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IP & Life Science News

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Counterfeit confusion

– how to avoid counterfeits in an increasingly complex market

Recent data from the European Commission show that counterfeit goods continue to make up around 2,5% of global trade and an estimated 5,8% of all imports from third countries in the EU.

An updated "piracy watch list" may help consumers avoid websites known to be engaged in counterfeit and pirating, but unfortunately counterfeits are still difficult to evade, especially in the growing market for second-hand goods.

IPR infringements cause high financial losses for rightsholders and undermine sustainable IP-based business models. A study by the EU Intellectual Property Office (EUIPO) and the Organisation for Economic Co-operation and Development (OECD) from 2021 reports that USD 464 billion worth of counterfeit and pirated goods were traded worldwide in 2019. In the EU, this amounted to approximately EUR 119 billion. Data from the study also shows that consumers find it especially difficult to distinguish between genuine and fake goods online.

Between 2018 and 2020 online retail sales rose by 41% in major economies.

According to Eurostat, 70% of Europeans shopped online in 2020, and 9% claim to have been misled into buying counterfeits.

Piracy Watch List, p. 2-3

Verification methods

Different forms of verification methods exist to help consumers with only buying authentic products. However, verification may not be the same as authenticity.

Private verification labelling

The sale of counterfeit goods on the internet presents a threat to rightsholders, consumers and platforms. To help combat counterfeits and to comfort consumers in their online retailing, some e-commerce platforms have introduced their own verification methods towards primarily second-hand products, sometimes referred to as "private verification labels".

The use of private verification labels describes a platform's own verification process which is not endorsed by the original brand. The method raises issues, illustrated in a noteworthy number of examples, where brands have discovered that platforms (unintentionally) advertise counterfeit products as "authentic" or "verified authentic" pursuant to the platforms' own teams of authentication experts conducting the verification process. Thereby, consumers may end up buying counterfeit products while believing that the opposite is the case.

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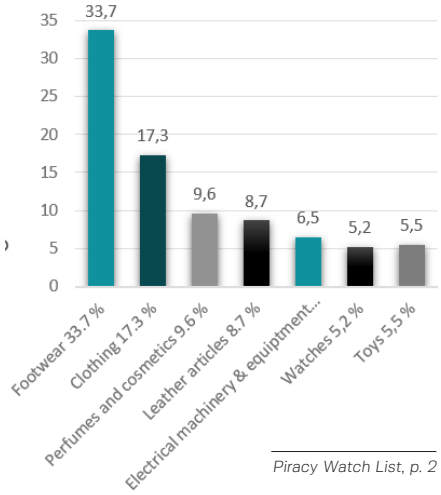
AI-powered authentication services

Another way of authenticating products is by using Artificial Intelligence (AI)-powered authentication services. The method helps automate and expand the process, by using algorithms for counterfeit recognition. The machines are designed to detect details that separate legit items from counterfeits and are used both by second-hand platforms and brands. More specifically, logo detection provides brands with the ability to automatically analyse marketplaces for counterfeit products purporting to be genuine articles under their brand. In addition to this, they can also use visual search to spot common design imitation, such as distinctive patterns. With this technology, brands can analyse hundreds of millions of images per day.

Endorsed brand authentication

Endorsed brand authentication is conducted by an authorised distributor or the original brand, and obviously represents the safest way in terms of ensuring the purchased product's authenticity. Some brands further argue that only they hold the necessary skill, training, know-how and special equipment on site to guarantee the authenticity of each product. However, this stand may raise concerns from a competition perspective, and may not be desirable from a market perspective.

The EU detentions of counterfeits linked to e-commerce include a broad range of products led by:



Piracy Watch List, p. 2

The 2022 Watch List

The Commission has prepared a "Counterfeit and Piracy Watch List", which lists examples of reported marketplaces and service providers whose operators or owners are allegedly residents outside the EU, and who reportedly engage in, facilitate or in other ways benefit from counterfeit sales. The aim of the list is to raise consumer awareness and encourage authorities to take the necessary actions to reduce the sale of IPR infringing products on these markets. Since the publication 2020 Watch List, several enforcement actions and measures have been taken, and e-commerce platforms are adopting developments, including protection portals, reporting tools and policies.

Accura comments

With the continuous rise of e-commerce and non-authentic/counterfeit products becoming increasingly difficult to separate from authentic products, great emphasis is put on the operators' verification methods. The ability to adequately verify third-party sellers has proven to be challenging, why efforts should be made to improve mechanisms for identifying counterfeit items and responses to the dynamic emerging challenges. Ultimately, these concerns, and the more significant issues they raise, will likely continue to arise and gain relevance as the value of the resale market increases.

When shopping online, following these steps may help avoid counterfeit and pirated products:

1. Check the identity of the seller
2. Search other consumers' reviews
3. Check if the URL is strange
4. Know the hallmarks of the real product
5. Watch if the price is suspiciously low
6. Check the platforms' verification method
7. Consult the Counterfeit and Piracy Watch List
8. Always pay by card, so you can dispute the payment

Broadened scope for the Danish Medicines Council's assessment by direct classification

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The Danish Medicines Council recently announced a broadening of its procedure to have new medicinal products assessed by direct classification in treatment guidelines.

The broadening regards medicinal products not considered "equivalent to medicinal products covered by an existing treatment guideline in the therapeutic area" due to special reasons such as safety considerations. Going forward such non-equated medicinal products will be eligible for assessment through direct classification – just as equated medicinal products.

Until now, the assessment of medicinal products that could not be equated was carried out in a lengthier two step procedure: First, the pharmaceutical company needed to obtain the Medicines Council's recommendation concerning the medicinal product, despite the existence of a treatment guideline in the therapeutic area concerned. Second, the pharmaceutical company then had to wait (often for a longer time than the four months deadline issued by the Medicines Council itself) for the medicinal product to be classified in the treatment guideline once the guideline was subsequently updated by the Medicines Council.

Going forward, the Medicines Council will be able to recommend and classify non-equated medicinal products in a treatment guideline in one single step, as if the medicinal product was equated.

Pharmaceutical companies wishing for the Medicines Council to make use of this procedure must indicate so when submitting a request for the Medicines Council's assessment. A specific application form for this process is currently being drawn up by the Council.

The Medicines Council can, however, also decide *ex officio* to carry out the assessment of a non-equated medicinal product in the "single step"-procedure (assessment through direct classification).

The new procedure does not concern medicinal products expected to be better than current standard treatments in Denmark.

Accurra comments

The broadening of the procedure for assessment through direct classification in a treatment guideline is expected to receive a warm welcome by pharmaceutical companies seeking to obtain recommendations from the Medicines Council as the single step-procedure is likely to significantly reduce the lengthy processing times of the Danish Medicines Council.

If you have any questions regarding the new procedure or the Danish Medicines Council's work, you are welcome to contact Accura's Life Science experts.

Cost-neutrality requirement abandoned by the Danish Health Technology Council

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When requesting the Danish Health Technology Council for its assessment of a new medical device or health technology product, companies are no longer required to render probable that the new product will not lead to an increase in costs for the Danish healthcare sector.

The "cost-neutrality" requirement has constituted a significant obstacle for companies in the application process. The hope is that the abandonment of the requirement will lead to an increase in the recommendations of new and innovative technologies and solutions.

Cost-neutrality

Until now, medical device companies had to render probable that the new product, which the company requested the Health and Technology Council to assess, would not lead to an increase in expenses for the Danish healthcare sector. This should be rendered probable in the light of competing products or solutions used in the Danish health sector. The purpose of the requirement was to ensure that the Council's resources were only used for cost-neutral or more cost-efficient solutions. Should a company's more expensive solution be required by the healthcare sector, the idea was that the company could easily submit a request for an assessment via the Danish Regions or hospitals. However, in practice this has not been the case.

The requirement has now been fully abandoned with immediate effect following approval by the Danish Regions. The Council is soon expected to amend its procedural guidelines for submitting a request for assessment in accordance herewith.

The Health and Technology Council was established by the Danish Regions in 2021. The objective is to ensure that the resources of the Danish healthcare system are adequately targeted towards technologies and inventions **granting the best value for money**. To achieve this goal, the Council assesses and recommends medical devices and health technology products to the Danish regions and hospitals.

The Council's assessments of the value of a specific technology **considers clinical efficacy and safety, a patient perspective and health economics**, and constitutes a comparison to the value of the best existing, implemented alternative technology used in the Danish healthcare sector.

A recommendation from the Council is not required to market medical devices and health technology products, but **a recommendation from the Council should make sales more obtainable.**

Accura comments

The abandonment of the cost-neutrality requirement is likely to be happily received by the Danish medical device sector, as it opens up for more applications and should make it possible to ensure a smoother process for requesting an assessment. The change will remove a significant obstacle for medico companies, especially those providing new and innovative solutions to the Danish healthcare sector.

PR bureaus beware!

You may (also) be (co-)liable for hidden advertisement

In a new press release regarding hidden advertisement, the Danish Consumer Ombudsman emphasised that PR bureaus and others assisting companies with their advertising, can become co-liable by complicity if the advertisements do not comply with the rules in the Danish Marketing Practices Act.

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The case at hand

In the recent press release, the Consumer Ombudsman emphasised to a PR bureau the rules on hidden advertisement and its responsibility for highlighting any commercial intend. The PR bureau had assisted companies with their PR activities by writing advertorial press releases about the companies and their products. The PR bureau distributed the press releases to editorial medias with the instruction that the press releases were for "free editorial use" and could therefore be used as is. However, as the press releases had a clear commercial purpose (promoting the companies and their products), they were considered *de facto* advertisements and should consequently be clearly marked as such. By not ensuring the proper indication that "the material constitutes an advertisement", the PR bureau contributed to violating the ban against hidden advertisements.

According to the Marketing Practices Act section 6, a company must at all times clearly identify the commercial intent of their advertising. The purpose is to ensure that the consumers are aware of the commercial content and thereby evaluate the content based on the commercial context.

Further, paragraph 11 of Annex 1 to the Marketing Practices Act stipulates that it is misleading to use editorial content in the media to promote a product, when a trader or a company has paid for the promotion, without this being evident in the content or in images or sound that can be clearly identified by the consumers.

Advertorials

Advetorials, advertising material that look like journalistic articles, are a commonly used advertising tool. But if the commercial intent is not clearly identifiable, the advertorial breaches the ban against hidden advertisement.

Readers need to know if they are reading an editorial article or text with a commercial intent. In this regard, the Consumer Ombudsman has previously stressed the importance of maintaining the confidence in the media. Advertorials, just as any other piece of advertisement, must therefore clearly state that the article or press release is in fact an advertisement.

An earlier press release from the Consumer Ombudsman shows that the mere use of the word "advertorial" is not sufficient to mark advertising material. The commercial purpose of a (hidden) advertisement can, instead, be indicated by using disclaimers such as "sponsored content" or "advertisement". Further, companies (whether the advertiser or the marketing bureau creating and distributing the advertisement) must ensure that the commercial disclaimer is presented to the receiving party (i.e., the consumer) in a clear and unambiguous manner.

Accura comments

While not a new departure, a key-takeaway and important reminder from the recent press release from the Consumer Ombudsman is, however, that advertising agencies also have a responsibility to ensure the proper marking of the content as advertising, as they can be held co-liable for tviolations of the Danish Marketing Practices Act.

When assisting companies with their marketing, PR bureaus or others, should conduct its own examination of the created advertisement as well as the platform on where it is published to assess whether it complies with the Danish Marketing Practices Act, including presenting the material as an advertisement in a sufficiently clear manner. As a main rule, the less the advertisement looks like such, the more clearly the commercial intent must be stated.

Feel free to reach out to any of Accura's IP & Marketing experts if you have any questions about the relevant regulations or a specific advertisement which you plan to publish in the future.

Food for thought:
Is your business' food marketing compliant?

Companies using health and nutrition claims in their marketing for food products shall pay close attention to the special regulation governing this area.

A control campaign conducted by the Danish Veterinary and Food Administration (DVFA) on Danish companies' use of health and nutrition claims shows that this area and the regulation can be difficult to navigate.

What are health and nutrition claims?

In context of marketing of food products, claims about the product in question are subject to special requirements set out in 'Regulation (EC) no 1924/2006 on nutrition and health claims made on foods' (the "Regulation").

In this regard, a 'claim' is understood as any message or representation about the food product, which is not mandatory to give to the consumer, and which states, suggests or implies that a food has particular characteristics. It is worth noting that such a claim can be presented not only by text but also by presentation through photos or symbols, if it indicates that the particular food has certain characteristics.

With regard to the Regulation, claims can essentially be divided into:

a. *"Health claims"*:
Claims that state, suggest or imply that a relationship exists between the food category, the food product or one of the product's constituents and health. Health claims can further be divided into functional health claims, risk reduction claims and claims referring to children's development.

b. *"Nutrition claims"*:
Claims stating, suggesting or implying that a food has particular beneficial nutritional properties.

Overall requirements for health and nutrition claims

According to the Regulation, nutrition and health claims must be based on and substantiated by generally accepted scientific data and may not be false, ambiguous or misleading. These general requirements are not that different from what follows from the general marketing regulation. However, the Regulation includes certain additional requirements with respect to health and nutrition claims.

For *health claims*, these are prohibited unless they a) are included in the list of authorised health claims, which is referenced in the Regulation and b) comply with certain specific conditions applicable to the health claims in question. The updated list of authorised health claims is available at the Commission's website, where the specific conditions relating to each claim are also found. It is possible to alter the wording of an approved claim provided the wording have the same substance and meaning to the consumer as the authorised claim listed in the EU-register.

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For *nutrition claims*, these are only allowed if mentioned in the Annex to the Regulation. Nutrition claims can be divided into claims which state that a food either contains (e.g., a certain vitamin), contains less of (e.g., fat) or does not contain a specific component (e.g., sugar). In this regard, it is important to note that each nutrition claim has specific conditions, which must be fulfilled before the claim can be made. For example, a claim stating that a food has "no added sugar", (or any other claim which is likely to have the same meaning) may only be made where the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties. For some claims, additional conditions for labelling apply.

The DVFA control campaign

The control campaign focused on controlling nutrition and health claims on everyday food products, where the claim was either placed directly on the product or given in connection with the marketing of the relevant product. A similar campaign was conducted in 2019 and the 2022-campaign therefore examined if compliance had in- or decreased since the last campaign.

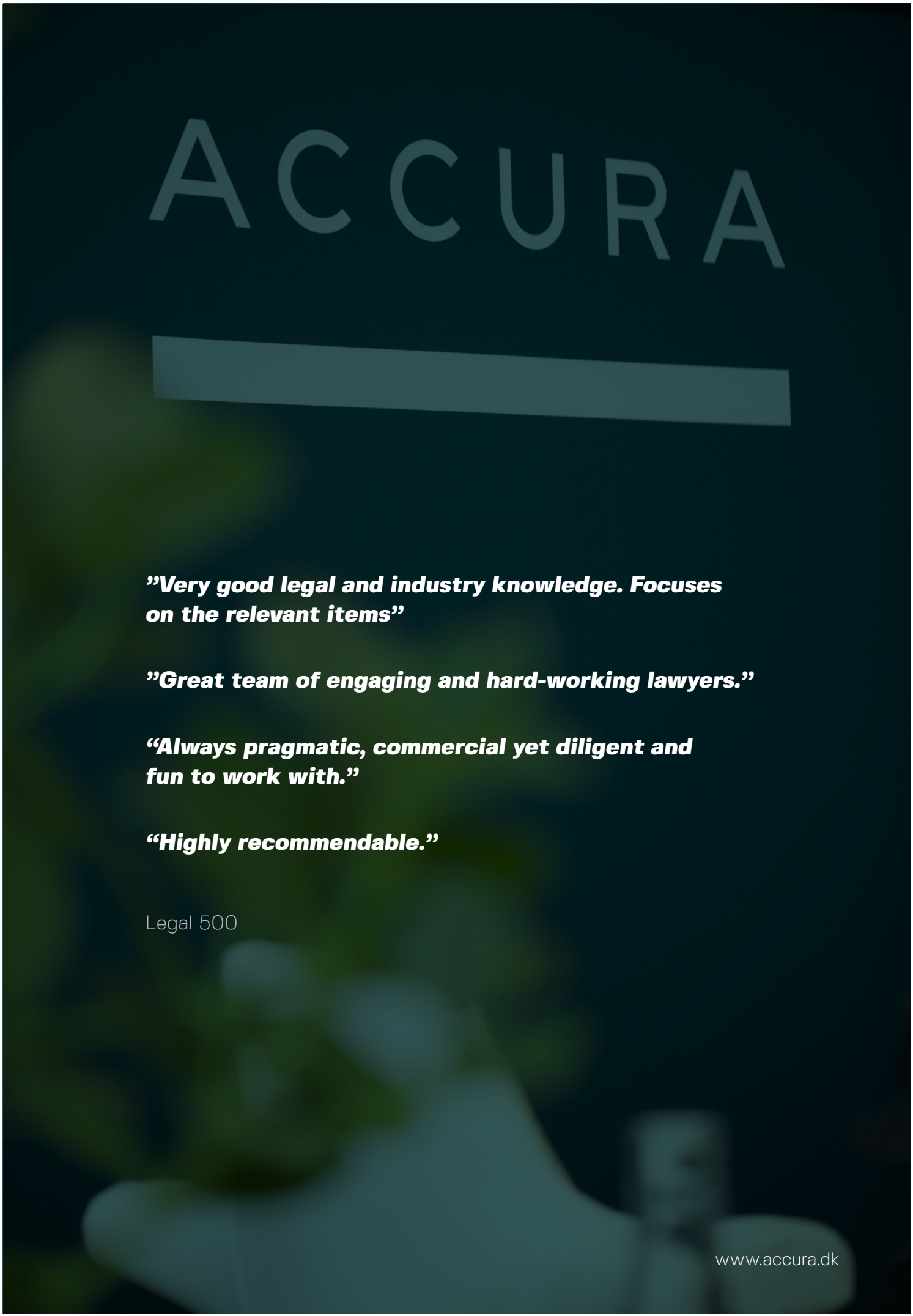
Of the 301 campaign control visits, a total of 253 companies made use of nutrition and health claims, and out of these 253 cases, 33% were not compliant with the rules on nutrition and health claims. In comparison with the control campaign from 2019, the 2022 campaign reported almost twice as many cases of non-compliance.

The DVFA's control campaign report from 2022 can be retrieved here (only available in Danish).

Accura recommends

The rules on health and nutrition claims contain many pitfalls, which companies need to be aware of when marketing food products. The DVFA's control campaign and the results thereof highlight that particularly the use of non-approved or unspecified claims, as well as the fulfilment of the specific conditions relating to the use of approved claims, cause problems when dealing with food marketing. It is, therefore, advisable for all companies to regularly crosscheck that a used or contemplated claim is included in the above-mentioned lists, fulfils the general requirements and is applicable to the specific food.

Contact Accura's IP & Life Science team if you have questions regarding your business' marketing of food products.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