

Comparative Advertising for Medicinal Products in the EU and the UK

Legal framework and requirements for
advertising medicines

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Introduction

What is Comparative Advertising?

- Definition: Advertising that explicitly or implicitly identifies a competitor or their products.
- Purpose: To highlight differences or advantages of one product over another.

Focus of the Presentation:

- Legal framework in the EU and the UK.
- Key requirements and restrictions.
- Practical implications for medicinal products

Legal Framework in the EU and UK

Comparative advertising

- **EU** - Directive 2006/114/EC on Misleading and Comparative Advertising
- **UK** - Retained EU law: The UK continues to follow the principles of Directive 2006/114/EC

Medicinal products

- **EU** - Directive 2001/83/EC (Community Code on Medicinal Products)
- **UK** - Similar requirements under the Human Medicines Regulations 2012

Health Authority Guidance/approval procedures

Advertising Standards Authorities

Legal Comparative advertising

Key Requirements:

- Must not be misleading.
- Must compare products meeting the same needs or intended for the same purpose.
- Must objectively compare one or more material, relevant, verifiable, and representative features.
- Must not discredit or denigrate competitors, trade marks, trade names or other distinguishing signs.

Specific Rules for Medicinal Products

EU Perspective

EU Perspective:

- Directive 2001/83/EC (Community Code on Medicinal Products):
 - Prohibits misleading advertising of medicinal products.
 - Requires claims to be consistent with the Summary of Product Characteristics (SmPC).

UK Perspective:

- Similar requirements under the Human Medicines Regulations 2012.
- MHRA guidance emphasises accuracy, balance, and evidence-based claims

Key Restrictions

Prohibited Practices:

- Misleading comparisons.
- Comparisons that create confusion between competitors.
- Denigration of competitors or their products.

Practical Examples:

- Misrepresentation of clinical data.
- Overstating efficacy or safety.

Local approach

Countries with barriers to comparative advertising

- France
- Italy
- Spain
- Germany
- Ireland

Strict evidentiary requirements, risk of dispute or sanctions, cultural/regulatory preferences



Countries where comparative advertising is more prevalent

- UK
- Netherlands
- Sweden
- Denmark

Clear guidance, cultural acceptance, lower risk of challenge

Practical Implications for Businesses

Compliance Tips:

- Ensure claims are evidence-based and verifiable.
- Avoid subjective or exaggerated statements.
- Seek legal review.

Risk Management:

- Monitor competitor activity.
- Be prepared to respond to challenges or complaints.

Do's / Don'ts

Top 5 Do's

- ✓ Verify all claims with robust, accessible data (SmPC, peer-reviewed studies)
- ✓ Keep tone neutral and factual — avoid “puffery”
- ✓ Ensure comparisons are between products serving the same therapeutic purpose
- ✓ Check local practice: litigation vs self-regulation varies greatly
- ✓ Document substantiation in case of regulator/competitor challenge

Top 5 Don'ts

- ✗ Don't advertise Rx medicines to the public — universally prohibited
- ✗ Don't denigrate competitor products, even implicitly
- ✗ Don't use competitor trade marks beyond what's strictly necessary
- ✗ Don't rely on data outside the approved MA/SmPC unless clearly acceptable locally
- ✗ Don't assume EU harmonisation = identical enforcement — **local flavour matters**

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