assurance				
Marketing				
Commercial Leadership				
"Eco-friendly"				

Stakeholder Management Checklist:

- Identified all relevant stakeholders for approval.
- Created clear timeline for review process
- Provided complete information package to reviewers.
- Documented all feedback systematically.
- Addressed all concerns before final approval.
- Maintained audit trail of changes and approvals.
- Ensured final version matches approved content.
- Created archive of approved materials.
- Established process for periodic review/updates.

05 Country-specific *considerations.*

Medical device marketing regulations vary significantly by country. This section outlines key regional considerations.

UK Requirements

- Complied with UK Medical Devices Regulations 2002 (as amended).
- Added UKCA marking (or CE marking during transition period).
- Followed Advertising Standards Authority (ASA) guidelines.
- Complied with CAP/BCAP codes for advertising.
- Ensured compliance with MHRA guidance.
- Added UK-specific disclaimers and warnings.
- Verified product is registered with MHRA if required.
- Ensured UK Responsible Person is identified if necessary.

EU/MDR Requirements

- Complied with Medical Device Regulation (EU) 2017/745.
- Added CE marking with correct Notified Body number.
- Included EU Authorized Representative information.
- Ensured compliance with language requirements for target countries.
- Verified materials meet individual member state requirements.
- Confirmed UDI information is correctly presented.
- Added EU-specific disclaimers and warnings.
- Verified compliance with EUDAMED requirements.

Other International Considerations

USA:

- Complied with FDA regulations for device class.
- Added appropriate FDA clearance/approval statements.
- Followed FTC advertising guidelines.
- Ensured consistency with FDA-approved labeling.

Australia:

- Complied with Therapeutic Goods Administration requirements.
- Added ARTG registration information if applicable.
- Followed Therapeutic Goods Advertising Code.

Canada:

- Complied with Health Canada requirements.
- Added appropriate licensing information.
- Followed advertising guidelines from PAAB if applicable.

06

Consequences of *non- compliance.*

Understanding the potential repercussions of non-compliance can help prioritise proper processes and procedures.

LEGAL REPERCUSSIONS:

- Regulatory enforcement actions (warnings, recalls, marketing suspensions).
- Fines and financial penalties.
- Criminal liability in severe cases.
- Enforced corrective advertising.
- Legal proceedings from competitors for unfair practices.
- Potential personal liability for company officials.

BUSINESS IMPACT:

- Exclusion from public tenders:
  - Under Public Contracts Regulations, suppliers with past compliance issues can be excluded from future tenders.
  - Recent Procurement Bill makes exclusion for past poor performance easier.
- Product recalls and market withdrawals.
- Loss of certification marks (CE, UKCA).
- Increased regulatory scrutiny for all products.
- Marketing campaign cancellations and rework costs.
- Delays in product launches and market access.
- Impact on merger/acquisition due diligence.
- Non-compliance issues discovered during due diligence can affect valuation.
- May require indemnities or price reductions.

REPUTATIONAL DAMAGE:

- Public ASA rulings and regulatory notices.
- Negative media coverage.
- Erosion of healthcare professional trust.
- Damaged patient/consumer confidence.
- Competitive disadvantage.
- Long-term brand value erosion.
- Increased skepticism from payers and procurement teams.

CASE STUDY: TECHNICAL NON-COMPLIANCE IMPACT:

In a documented case, a medical device manufacturer made absolute claims about product performance that couldn't be fully substantiated. The consequences included:

1. ASA ruling against the company.
2. Requirement to withdraw all marketing materials.
3. Exclusion from a major public tender based on previous non-compliance.
4. Failed acquisition when issues were discovered during due diligence.
5. Estimated financial impact: £2.7M in direct costs and lost opportunities.

Risk Mitigation Checklist:

- Implemented robust review and approval process.
- Created clear substantiation files for all claims.
- Established monitoring process for regulatory changes.
- Conducted regular compliance training for marketing team.
- Engaged early with regulatory team on campaign concepts.
- Created compliance review schedule for existing materials.
- Developed crisis management plan for potential compliance issues.
- Established relationship with regulatory consultants for complex issues.

APPENDIX A: GLOSSARY OF TERMS.

Absolute Claim: An unqualified claim without caution or uncertainty, using terms like “best,” “most,” or “essential.”

ABPI Code: The Association of the British Pharmaceutical Industry Code of Practice.

Adverse Event: An undesirable experience associated with the use of a medical product.

ASA: Advertising Standards Authority, the UK’s independent advertising regulator.

BCAP Code: The UK Code of Broadcast Advertising.

CAP Code: The UK Code of Non-broadcast Advertising and Direct & Promotional Marketing.

CE Marking: Certification mark indicating conformity with health, safety, and environmental protection standards for products sold within the European Economic Area.

Class I, IIa, IIb, III: Medical device risk classifications, with Class III representing the highest risk.

Conformity Assessment: The process of demonstrating whether specified requirements relating to a product have been fulfilled.

MDR: Medical Device Regulation (EU) 2017/745, the European regulation for medical devices.

MHRA: Medicines and Healthcare products Regulatory Agency, the UK regulatory body.

Notified Body: An organization designated by an EU country to assess the conformity of certain products before being placed on the market.

Off-Label: Use of a medical product for an indication, dosage, or patient population not approved by the regulatory authority.

SmPC: Summary of Product Characteristics, the basis for information for healthcare professionals on how to use a medicine.

Substantiation: Evidence supporting a claim made about a product.

Technical Non-Compliance: Failure to comply with technical regulatory requirements.

UKCA Marking: UK Conformity Assessed marking, the UK product marking for Great Britain (England, Wales, and Scotland).

UDI: Unique Device Identification, a system to mark and identify medical devices.

APPENDIX B: USEFUL RESOURCES.

Regulatory Websites

- **MHRA (UK):** https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
- **European Commission Medical Devices:** https://ec.europa.eu/health/medical-devices-sector/overview_en
- **FDA (US):** https://www.fda.gov/medical-devices
- **ASA (UK):** https://www.asa.org.uk/

Industry Associations

- **ABHI (Association of British HealthTech Industries):** https://www.abhi.org.uk/
- **MedTech Europe:** https://www.medtecheurope.org/
- **AdvaMed (US):** https://www.advamed.org/

Advertising Codes

- **CAP Code:** https://www.asa.org.uk/codes-and-rulings/advertising-codes/non-broadcast-code.html
- **BCAP Code:** https://www.asa.org.uk/codes-and-rulings/advertising-codes/broadcast-code.html

Guidelines

- **MHRA Blue Guide:** Advertising and Promotion of Medicines in the UK.
- **Green Claims Code:** CMA guidance for environmental claims.

APPENDIX C: APPROVAL DOCUMENTATION TEMPLATES.

Marketing Material Approval Form:

Product Name:

Material Type:

Reference Number:

Date Created:

Target Audience:

Distribution Channels:

Key Claims:

Claim	Substantiation Reference	Approved (Y/N)

Stakeholder Approval:

Department	Name	Signature	Date	Comments
Regulatory				
Legal				
Medical				
Marketing				
Other:				

Final Approval	
Date:	
Version Approved:	
Expiry/Review Date:	

Claim Substantiation Record:	
Claim:	
Product:	
Context of Use:	

Evidence Type:
☐ Clinical Study
☐ Technical Validation
☐ Comparative Testing
☐ Literature Review
☐ Expert Opinion
☐ Other:

Evidence Details:
Source(s):
Date of Evidence:
Strength of Evidence:
☐ Strong
☐ Moderate
☐ Limited

Limitations or Qualifications::
Approved for Use In:
☐ All Markets
☐ Specific Markets Only:
☐ HCP Communications Only
☐ Patient/Public Communications

Approved By:	
Date:	
Review Date:	

D

APPENDIX D: CREATIVE BRIEF COMPLIANCE CHECKLIST

Use this checklist when developing creative briefs to ensure compliance considerations are integrated from the start.

- Clearly identified device classification.
- Listed approved indications/uses.
- Identified key claims and their substantiation.
- Noted specific compliance requirements for the channel.
- Identified target audience (HCP, patient, public).
- Listed required disclaimers and warnings.
- Included regulatory considerations in timeline.
- Identified country-specific requirements.
- Noted comparative claims considerations if applicable.
- Included previous compliance feedback on similar materials.
- Identified review and approval stakeholders.
- Added considerations for monitoring (e.g., social media).

This document is for guidance only and does not constitute legal advice. Regulations change frequently, and marketing teams should always consult with regulatory and legal experts specific to their products and markets.

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