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IP & Life Science News

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Amendments to the Danish Pharmacy Act provides new opportunities and strengthens the collaboration between various parts of the Danish healthcare sector

On 1 July 2024, numerous amendments to the Danish Pharmacy Act will enter into force. Among the amendments is a new economic model for pharmacists. Other amendments are aimed at making use of the professional competences of Danish pharmacies to better relieve other parts of the Danish healthcare sector, which are currently under pressure.

The text of the new Pharmacy Act is available here.

On 4 June 2024, the Danish Parliament passed numerous amendments to the Danish Pharmacy Act. The amended act will benefit citizens by providing easier access to medicinal products reserved for dispensation at hospitals, medicinal consultations, immunization and other healthcare services. The new Pharmacy Act also strengthens the role of pharmacies in the healthcare sector by allowing pharmacies to take on more tasks.

The overarching purpose of the new Pharmacy Act is to create the right conditions for the pharmacy sector by refocusing on its core task of advising on and dispensing medicinal products as well as supplying associated healthcare services. To achieve this, an important element of the reform is to recalibrate the economic model for pharmacists.

These amendments to the Danish Pharmacy Act will enter into force on 1 July 2024 except for the modification of the economic model, which will apply from 1 January 2025.

Below, we have highlighted some of the key elements of the new Danish Pharmacy Act.

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The economic model for pharmacists

Under Danish law, pharmacists are awarded licenses from the state to operate, and they have a monopoly on the dispensation of prescription medicinal products to patients. Pharmacists are also allowed to sell other products and services from physical and online pharmacies. A gross profit agreement between the state and the Association of Danish Pharmacists has regulated the amount that pharmacists' total profits on their business is allowed to reach, thus limiting some pharmacists' total profits.

For some time, the pharmacists' profits from selling other products and services have exceeded the limits of the gross profit agreement. These surplus profits have been offset against the profits from the sale of prescription medical products.

According to the new Pharmacy Act, the profits from sales of prescription medicinal products and the profits from sales of other products and services of to be dealt with separately. Going forward, pharmacists will receive a known and fixed fee income for dispensing and advising on prescription medicinal products. Pharmacists will accordingly not suffer loss of profits from sales of prescription medicinal products because the limits of the gross profit agreement have been exceeded. This change is intended to maintain incentives for carrying out the core task of pharmacists.

Hospital pharmacies are able to dispense medicinal products

In another change, the new Pharmacy Act will allow hospital pharmacies to dispense medicinal products directly to a patient who is being treated at a hospital, thus bypassing the need for clinicians to be involved in the practical act of providing patients with their medicinal products.

Immunization and medicinal consultations at the pharmacy

Furthermore, the new Pharmacy Act will provide more possibilities for citizens to be immunized at the pharmacy within the scope of public immunization programmes. However, it will remain a requirement that immunization at a pharmacy must be carried out by a medical practitioner, or another healthcare provider licensed to carry out immunization.

In the future, pharmaconomist will also be able to hold medicinal consultations with patients, creating an opportunity for pharmacists to devote more time to other tasks.

Protection of the term "pharmacy"

The new Pharmacy Act also broadens the prohibition against using the term pharmacy (in Danish: "apotek") as a sign (trademark) for anything other than a licensed pharmacy. As a consequence of this change, pharmacy-like terms, which in Danish or other languages may give a consumer reason to believe that they are shopping at pharmacy, are also reserved for use by licensed pharmacists.

Accura comments

The amendments to the Pharmacy Act open up for the possibility of pharmacies contributing even more to the work of the public healthcare sector, and the changes have been broadly welcomed by pharmacists and other key stakeholders. With 1 July 2024 coming up soon, pharmacies will be busy preparing to implement the changes brought about by the new Pharmacy Act.

New Danish rules on mandatory emergency stocks of critical medicinal products

Across Europe, legislation addressing the issue of mandatory stocks of critical medicinal products is being adopted in various forms. On 4 June 2024, the Danish Parliament adopted new rules that require companies to keep an emergency stock of critical medicinal products. The aim of the new legislation is to avoid supply shortages of vital medicinal products in the event of short-term supply shortages – but the passing of the new rules was not without difficulties.

The enacted legislation

From 1 July 2024, companies placing a critical medicinal product for humans, which is used in the primary healthcare sector, on the market in Denmark must keep an emergency stock of the concerned critical medicinal product. The emergency stock must correspond to eight weeks of sale of the product in question.

Further, companies that place such a critical medicinal product on the market in Denmark must report its stock of the critical medicinal product in question to the Danish Medicines Agency every fortnight.

The stockpiling and the reporting obligations are intended to give the Danish Medicines Agency and other stakeholders time to initiate necessary measures that can mitigate the consequences of long-term supply shortages that cannot be covered by the stocks.

The Danish Medicines Agency determines if a medicinal product constitutes a critical medicinal product, and according to the draft act it encompasses around 400-600 critical medicinal products.

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The implementation of the new legislation on mandatory emergency stocks of critical medicinal products has received much criticism during the legislative process from various industry stakeholders, e.g. the Danish Chamber of Commerce (Dansk Erhverv) and the Danish Association of the Pharmaceutical Industry (Lif), scientists and pharmaceutical companies, as they fear that mandatory emergency stocks will lead to waste of medicinal products and increased medicine prices.

It is also worth noticing that parallel importers and parallel distributors are exempt from the mandatory stockpiling. This is justified by the fact that it can be particularly difficult for parallel importers and parallel distributors to maintain a stock of medicinal products, because they are less able to manage or predict their supply, since they are dependent on the purchase of medicinal products from external actors in other EU Member States. In order to avoid the risk of the parallel importers and parallel distributors withdrawing their shares of their products from the Danish market, it has been decided that parallel importers and parallel distributors are not covered by the mandatory stockpiling. However, they are covered by the reporting obligations.

Accura's team of IP & Life Science experts will follow the implementation of the legislation closely.

An update of the Guideline on Advertising, etc. of Medical Devices is on its way

On 3 May 2024, the Danish Medicines Agency published its proposal for a revised version of the Guideline on Advertising etc. of Medical Devices (the "Guideline") while also initiating a consultation procedure among relevant authorities and organisations, which ended on 31 May 2024. The proposed updates of the Guideline reflect the many amendments made to the Executive Order no. 715 of 24 May 2022 on Advertising etc. of Medical Devices (the "Advertising Order"), most recently in 2022, while the existing Guideline has remained unchanged since 2014. Below, we outline the most material (proposed) changes. The updated Guideline can be retrieved in Danish here.

Key updates to the Guideline

Advertisement conducted by employees of medical device companies

In general, the rules on advertising of medical devices are not limited to apply when the advertisement is published by specific senders or media. Thus, it is not a prerequisite that the advertisement is published by a business for profit or by an individual that has a certain association with the manufacturer of the device. Instead, it is specified in the Guideline that the given nature of the advertising activity and the message included therein are factors to include in the assessment of whether such activity is considered advertising.

However, the Guideline now specifies that actions by employees of medical device companies such as posts on social media may be considered advertising, when the employee e.g. shares or likes an advertisement or a post regarding the company's medical devices or other promotional materials containing positive claims or other positive mentioning of the company's devices. This applies even if such actions are conducted on the employees' own initiative.

Essential to note, however, is that the medical device company will not be held liable for the given employee's (advertising)-actions on social media, if the company has not encouraged or otherwise contributed to such action and such action is not carried out under the company's authority.

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The Danish rules on advertising for medical devices

In Denmark, specific rules regulate advertisement of medical devices with an overall aim of protecting the public health. These rules are set out in the Executive Order no. 715 of 24 May 2022 on Advertising etc. of Medical Devices ultimately reflecting the EU Regulations 2017/745 and 2017/746 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) and in vitro diagnostic medical devices (IVDR). As a form of interpretative help, the Danish Medicines Agency has issued the Guideline on Advertising etc. of Medical Devices, which e.g. clarifies and elaborates on the Advertising Order's rules, definitions, requirements and prohibitions.

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Influencers and bloggers

The Guideline further clarifies that influencers and bloggers may be held liable pursuant to the rules of the Advertising Order if they advertise medical devices. As an example, an influencer or a blogger could be held liable for a promotional post on social media or a blog containing a review of a given medical device or positive mentioning of the medical device company as such.

Serious diseases

The Advertising Order generally prohibits any mentioning of serious diseases in advertisement towards the public. Among serious diseases are e.g. cancer, multiple sclerosis and epilepsy.

With the updated Guideline, the Danish Medicines Agency proposes that serious diseases can be mentioned towards the public in extraordinary cases, if warranted by particular health considerations. However, this exemption does not extend to advertising in television, film, video, or the like.

Donations

In the proposed Guideline, a section on donations is added, according to which the rules on economic benefits to healthcare professionals (HCPs) in the Advertising Order do not apply when donating medical devices to public healthcare institutions, regions, municipalities or private hospitals (where the company is not owned by a HCP personally or a group of HCPs).

Payment for advertising space

Also, the proposed Guideline introduces the possibility for medical device companies to purchase advertising space. More specifically, medical device companies can pay for advertising space in connection with a professional event for HCPs.

In order for a medical device company to purchase such advertising space, the payment must be proportional to the actual advertising space and may not exceed the market price. In this aspect, the Guideline adds that DKK 2,000, incl. VAT and administration fees, as price per square meter for a full-day event with approx. 50 – 80 participants, is generally considered to be a reasonable and proportional amount.

Products without a medical purpose

The proposed update to the Guidelines further includes a new section on advertising for products without a medical purpose and concludes that these types of products are also subject to the rules on advertising for medical devices. This update is a direct result of the exhaustive list of products without a medical purpose included as annex 16 of the MDR that are now also included in the Advertising Order by virtue of sections 9 – 20 regarding gifts, competitions, professional services, representation and sponsorship, public meetings and entertainment. The products listed exhaustively in annex 16 of the MDR include devices for liposuction, lasers for tattoos and hair removal and devices for stimulating the brain using electrical power.

Accura comments

While the proposed update of the Guideline does not introduce major changes, it includes clarifications reflecting current advertisement trends and drawing parallels to similar regulation on advertisement for medicinal products.

Please reach out to Accura's team of IP & Life Science specialists if you have questions to the Guideline or the rules on advertisement of medical devices in general.

Trademark infringements – criminal enforcement

Trade in illegal counterfeit goods may damage rightsholders' reputation and undermines consumer confidence. Therefore, there are consequences when you infringe the trademarks of others – both in terms of civil law and criminal law.

In January 2024, the European Union Intellectual Property Office, EUIPO, published a study showing, among other things, that illegal counterfeit goods are sold in the EU for approx. EUR 16 billion a year, which in the clothing industry alone means that original manufacturers suffer a loss of revenue from the sale of original goods of approx. EUR 12 billion a year.

In this article, we focus on the enforcement of trademark rights in connection with the sale of counterfeit goods, and, in particular, criminal prosecution in the light of recent Danish case law.

Civil law claims

In the event of a trademark infringement, the rightsholder may decide to assert the usual civil law claims for prohibitory injunction, seizure of property and destruction and also to claim financial compensation from the infringer. The rightsholder may also claim damages, payment of a fair compensation and compensation for non-pecuniary damage (market disruption).

Civil proceedings must be brought before the ordinary courts or settled out of court.

Criminal prosecution

However, trademark infringements may also be reported to the Danish Special Crime Unit (*National Enhed for Særlig Kriminalitet*), which has the exclusive right in Denmark to investigate and prosecute trademark infringements for public law purposes. The Danish Special Crime Unit may prosecute trademark infringements if it is in the public interest, or if the infringement has been committed intentionally, under aggravating circumstances and if requested by the aggrieved party (i.e. the rightsholder).

Intentional and grossly negligent trademark infringements are punishable by fines. The amount of the fine will be determined taking into account the nature and seriousness of the infringement and the infringer's ability to pay.

Moreover, intentional infringements committed under aggravating circumstances are punishable by imprisonment of up to 1 year and 6 months. Aggravating circumstances exist if the infringement was aimed at obtaining a substantial and obviously unlawful gain, and the sentencing may also take into account the number of illegal counterfeit goods, the value of corresponding authentic products and the product category.

Particularly serious trademark infringements are punishable by imprisonment of up to 6 years under section 299 b of the Danish Criminal Code (*straffeloven*). Particularly serious circumstances may exist if the infringement has been committed with the intention of obtaining a substantial unlawful gain for the infringer or others.

Eight months' imprisonment for the sale of more than 2,000 counterfeit goods

In 2019, a 36-year-old man was sentenced by the Court of Aalborg to eight months' imprisonment, of which 5 months were suspended provided that he carried out 100 hours' community service and confiscation of the proceeds of DKK 552,000.

Over a period of more than two years, the convicted person had sold more than 2,000 counterfeit goods worth more than DKK 1,000,000 of brands such as Peak Performance, Ralph Lauren and Tommy Hilfiger via closed groups on social media. The case was litigated by the Danish Special Crime Unit (the former "Danish State Prosecutor for Serious Economic and International Crime") on behalf of the prosecution.

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40 days' suspended imprisonment for storing 292 illegal counterfeit goods

In 2020, the Court of Aalborg sentenced a 31-year-old man to 40 days' suspended imprisonment for illegal trademark infringement under aggravating circumstances. The court found the convicted person guilty of having stored 292 illegal counterfeit goods for the purpose of resale and, in one case, of having resold counterfeit goods via Instagram.

On the basis of an anonymous tip, the North Jutland Police and the Danish Special Crime Unit conducted a coordinated search of the convicted person's premises as part of the investigation. In that connection, the Danish authorities seized a large number of well-known clothing brands suspected of constituting trademark infringements.

14 and 30 days' suspended imprisonment for the attempted sale of 330 illegal counterfeit goods

A married couple had put a large number of illegal counterfeit goods up for sale at the flea market "Bellahøj Kræmmermarked", including clothing, which included well-known trademarks such as Armani, Burberry, Calvin Klein and Gucci. The case was investigated by the Copenhagen Police on the basis of information which led to the seizure of 330 counterfeit goods. The case was litigated by the Danish Special Crime Unit on behalf of the prosecution.

In 2022, the Court of Frederiksberg found that the married couple had acted with intent to sell the counterfeit goods at the flea market and that this constituted trademark infringements under aggravating circumstances. The couple was sentenced to 14 and 30 days' imprisonment, respectively, and 30 and 40 hours' community service, respectively.

30 days' suspended imprisonment for the sale of 241 illegal counterfeit goods

A sole proprietorship had sold 241 sweatshirts as a supplier to various private customers and trading partners. Well-known trademarks were affixed to the sweatshirts in question.

In its judgment in 2024, the Court of Elsinore found that the owner of the sole proprietorship must have realised that it was highly probable that the products sold constituted an infringement of the trademark rights of well-known trademarks. Considering the number of illegal counterfeit goods and the value of the corresponding authentic products, the court assessed that the infringement was of a particularly serious nature. The owner was then sentenced to 30 days' suspended imprisonment. In addition, an amount corresponding to the financial proceeds of the criminal offence was to be confiscated.

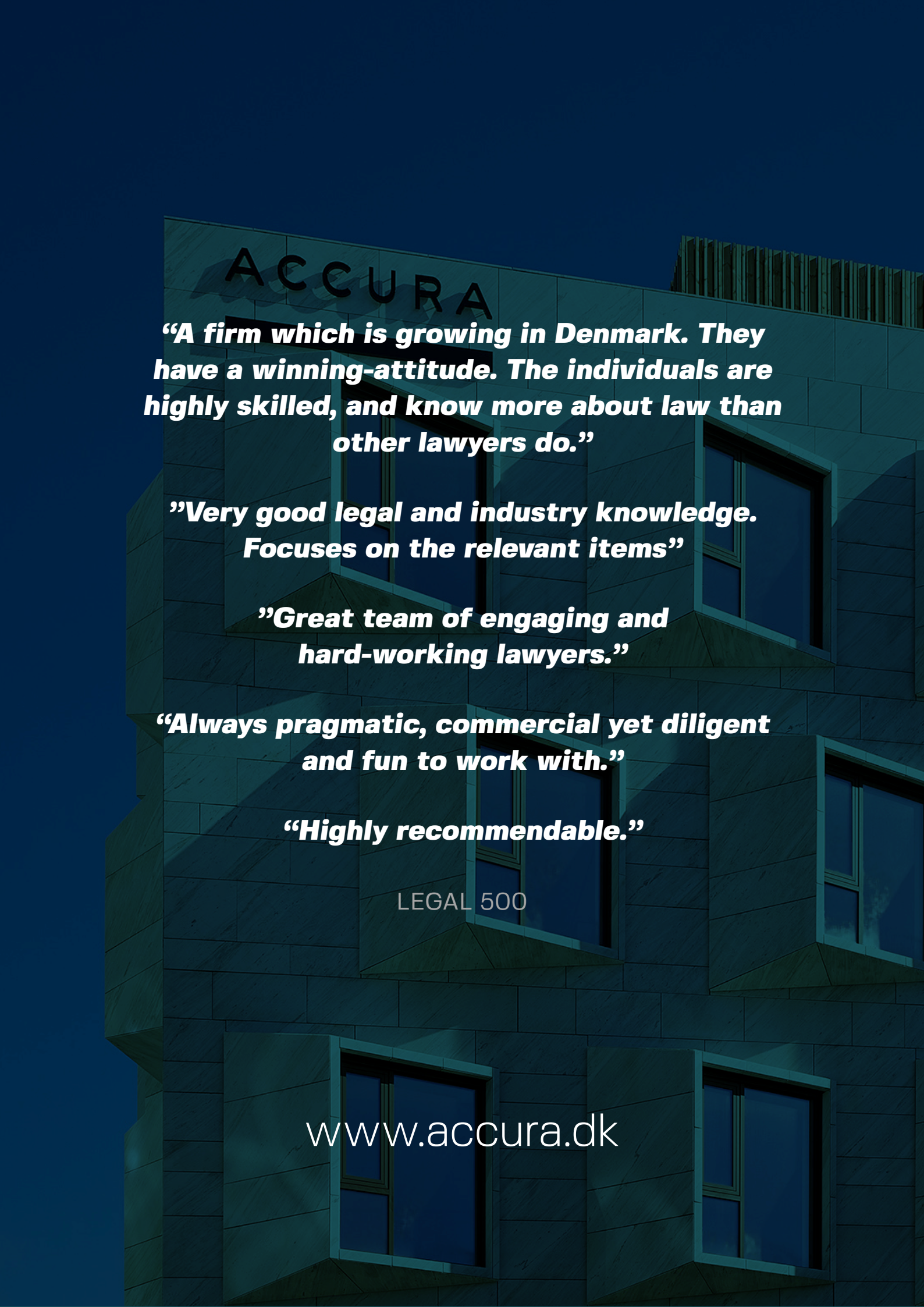
Accura's comments

In recent years, the Danish Special Crime Unit has litigated several cases concerning trademark infringements of a particularly serious nature. In several cases, this resulted in a suspended prison sentence being imposed on the defendant as well as confiscation of the proceeds.

The judgments delivered emphasise that the mere storage of a sufficient number of counterfeit goods may constitute a criminal offence if the goods are deemed to have been stored for the purpose of a subsequent resale. Case law also shows that the sale or attempted resale of an even relatively small number of illegal counterfeit goods may have significant personal and financial consequences. Therefore, it is important that both rightsholders, infringers and, not least, consumers are aware that trade in illegal counterfeit goods is a serious offence of great importance to society and, therefore, also has significant criminal law consequences.

Therefore, it is important for businesses to have the right strategy for enforcing their rights and also to consider the option of instituting criminal proceedings in such cases. Especially because the investigative possibilities are better, but also because public prosecution does not bar the option of claiming civil damages.

At Accura, we have extensive experience in assisting rightsholders in cases concerning infringement of IP rights, including both civil proceedings before the ordinary courts and collaboration with the Danish Special Crime Unit in proceedings involving criminal law aspects. We also provide ongoing assistance with surveillance and enforcement through the Danish Customs Agency and in connection with the verification of the authenticity of goods in customs surveillance operations. Such operations may also give rise to criminal enforcement.



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