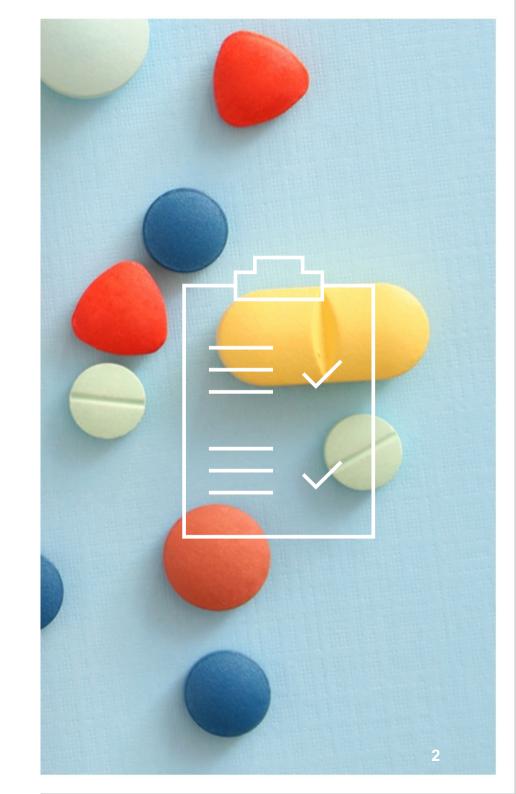


Agenda

- 1 Relevance of green claims to the pharmaceutical industry
- **2** Legal basis (Germany and UK)
- 3 Fictional case studies
- 4 Pitfalls and How to Avoid Them
- 5 Outlook
- 6 Key take-aways and sanctions





First Things First

How to: Reduce environmental impact

Four Types

1 Green Chemistry

Improving the life cycle of medicinal products while reducing or eliminating pollutants. Using predominantly organic resources.

2 Use of secondary raw materials and waste

Using recycled paper and glass containers while considering landfill or thermal recycling as a last resort.

Switch to renewable energies and zero-emissions targets

As in any manufacturing sector, the pharmaceutical industry might optimise the efficiency and environmental footprint of the resources it uses. (e.g. photovoltaic solar systems or electric vehicles)

Packaging

Using clear recycling instructions and environmentally friendly packaging designs. Biodegradability of packaging. Packaging reduction.

Comprehensive measures are already being taken in all these areas and are also being advertised!

Green Claims in General

Two types of advertising opportunities for pharma companies with environmental claims

1 Product-related advertising

Information on specific characteristics of individual products or product categories (e.g. "organic", "environmentally friendly" "recycled")

Use of







- Company-related advertising (image advertising), two alternatives:
- Indication of special environmental/sustainability characteristics of the company itself "without consideration"
- Indication of special commitment of the company / sponsoring in connection with the purchase decision (keyword "rainforest project")

For pharma companies selling solely prescription-only products – Corporate Advertising is the only option available

Important for reputation and increasingly for investor decisions: Getting it wrong has a negative reputational impact.

Customer Expectations (P and G medicines)

Ever Growing consumer awareness of environmental issues

- Pharma-Industry is considered one of the most polluting industries worldwide
- Studies found, that the emissions of the pharmaceutical industry exceed those of the automotive industry by 55 percent (cf. Lotfi Belkhir in Journal of Cleaner Production vol. 214, March 2019, "Carbon footprint of the global pharmaceutical industry and relative impact of its major players" p. 185)

Consequence for pharmacy only and general sale medicines:

- Strong emotional involvement of the consumer (fear, guilt, pride)
- Preference for goods with special environmental compatibility

Great opportunity to promote sales and image with highly emotional advertising



Information on environmental compatibility of products/ companies is an important part of CSR marketing





Results of the EU-Sweep 2021

European Commission - Press release



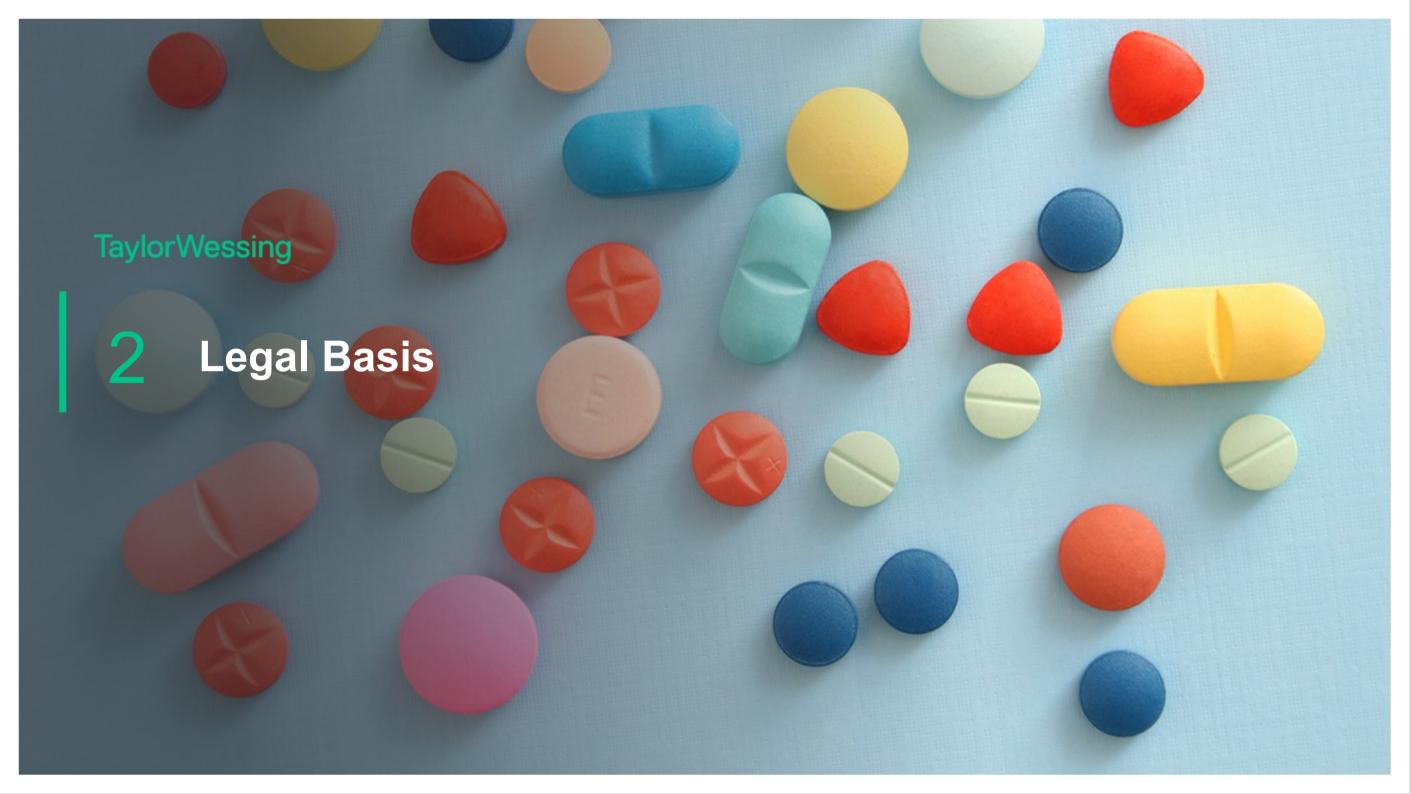


Screening of websites for 'greenwashing': half of green claims lack evidence

In more than half of the cases, the company did not provide consumers with sufficient information to assess the accuracy of the claims.

In 37% of the cases, vague and general claims such as "conscious", "environmentally friendly" and "sustainable" were made with the goal of giving consumers the unfounded impression that a product has no negative impact on the environment.

In 59% of cases, companies had not provided readily available evidence to support their claims.



Legal Basis (Germany)

Prohibition of misleading Advertising, §§ 5, 5a UWG (Unfair Competition Act)

§ 5 UWG

Misleading through deception

"Environmental claims" usually describe

 the nature, design, composition, method of manufacture or quality of a product (para. 2 No. 1),

or

characteristics of the entire company (para. 2 no. 3)



Claims must not be incorrect / give a false impression

§ 5a UWG

Misleading by withholding essential information



No deception / misconception has to be caused



Sufficient that:

- the information is necessary for an informed decision, and
- the absence is likely to lead the consumer to make a transactional decision that he would not have made otherwise

Legal Basis (Germany)

Special legal requirements: Prohibition of deception

- § 3 HWG (Law on Advertising in the Field of Medicine) and
- § 8 AMG (Medicinal Products Act)

§ 3 HWG and § 8 AMG

Misleading through deception about

therapeutic effect

guaranteed treatment success

the composition of the product

the [...] successes of the manufacturer



Legal Basis (UK)

The Law

To Consumers

Authority (ASA)

The Consumer Protection from Unfair Trading Regulations 2008/2017 – to be amended by the Digital Markets, Competition and Consumers Bill (in the legislative process) (protections to consumers from **unfair commercial practices**). Enforcement by the **Competition and Markets Authority (CMA)**Supported by: CAP Code and BCAP Code – enforced by the **Advertising Standards**

To Business

The Business Protection from Misleading Marketing Regulations 2008/ 1276 – prohibition on misleading advertising

Prescription only

ABPI Code ("B2B")

6.1 "Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis."

Pharmacy only and general sales

PAGB Code ("B2C")

Prohibition of misleading or false product claims

ASA and CMA Principles for Environmental Advertising (UK)

Starting point

CMA – Green Claims Code

ASA – CAP/ BCAP Codes, 11: Environmental Claims, in summary:

- Clarity, truthfulness, accuracy and lack of ambiguity in claims
- Should not omit or hide significant/ important information
- Substantiation for all claims, and any absolute claims require a high level of substantiation
- Comparisions ("greener" "environmentally friendlier") must reference the compared product and be fair and meaningful
- Environmental claims must be made on the full life cycle of the advertised product (or be clear if not).
- Claims should not be made where they are not universally accepted/ or are not accepted by a significant division of scientific opinion
- No claims based on absence of an ingredient if that ingredient is not either usually found in competing products or highlighting a benefit that is a legal requirement



Requires a thoughtful analysis of any planned environmental claims, considering the consumer perspective and whole product life cycle







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Imagine:

We are a marketing team wanting to get on the eco-band wagon by using environmental claims in corporate advertising.



What we would like to say:

Medicine supplied in syringe used in hospitals and at home, is "100% recyclable".

But: because including a sharp, a sharps bin would always be used and the whole syringe would be disposed of following special rules on medicinal waste.

We use 85% biodegradable materials in our plasters and bandages. These nevertheless usually take more than 5 years to break down in landfill under typical conditions.

Marketing team wants to say:



The company has improved the environmental profile of its products



Through using a significant volume of biodegradable materials in its products.

Can we explicitly advertise another 5% improvement in our products biodegradability rate if at the same time 20% more CO₂ is emitted in the production of the "improved" product and more water is required to manufacture it?

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Fictional Case Study

Our company is converting its factories to use sustainable energy. We want to express, that "We are listening to the environment and aiming for net-zero products by 2030".

But: The company has not reviewed the environmental profile of its suppliers.



Can we call our company "climate neutral" if we have offset all the emissions we cause with emission certificates, without taking any measures to reduce our environmental impact?

Climate change doesn't do borders.

Neither do rising sea levels. That's why SuperPharmaCo is aiming to provide up to \$1 trillion in financing and investment globally to help our suppliers transition to net zero.

Climate changes doesn't do borders.

So in the UK and Germany, we're helping to plant 2 million trees which will lock in 1.25 million tonnes of carbon over their lifetime.



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Fictional Case Study

We have tested and certified our new anti-dandruff shampoo in the categories CO₂ emissions, nutrient input, acidification, summer smog and ozone depletion.

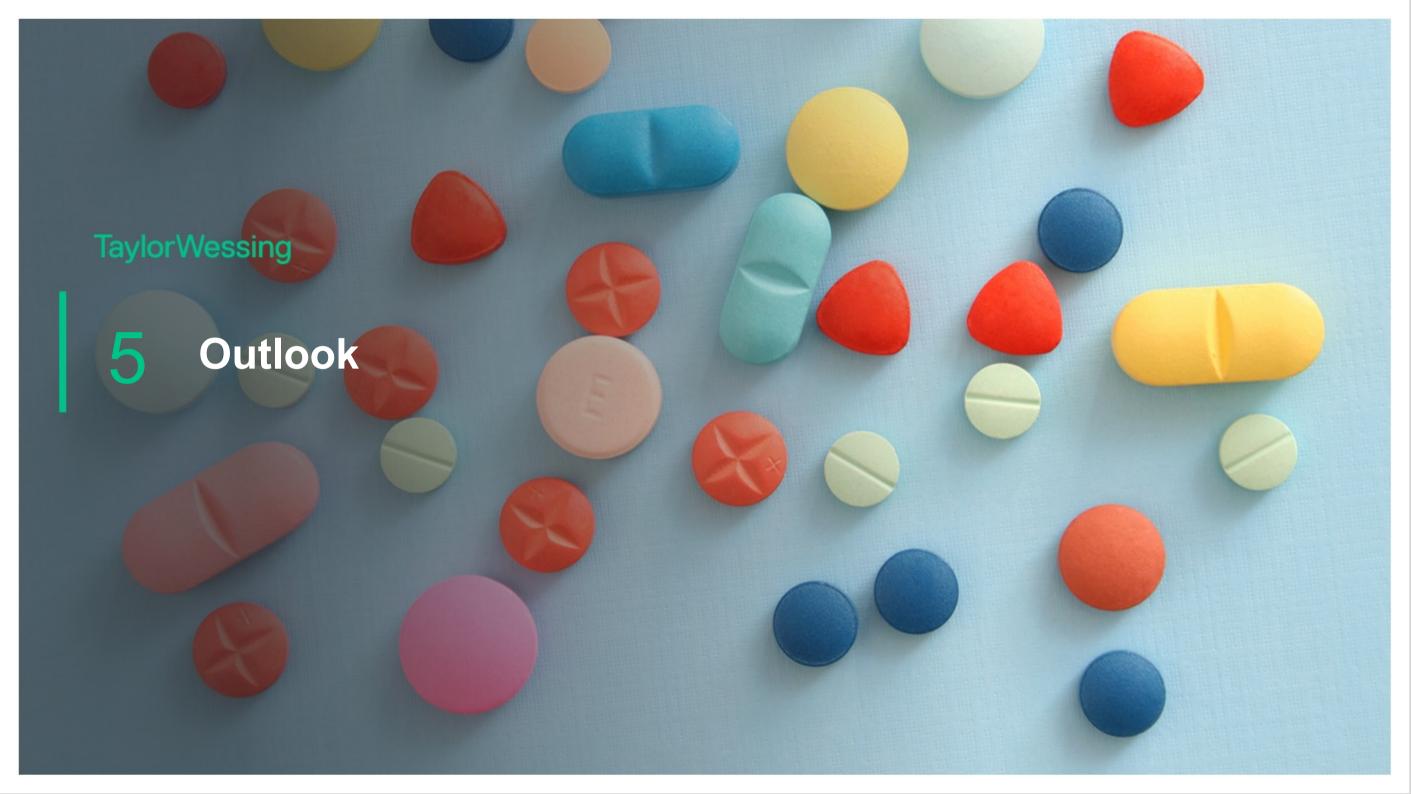
It is proven to be environmentally neutral, i.e. it has no negative impact on the environment in these categories.

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We want to label our medicinal teas with our self-created logo as it is too complicated and time consuming to apply for an official Eco-Certificate. Is this permitted?





New EU-Directives

Draft of Directive 2022/0092 (COD)

"empowering consumers for the green transition through better protection against unfair practices and better information"

and

Draft of Directive 2023/0085 (COD)

"on substantiation and communication of explicit environmental claims (Green Claims Directive)"



On September 19 2023, EU Council and EU Parliament reached a provisional agreement to empower consumers for the green transition!



New EU-Directives in Draft Stage

Draft of Directive 2022/0092 (COD)

"empowering consumers for the green transition through better protection against unfair practices and better information"

Provides for stricter rules on advertising with sustainability aspects

Consumers shall be informed transparently and truthfully so that they can make informed purchasing decisions and contribute to sustainability



Transparent and truthful information for Consumers, so that they can make informed purchasing decisions and contribute to sustainability



Legal certainty for companies

$\sqrt{1}$

New EU-Directives in Draft Stage

"per se" ban on

- Using sustainability labels that are not based on a fixed certification system or has not been set by public authorities.
- Making general environmental claims if the business cannot prove the advertised environmental impact or if the specification of the statement is not clearly and is stated in a prominent manner
- Making an environmental claim about the whole product, even though the claim only relates to a specific aspect
 of the product.
- In addition, stricter standards will also be applied to advertising with environmental goals
 - Environmental claims about the future environmental performance without clear, objective and verifiable commitments and targets as well as an independent monitoring system are inadmissible.

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New EU-Directives in Draft Stage

Draft of Directive 2023/0085 (COD)

"on substantiation and communication of explicit environmental claims (Green Claims Directive)"

- Complements the March 2022 proposal on "Empowering Consumers for Environmental Change" by setting more specific rules for environmental claims alongside a general ban on misleading advertising
- Covers all voluntary advertising claims about environmental impacts, aspects or performance of products, services and the companies themselves



More clarity for Consumers through reliable, comparable and verifiable information



Benefits environmentally friendly companies. They will be clearly recognisable and can win over consumers and increase their sales.

New EU-Directives in Draft Stage

Green Advertisement only allowed,

- if detailed information and evidence to substantiate the environmental claim is directly available to the consumer
- If the explicit environmental claim relates to a future environmental performance of a product or business, it shall include a time-bound commitment for improvements within the business operations and value chain.
- companies must obtain confirmation of compliance with the requirements of the Directive from a independent audit body before using a Green Claim.

Use of Eco-labels

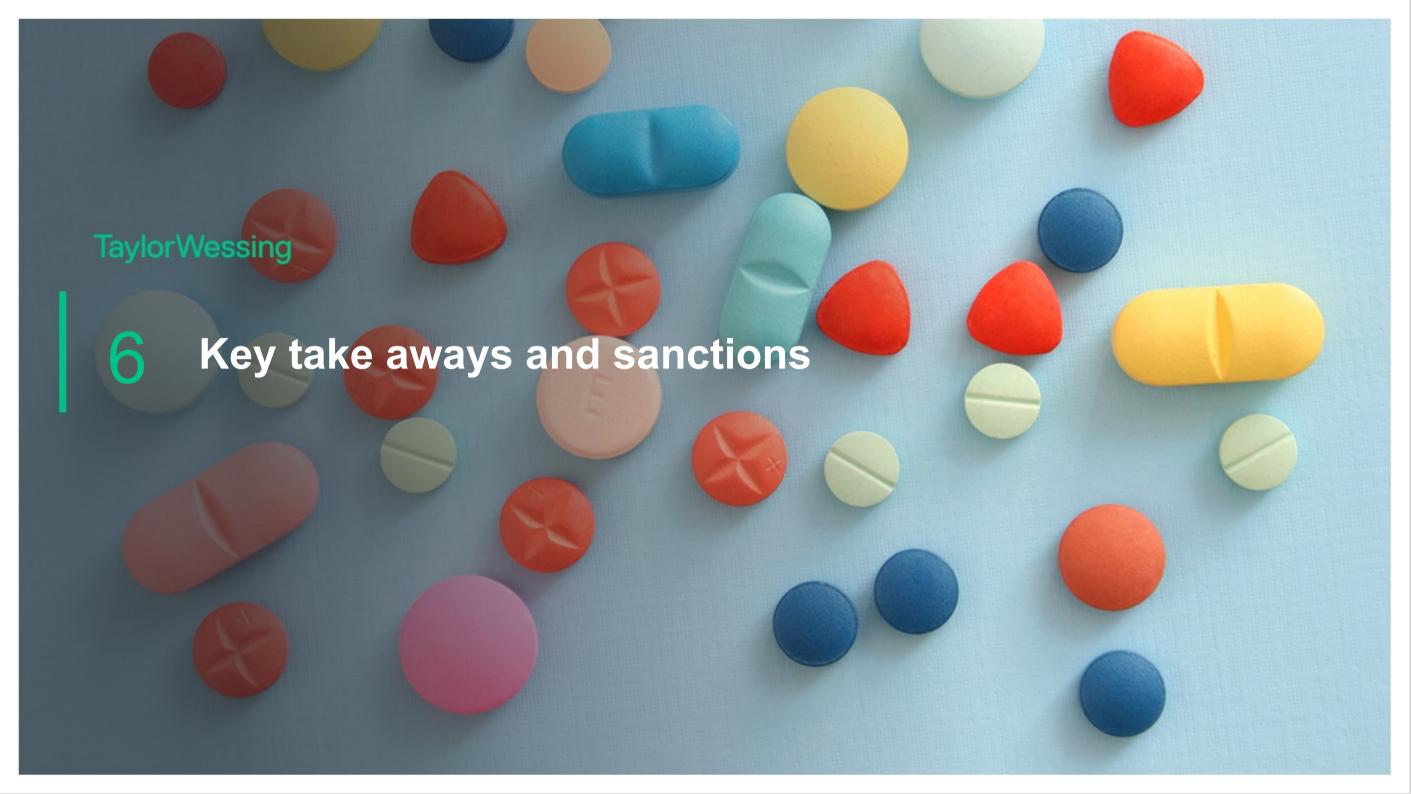
new public schemes, unless developed at EU level, are not allowed, and new private schemes are only allowed if they pursue more ambitious environmental objectives than existing eco-label schemes and are approved in advance

New legislation in the UK

Digital Markets, Competition and Consumers Bill

- Solely relates to consumers
- Prohibits unfair commercial practices
- Includes both acts and omissions which mislead
- A misleading act is one where the provision of false or misleading information or an overall presentation is likely to deceive the average consumer about a matter, in each case relating to a product, trader or any other matter relevant to a transactional decision
- Enforced locally or by the CMA
- Consumer right of redress if they acted on the unfair practice and it was a significant factor in their decision
- Redress: right to unwind, to a discount or damages
- Criminal liability of individuals and also by a "body corporate" if done with the consent or connivance of an officer or due to their neglect





Key take aways

Is the green claim true?

Think about whether the green pledge is true and consistent with reality.

Does the customer have all the information to understand the green claim correctly?

Environmental topics are often complex and cannot be understood by laypeople unless they are explained. Only if customers know what is behind a green claim, they can decide whether they want to support the product by buying it.

What is the customer perspective – what would they understand?

Consider consumers to take quite a literal view of claims.

Is it clear what the green claim refers to?

Is it clear to the customer, whether the green claim refers to the whole product or only to individual parts of the product or areas of the life cycle?



Key take aways

Visuals - what overall impression does the advertisement convey?

Check not only the actual text, but the entire design of the green claim. The visuals used to present a product can also be misleading (icons, images, choice of colours, arrangement)

Have you got supporting evidence for your claims?

Evidence to support any green claim is crucial. This can be provided by expert reports, studies, certificates, or professional articles. "Field reports" are usually not enough to prove the truth of a statement in court.

Does the advertised environmental benefit hide another negative effect?

If a green claim over emphasises an environmental aspect even though its impact is marginal, this could constitute greenwashing. The advertised aspect of the product should be given appropriate weight.



Sanctions

Think about the legal consequences of making misleading green claims

"Greenwashing" can have a variety of legal consequences in addition to (considerable) financial penalties, including:

- actions for injunction
- banning of 'greenwashing' ads (for example, pasting over posters with inadmissible claims)
- claims for damages
- reputational damage
- potential criminal liability for company and individuals

If you keep the points just mentioned in mind, you can avoid many unnecessary risks. Nevertheless, there is **no guarantee** that courts will find the statement admissible.





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Wiebke is a trademark lawyer specialising in advice and litigation in the fields of intellectual property law and competition law. With over 20 years of professional experience during which she has handled a multitude of well-known, primarily international client matters, Wiebke has earned herself an excellent reputation winning a number of awards in trademark and design law.

Her work focuses on German, European and international trademark applications as well as on opposition and appeal proceedings before the DPMA and the EUIPO. Another focus is the drafting and negotiation of licence agreements. Her clients – ranging from SMEs to global players - include companies in the media, fashion, toy and food industries.



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Alison co-heads the Taylor Wessing international life sciences team. Alison is recognised as a top regulatory and transactional life science lawyers in Europe and is qualified in England & Wales and the Irish Republic. She works with mid-sized and large pharmaceutical and medical device manufacturers, helping them to design new product offerings to meet regulatory requirements and to facilitate product commercialisation across the UK and EU. Alison frequently negotiates optimal positions for pharma and medical device companies with regulators such as competent authorities, notified bodies, and industry bodies with voluntary codes.

Alison's analytical understanding of strategy and business, which comes from over 25 years helping hundreds of life sciences companies manage the range of legal challenges that arise in putting medicinal products and medical devices on the market has encompassed corporate, competition, IP and compliance with anti-bribery laws and codes. She applies this breadth of knowledge to help companies achieve their business goals at the same time as regulatory and compliance requirements and she is consequently known for providing highly pragmatic advice.

