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Current and Proposed Controls on "Greenwashing" in the EU and UK


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Increasingly, businesses are expected to consider their environmental credentials and to demonstrate sustainable practices. The use of "green" claims may therefore be highly effective in promoting products, including medicines and medical devices, potentially at a premium price, to both businesses, such as healthcare organisations, and consumers. However, the basis for such advertisements may be inconsistent, poorly defined and misleading, with the result that the claims are described as "greenwashing".

Current Measures Controlling Use of "Green" Claims at EU Level

Existing EU legislation aims to prevent inaccurate and misleading advertising. Directive 2006/114/EC therefore protects businesses against misleading claims including comparative advertising. Directive 2005/29/EC (the Unfair Commercial Practices Directive) prohibits unfair business-to-consumer commercial practices, defined as activities that are likely to materially distort the economic behaviour of the average consumer in relation to the product. These two directives, together with appropriate arrangements for enforcement, are implemented in national law in the EU Member States.

In addition, there are a number of existing regulations and directives that address green claims and labels for specific products, e.g., Regulation (EC) No 66/2010 (EU Ecolabel Regulation), Regulation (EU) 2017/1369 providing a framework for energy labelling, and Regulation (EU) 305/2011 on marketing of construction products.

Claims in relation to medicinal products are controlled by sector-specific legislation. Directive 2001/83/EC, on the Community Code relating to medicinal products for human use, provides at article 87 that:

"the advertising of a medicinal product:

- shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties,
- shall not be misleading".

The provisions of EU legislation may be supplemented by national laws and codes of practice in the Member States.

Proposed Directive on Environmental Claims

In March 2023, the European Commission ("Commission") published a proposal for a directive on substantiation and communication of explicit environmental claims made by businesses to consumers in the EU about their products or in relation to their commercial practices ("Proposed Green Claims Directive" or the "Proposed Directive"). This aims to combat increasing trends of greenwashing and use of misleading environmental statements by introducing common criteria for the substantiation and communication of such claims. A set of harmonised rules are offered to unify the regulation of labelling schemes.

Environmental claims are defined as "*any message or representation, which is not mandatory under Union law or national law, including text, pictorial, graphic or symbolic representation, in any form, including labels, brand names, company names or product names, in the context of a commercial communication, which states or implies that a product or trader has a positive or no impact on the environment or is less damaging to the environment than other products or traders, respectively, or has improved their impact over time*". The Proposed Directive applies to explicit (expressed in a textual form or in a label) and voluntary environmental claims made by traders abouts their products and business practices in a business-to-consumer setting, and to labelling schemes. It covers all voluntary claims about the environmental impacts, aspects or performance of a product, service or the trader itself as long as they are not specifically addressed by another EU legislative act.

The proposed rules are relevant to companies whose products or services are transacted to customers in the EU even if those companies are based outside of the EU. Microenterprises (with fewer than 10 employees and less than €2 million turnover) are exempt from application of the rules unless they wish to be covered because they want to use a particular certification. Also, there are measures aimed at easing the process and financial burden for small and medium-sized enterprises ("SMEs") who may be entitled to receive financial support, training and technical assistance.

Requirements under the Proposed Directive

Under the Proposed Directive, traders will have to substantiate all environmental claims they make, and to ensure they are based on reliable, comparable and verifiable information. All such claims will need to be independently verified and proven with scientific evidence before being communicated to customers. It is envisaged that there will be several elements against which claims will be assessed by verifiers under verification procedures to be set up by Member States, including whether:

- The claim refers to the whole, a part or an aspect of a product or of the activities of a trader.
- The claimed environmental benefits are significant from a life-cycle perspective.
- The claim is limited to requirements that the product must meet according to the law.
- The products or traders subject to the claim perform significantly better in terms of environmental impacts, aspects and performance than what is common practice for those products and traders.
- The products or activities that lead to environmental benefits also cause significant harm.

Verifiers will be independent third-party accredited bodies duly qualified to carry out the assessment of conformity.

The Proposed Directive introduces new requirements on comparative claims, namely that the data, coverage and

assumptions used to compare between products and activities should be equivalent for the products/services being compared.

Traders will only be allowed to communicate to the public claims for environmental benefits that are significant for the product or trader. When those claims concern a final product, the claim will have to be accompanied with information on how the customer should use the product to achieve the claimed benefits. If the claimed benefits are expected in the future, the claim will have to come with a timeline commitment. When communicated to the public, information will need to be made available in physical and digital form (weblink, QR code, etc.) and will have to address a number of data points.

If the Proposed Directive comes into force unamended, labelling schemes will only be set up under EU law and new national or regional labelling will no longer be permitted. Existing labelling schemes will continue as long as they meet the criteria established by the Proposed Directive. Environmental labelling schemes set up by private or public organisations outside of the EU will likely need to also go through a pre-approval process.

Enforcement actions and actors

Enforcement of the rules will be entrusted to national authorities and courts designated by the EU Member States. Authorities will have powers to start investigations on their own initiative or following complaints by natural or legal persons or organisations with legitimate interest. They will have powers to access and require natural and legal persons to provide any relevant documents and data.

If the competent authorities determine that a claim or labelling scheme does not comply with the rules, they will inform the trader and require them to make corrections within 30 days or to cease the use or reference to the non-compliant claim. Injunctive relief may be considered.

To the extent that the practices addressed by the Proposed Directive constitute unfair competition (which is likely), competitors would have access to private enforcement rights through the courts under Directive 2005/29/EC. Under the Proposed Directive, certain "qualified entities" such as consumer organisations would be able to bring collective actions against infringing traders under the EU's recent Collective Redress Directive (EU) 2020/1828, which will be amended for that purpose.

Proposed remedies and sanctions

It is up to EU Member States to adopt rules on penalties for infringements. The Proposed Directive requires the national enforcement provisions to take into account the nature, gravity, extent and duration of the infringement. Penalties may include:

- Fines of a maximum amount of at least at 4% of the trader's annual turnover in the Member State where the infringement occurred.
- Confiscation of revenue gained from transacting products with non-compliant claims or labels.
- Temporary exclusion from public procurement processes (including public tenders, grants and concessions) and from access to public funding for up to 12 months.

Procedure and next steps

The adoption of the Proposed Green Claims Directive is subject to the EU's ordinary legislative procedure and is now subject to approval by the European Parliament and the Council. Hence, the text of the proposal is not set in stone and is subject to negotiation between the EU legislators.

Once adopted, EU Member States will be required to transpose the provision into national laws. The proposal envisages a period of 18 months for implementation by the Member States.

What will the Proposed Directive mean for life sciences companies

The Proposed Directive is aimed at all sectors making green claims. If it is adopted in its current form, pharmaceutical and medtech companies that wish to make green claims in relation to products or services aimed at EU consumers will need to comply with the obligations contained in the Directive, in addition to the sector-specific rules on advertising contained in EU and national laws and codes of practice. Claims such as "Packaging made of 50% recycled plastic", "carbon neutral" and "sustainable" will all need to be substantiated with evidence, certified and communicated to consumers. These requirements will require time and resources, and may require that packaging and marketing strategies for medicines and devices be revisited. On the positive side, compliance with the additional regulatory burden may differentiate green companies from less environmentally friendly firms.

The Position in the UK

As the UK is no longer part of the EU, the Proposed Directive will not apply to environmental claims aimed at UK consumers.

However, a raft of general legislation, including the Trade Descriptions Act 1968, the Consumer Protection from Unfair Trading Regulations 2008 and the Business Protection from Misleading Marketing Regulations 2008 provide that descriptions of goods and advertising activity must be accurate and not misleading. In the case of medicines this requirement is stated at regulation 280 of the Human Medicines Regulations 2012 and, for companies which are members of the Association of the British Pharmaceutical Industry ("ABPI") or have otherwise agreed to adhere to the requirements of the ABPI Code of Practice ("Code"), Clause 6 of the Code sets out this requirement.

While existing legislation does not specifically address the requirements for "green" claims, guidance confirms the requirements for advertisers and misleading statements are subject to enforcement action.

The Competition and Markets Authority ("CMA") published its Green Claims Code in September 2021, and this has been in force since January 2022. The Green Claims Code sets out six general principles for companies seeking to comply with their obligations under consumer protection law:

1. claims must be truthful and accurate;
2. claims must be clear and unambiguous;
3. claims must not omit or hide important relevant information;
4. comparisons must be fair and meaningful;
5. claims must consider the full life cycle of the product or service; and
6. claims must be substantiated with robust, credible, relevant and up-to-date evidence.

If a business does not comply with these requirements, the CMA and other bodies, such as Trading Standards Services, may bring court proceedings. In some cases, businesses may be required to pay redress to any consumers harmed by the breach of consumer protection law.

In addition, the Committee for Advertising Practice ("CAP") Code issued by the Advertising Standards Authority ("ASA")

includes a section dealing with environmental claims. The CAP Code confirms, consistent with the principles set out in sector-specific codes, such as the ABPI Code in relation to prescription-only medicines and the Association of the British Healthcare Industries ("ABHI") Code in relation to medical devices, that claims must be accurate, balanced, fair, objective, unambiguous and based on up-to-date evidence. It states that absolute claims must be supported by a "high level of substantiation". Comparative claims such as "greener" or "friendlier" must be justified, for example, if the advertised product provides a total environmental benefit over that of the advertiser's previous product or competitor products and the basis of the comparison is clear. The ASA is already active in enforcement action against businesses who make environmental claims that are unsubstantiated or found to be misleading. Earlier this year, advertisements issued by several oil and gas companies were found to be misleading and banned on the basis that these promoted the companies' green offers and plans without including any reference to their larger polluting operations. Also this year, advertisements by two airlines were banned because these made misleading claims about the environmental impact of flying and, in 2022, the ASA banned advertisements by a bank for overstating the green credentials of certain of its investments and by a supermarket that claimed, without substantiating evidence, that its plant-based products benefitted the planet. The ASA is currently creating rules to govern when carbon neutrality and net-zero claims may be made.

Conclusions

While existing legislation prohibits inaccurate or misleading statements in advertising directed at both businesses and consumers, both the Proposed Green Claims Directive and the specific UK guidance dealing with environmental claims focuses on advertising to consumers, presumably on the basis that greater protections are required for this audience.

Overall, however, although the approach suggested in the Proposed Directive appears similar to that set out in the UK Green Code and the CAP Code, it goes further by requiring independent verification and certification of green claims prior to use.

Adela Williams is a Partner in Arnold & Porter's London office.
Her practice focuses on the regulation of medicinal products, medical devices, foods and cosmetics, particularly in relation to clinical trials, marketing authorisations, pharmacovigilance and advertising and promotion issues, including legal proceedings arising from the decisions of regulatory bodies.
In the context of advertising, she frequently assists clients in relation to compliance issues, including the coordination of cross-border programmes based on the EFPIA Code. She provides representation in proceedings before the UK Prescription Medicines Code of Practice Authority and its Appeal Board arising from alleged breaches of the ABPI Code of Practice and advises on enforcement action by the MHRA. She also has an extensive life sciences product liability practice. She is a registered medical practitioner and an Assistant Coroner.

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The team of lawyers specialising in this field in London is complemented by Arnold & Porter's highly regarded pharmaceutical and medical devices regulatory practice headed by Daniel A. Kracov in Washington, D.C., giving a combined team of over 40 lawyers.

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