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The Danish Medicines Agency's powers

to prevent supply shortage in light of COVID-19 are now permanent

At the outset of the COVID-19 pandemic, the Danish Medicines Agency (DMA) was conferred a set of time limited powers to prevent supply shortage during the emergent health crisis.

Along with the recent passing of the Epidemics Act, these powers have been made permanent, granting the DMA broad powers during the current pandemic and in future health crises.

The new Danish Epidemics Act

The new Danish Epidemics Act *(Epidemiloven)* (the "Act") entered into force on 1 March 2021 and provides a number of public authorities with measures to handle the COVID-19 pandemic and to generally improve the response to future outbreaks of similar diseases and other health crises.

Permanent powers to prevent supply shortage

The new Act is accompanied by amendments to, inter alia, the Danish Medicines Act *(Lægemiddelloven)* that aim at strengthening the medicinal preparedness in case of supply chain emergencies.

The amendments entail that the formerly temporary powers granted to the DMA during the initial response to COVID-19 are given permanent status (articles 76 to 76 b of the Medicines Act).

The key elements of the DMA's – now permanent – powers

The new article 76 of the Medicines Act provides the DMA with permanent powers to:

1. **Gain insight** – The DMA may order persons and undertakings subject to the Act to submit information on their stocks of medicines, including all documentation on active ingredients, intermediate products and medicinal products.
2. **Reallocate and prohibit distribution** – The DMA may reallocate or prohibit distribution of active ingredients and intermediate and medicinal products. Such power presupposes in general that the DMA is entitled to expropriate private property in accordance with the Danish Constitution *(Grundloven)* requiring such measure to be proportional and necessary.
3. **Regulate prices** – To prevent undue or disproportionate price increases on medicinal products during supply chain emergencies, the DMA can impose price caps on medicines to ensure that prices on medicinal products can only increase by a fixed percentage.

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Requirements for activation

Despite the measures becoming permanent, these may only be employed in situations of supply chain emergencies and in times when such a situation is imminent. Such situations could be cases of major national or international emergencies, such as epidemics, natural disasters or trade restrictions, which could potentially cause breaches of the supply chain of medicinal products and thereby cause a health emergency.

In order for the powers to be activated, the Danish Minister of Health must trigger the drug contingency arrangement following recommendation from the DMA. The drug contingency arrangement ensures maintenance of the medical supplies. Subject to the principle of proportionality, the drug contingency arrangement can be initiated at both action and precautionary (pre-crisis) level. On both levels, the DMA will be conferred certain powers to issue instructions and prohibitions.

The provisions in the Medicines Act and the Epidemics Act are already set to be revaluated by the Danish Parliament in the autumn of 2021.

The commercial reason for bad faith
as a ground for trademark invalidation

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Trademarks may be declared invalid if the applicant at the time of filing the application of a trademark had no intent of making loyal commercial use of the trademark in the market.

In 2020, the Court of Justice of the European Union (CJEU) delivered a judgment noticeably elaborating on the concept of bad faith in this regard.

The CJEU judgment *Sky v Skykick* (C-371/18) states that trademarks can be partially or wholly invalidated based on bad faith arguments if the applicant has filed for registration without any intention to actually use the trademark for some or all of the goods and services covered. Claims that trademarks should be invalidated based on bad faith are likely to become increasingly common following *Sky v Skykick*.

The CJEU's test for bad faith

In *Sky v Skykick*, the CJEU decided on whether the marks at issue were affected by the applicant's bad faith at the time of applying for registration of the trademarks. The CJEU applied a test for bad faith.

The CJEU stated that it constitutes bad faith to apply for trademark protection if the applicant has no intention to use the mark for the particular goods and services but instead seeks registration with the purposes of either:

1. undermining third parties' interest "in a manner inconsistent with honest practices", or
2. obtaining the trademark right for another purpose than those within the functions of a trademark.

The lack of intention to use a trademark may thus in itself establish invalidity based on bad faith. Bad faith requires a further lack of rationale for the application (e.g. the intention of either 1. or 2. as stated above).

If an applicant's bad faith can only be documented for certain goods or services referred to in the application for registration, the trademark will only be declared partially invalid (covering only those goods or services).

Accura comments

Sky v Skykick does not preclude trademark proprietors from applying for goods and services that are beyond their actual use or instantaneous intention to use. However, brand owners must bear in mind the risk of partial invalidation for older valid registrations where a broad range of goods and services may have been claimed beyond core products and services.

Brand owners, who have previously adopted an offensive registration strategy for purposes of hindering third party companies in making use of a name in the marketplace, will have to revise this strategy in light of *Sky v Skykick*. Past practice of speculating in and circumventing the genuine use doctrine[1] will no longer be accepted by continuously reapplying for the same mark and goods and services within the 5-year period. We expect that national courts, based on the *Sky v Skykick* decision will consider such behaviour to be acts of bad faith.

Acts of securing registration of non-active trademarks almost as a "ware-housing" asset may potentially and in worst case provide a right holder with an unfavourable monopoly in the marketplace. With this judgment and change of past practice, the CJEU is further favouring the principle of co-existence between trademarks for dissimilar goods and services and not least supporting a sound competition climate within the EU member states.

1 (subject to which a trademark, which has not been put to genuine use within 5 years from the time of registration, may be subject to invalidation upon a third-party-attack)

New recommendations to assist medicinal cannabis companies

in complying with security requirements – key takeaways

The Danish Medicinal Agency (DMA) has published recommendations as to how companies may ensure a compliant level of security when dealing with cannabis.

As a company engaged in the medicinal cannabis field in Denmark, it is important to meet the regulatory security requirements. Following the recommendations will prepare companies for inspection by the DMA.

Risk assessment

Companies dealing with cannabis in Denmark must conduct a risk assessment detailing the security of their production facilities. Based on the risk assessment, companies must identify and establish any necessary measures for the purpose of keeping the products inaccessible for unauthorised persons.

Upon inspection, the DMA will oversee whether such actions have been taken. Companies may choose to follow the DMA recommendations but are not obliged to. If a company has chosen to adhere to the recommendations, these must be observed when executing the risk assessment and establishing the necessary measures. In the event a company has chosen not to follow the recommendations, the company must account for the methods that have been applied instead and how sufficiently restrictive access is achieved through these means.

Following the recommendations from the DMA ensures a structured approach to risk assessment. This structured process is attained by dividing the risk assessment into 6 phases, of which we highlight the key takeaways below:

DMA RECOMMENDATIONS FOR COMPLIANCE – THE 6 PHASES

Phase 1:
Project specification and values

When compiling a risk assessment, it is initially advisable to:

- Identify and group the appropriate key personnel. It is recommended to organise people with different fields of responsibility and areas of expertise.
- Prepare a project specification in which the values of the company are described, e.g. the cannabis products, specific knowledge, material etc. The project specification must include the name(s), position(s) and phone number(s) of the person(s) who have prepared the document.

Phase 2:
Identifying vulnerabilities and threats

This phase entails that the company should:

- Identify and assess any vulnerabilities of and threats to the company, having due regard to the entire process from the handling of seeds to the distribution of the final product.
- Select realistic threats for each vulnerability. The recommendations provide examples of vulnerabilities and threats respectively:
  - Examples of vulnerabilities: storage facilities, operating facilities, production facilities, transport and handling of the products, personnel, suppliers and other third parties, etc.
  - Examples of threats: unauthorised access, theft or smuggling of cannabis products by personnel or visitors, break-ins, theft of safety equipment, ID cards, documents, etc.
  - Determine the necessary security level on the basis of the above.

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Phase 3: Risk assessment analysis

Based on the above, the company should:

- Analyse the realistic threats against the potential consequence(s).
- The analysis must be conducted for each identified vulnerability.

Phase 4: Risk evaluation

In this phase the company should:

- Assess the probability of a given threat's occurrence as well as the severity of the consequence.
- Use numerical values in relation to the above, as this enables the calculation of the risk factor: probability x consequence = risk factor.
- The different risk factors may be compared in a risk matrix which allows for the prioritisation of threats and serves to provide an overview of the company's risk profile.

Phase 5: Risk management

The purpose of the risk management is to act in the most appropriate manner in relation to the prioritised risk in order to ensure an acceptable level of security.

- The security measures may have different characteristics, i.e. they might be technical or human, preventative or retarding, detecting or reacting, etc.
- It is advisable that the company:
- Establishes the necessary safety measures in light of the preceding phases and prioritises the security measures that will have the greatest impact on the security level.
- The recommendations provide a list of security measures which should always be maintained, such as measures of access control, perimeter security, anti-theft storage and production facilities, security protocols and procedures for the handling of shipments.

Phase 6: Documentation, evaluation, adjustment and internal approval

In this phase the company should:

- Document, evaluate, adjust and finally approve the risk assessment.
- Prepare a security protocol which must include all relevant information about security and document the security conditions and the risk assessment for all relevant locations.

The geography
of geographical indications

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Geographical indications (GIs) are protected names and signs for products, such as wine, agricultural products and foodstuffs, with a quality or reputation ascribable to the product's geographical origin. That is why a blue cheese may only be named a Roquefort if it is produced in the French "commune" (municipality) of Roquefort-sur-Soulzon, a sparkling wine only champagne if it originates from the Champagne district in France and a whisky only a Scotch whisky if it is produced in Scotland. But did you know that GIs are not just for French wines, Italian cheeses and Scotch whisky? In Denmark, there are 13 protected GIs, five of them for wine.

Danish Geographical indications	
Vegetables	Lammefjordsgulerod Lammefjordskartofler
Cheeses	Esrom Danablu Havarti Danbo
Fresh meats	Vadehavsstude Vadehavslam
Wine	Dons Sjælland Jylland Fyn Bornholm

Function

GIs serve as indicators or certifications that a product retains a specific quality, reputation or certain characteristic ascribable to the product's origin. The characteristic(s) can be of geological, cultural or historical nature.

Value

GIs can be a valuable tool for businesses to safeguard the reputation and consumers' expectations to a product. A 2016 study from EUIPO showed that consumers are willing to pay a premium for GI products. The study found that consumers pay around 2.5 times as much for wine and spirits products covered by a GI and 1.5 times as much for cheese and agricultural GI products as for similar products without GIs. GIs can therefore potentially add to the product's market value and serve as a method of differentiation from competing products.

Protection

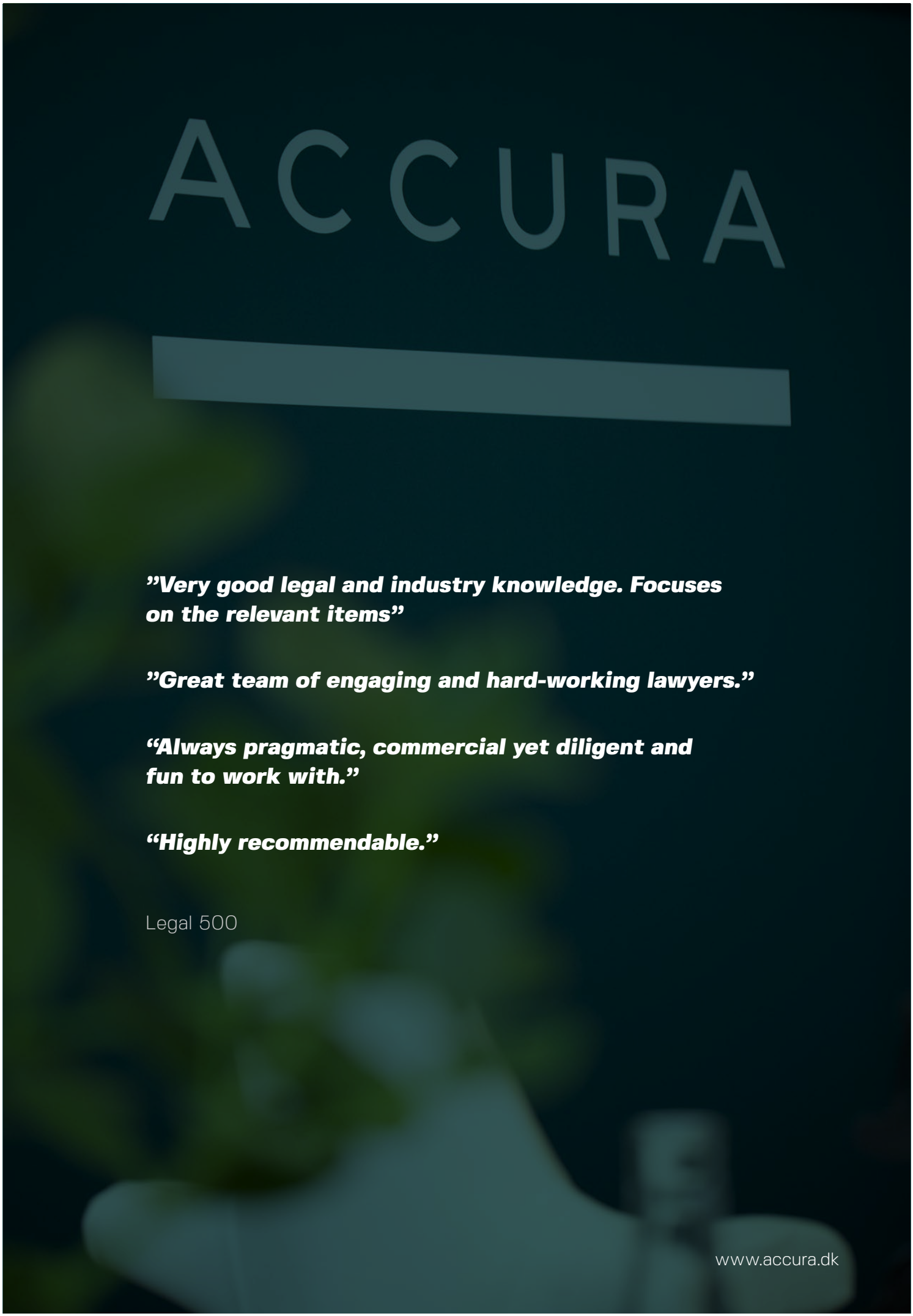
In the EU, GIs can be protected as sui generis IP right or by registration as either a *Protected Designation of Origin* (PDO) or a Protected *Geographical Indication* (PGI).

PDOs cover products that are both produced, processed and prepared in a territory from which the product's special characteristics can be derived. The requirements for PGIs are lower, as only one of the stages of production, processing or preparation must take place in a territory from which the product's special characteristics are derived.

It is the name of the origin, e.g., a region, a specific place or in some cases a whole country, that is protected. A registered GI name is protected against direct and indirect commercial use of the for comparable products not covered by the registration.

Once a GI is registered, the same name or sign cannot be registered as a trademark.

In Denmark, the Danish Veterinary and Food Administration (DVFA) oversees registrations. Obtaining registration is not easy. First, a product specification must be drawn up with a product description, limitation of area of protection, explanation for the link between the area and the product's quality and characteristics. Once the DVFA has reviewed the product description, a national hearing procedure is announced where national stakeholders can object to the application. If the DVFA finds no grounds for objection, the application is sent to the European Commission for examination. Here, an EU hearing period is initiated. If no objections are submitted or deemed valid, the application will be accepted.



”Very good legal and industry knowledge. Focuses on the relevant items”

”Great team of engaging and hard-working lawyers.”

“Always pragmatic, commercial yet diligent and fun to work with.”

“Highly recommendable.”

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