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# IP & Life Science News

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# ‘Pharma package’: EU’s biggest pharmaceutical reform in decades

**On the night of 11 December 2025, the Council and Parliament reached an agreement on a new set of rules for the EU pharmaceutical sector. After years of negotiations and debate on what the future of medicinal regulation in the EU should look like, the outcome is finally here: A comprehensive package of measures that will affect the way medicines are developed, approved and supplied across the EU.**

**At first glance, the package appears to be a mixed bag of compromises.**

## **1) A promise of boosting innovation - what’s changed?**

One of the main challenges in the Commission’s proposal for the reform was said to be to design measures to encourage innovation within the pharmaceutical industry, particularly for the development of medicines that address unmet medical needs.

However, a key element in the original proposal was a 2-year reduction in the standard data exclusivity period, meaning that companies launching new medicine would enjoy exclusive data rights only for a 6-year period, instead of an 8-year period. That said, such changes have not been made, and the new reform holds **a continuation of the current 8-year data exclusivity period.**

Though the data exclusivity period remains the same, **a change in the market protection period has been introduced.**

As opposed to the previous 2-year standard protection period, companies introducing new pharmaceuticals will now only enjoy the benefit of a **1-year market protection period**, before generics are given access to enter the market. The market protection period can, however, be extended by an additional year under specific pre-defined conditions, such as i) supporting clinical research, ii) timely applications in the EU, or iii) addressing unmet medical needs.

This reduction seemingly stands in contrast to the aim of boosting innovation for companies launching new medicines, though it is likely to receive a warm welcome from generics.

For **orphan medicines** – treatments for rare diseases – companies may receive extended data and market protection, from 10 to 12 years, if they meet specific criteria. **Early regulatory guidance** will also be available to accelerate patient access to promising therapies.



The reform also addresses the so-called “**Bolar Exemption**”, an intellectual property provision that allows generic and biosimilar companies to perform certain activities in preparation for the marketing of generics, biosimilars, hybrids and bio-hybrids, without infringing a patent that is still in effect, all with the aim of being ready to launch on the day the patent expires.

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According to the new "Bolar Exemption", patent rights will not be infringed when necessary studies, trials, and other activities are conducted for the purposes of obtaining market authorisations, conducting health technology assessments, obtaining pricing and reimbursement procedures, complying with subsequent practical requirements associated with the activities just mentioned, as well as submitting procurement tender applications to the extent that such activities do not entail sale, offering for sale or marketing of the medicinal product.

This is both a clarification and expansion of the previous bolar exemption in Directive 2004/27/EC, amending Directive 2001/83/EC, in which only conducting necessary studies and trials with a view to the application of a market authorisation was exempt.

The new exemption aims to resolve the issue of long-standing inconsistencies in the scope and interpretation of bolar exemptions in national legislations across Europe, by creating a harmonised understanding of the scope of the exemption. By expanding the scope, the aim is also to speed up the timeframe for which generics can enter the market after a patent

For Denmark, it will be an expansion of the current national exemption rule in section 3(3), sub-point 4 of the Danish Patents Act.

## 2) Introducing transferable data exclusivity vouchers and a blockbuster clause

The reform also introduces **transferable data exclusivity vouchers**. Companies developing **prioritized antibiotics** will be granted an additional 12 months of data exclusivity that can be used for any pharmaceutical product of their choice. The aim of the voucher is to give incentive to companies to help fight antimicrobial resistance.

To limit the potential impact on national healthcare budgets, the reform introduces the **"blockbuster clause"**, in which the use of the voucher on a medicinal product other than the priority antimicrobial can only take place in the fifth or sixth year of the standard data exclusivity period, and only if the company can demonstrate that the sales of that medicinal products has not exceeded EUR 490 million annually in the first four years after the market authorisation has been granted.

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**3) Addressing medicine shortages in Europe – a new monitoring system and accelerated procedure rules**

To ensure medicine availability, the reform will give EU member states the power to require companies to **report shortages promptly, implement prevention plans, and ensure adequate supply of critical medicines.** Furthermore, the EU may also establish a list of essential medicines to monitor availability.

For the European Medicines Agency (EMA), new requirements aimed at simplifying the regulatory framework will be set. To help accelerate the pre-authorisation of new medicinal products, **the reform will make the EMA more efficient with a reduction in assessment time for scientific evaluations.** Once a medicine is authorised by the EMA, it can be sold in all EU member states.

**The next step:**

The agreement reached between Parliament and the Council is an early second reading agreement, following negotiations subsequent to Parliament’s adoption of its first reading in plenary. The Council is anticipated to formalise its position which could then be endorsed by Parliament at second reading. If the Council’s position is approved, the proposal will be adopted.

**Accura comments**

It is evident that Parliament and the Council have had to significantly revise the Commission’s original proposal submitted in early 2023 to strike a balance between creating an innovative-welcoming environment for research and development and to restore the EU’s competitive edge, all while aiming to increase access to medicinal products for patients.

For the time to come, it will be put to the test whether EU’s new pharmaceutical reform will have success in achieving its ambitious goals.

If you want to know more about the reform, please reach out to Accura’s team of specialists in IP & Life Science.



# From Dispute to Decision: How the Danish Design Board Handles Cases

**The Danish Design Board (DesignNævnet) decides on cases related to design, architecture, and applied arts and crafts, including whether a design is protected by copyright, design rights, marketing law, or an ethical code, and/or whether any such rights have been infringed. The Design Board consists of leading specialists in law, architecture, design, and applied arts, appointed by the Association for Legal Protection of Architecture, Design, and Applied Arts ("Foreningen for Retsbeskyttelse af Arkitektur, Design og Kunsthåndværk").**

## **Step-by-step process of complaints before the Danish Design Board**

The Design Board handles complaints concerning specific legal disputes on one or more of the following issues:

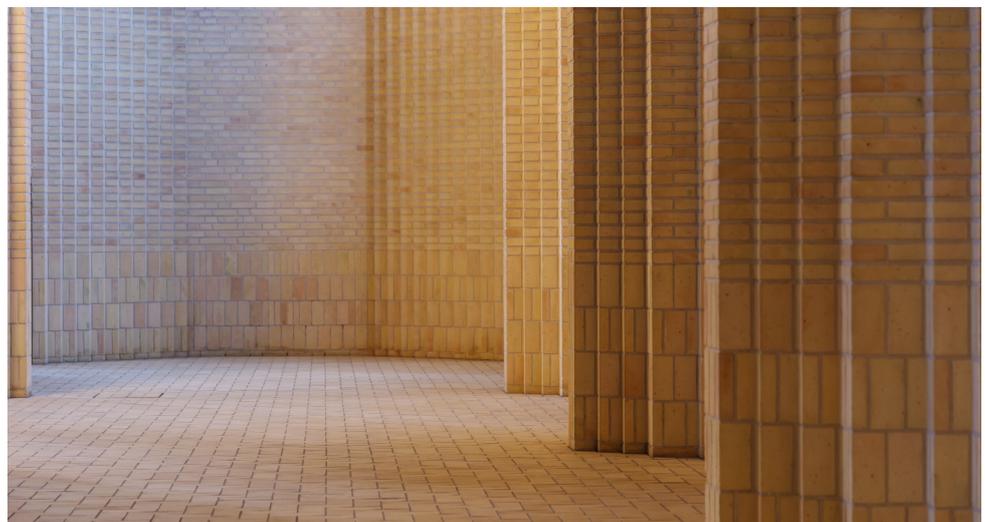
- a)** Whether a creation in the form of architecture, design, or applied art is protected under the copyright and/or design law rules applicable in Denmark.
- b)** Whether a party's rights under the rules mentioned in (a) on copyright and design law have been infringed by the other party.
- c)** In connection with a decision on an issue under (b), the Design Board may also determine whether a party's actions in Denmark relating to architecture, design, or applied art constitute a violation of good marketing practice pursuant to section 3 of the Danish Marketing Practices Act, or of an ethical code.

Members of the Design Board are selected based on professional expertise and relevant experience. Since start the most prominent Danish professors and industry experts have been appointed to the Board. The current Chairman and Vice-chairman are, respectively, a judge of the High Court and a District Court judge.

The Design Board aims for a processing time of no more than six months from the filing of a case until its completion, making it a faster alternative to regular litigation proceedings before the courts.

The initial fee for filing a complaint is DKK 3,750. If the case is not settled during the preparatory phase and the Design Board must therefore render a decision, an additional fee of DKK 51,250 will apply. The Design Board will not begin processing the complaint until the fee has been paid.

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**The legal effect of the Design Board's decisions**

Decisions from the Design Board are generally not judicially binding on the parties, meaning that they cannot form the basis of enforcement unless it is decided between the parties that the Design Board shall function as an arbitral tribunal. Such an agreement implies that the proceedings are subject to the Danish Arbitration Act and the Design Board's decisions will consequently be binding on the parties. It also means that a decision can be enforced by the bailiff's court in the same way as a judgment rendered by a regular court.

As an arbitral tribunal, the Design Board can also make decisions regarding the interpretation of a contract between the two parties and the amount of compensation owed to the injured party.

If it is decided that the Design Board shall act as an arbitral tribunal, the decision cannot be appealed.

Where the parties have not agreed for the Design Board to act as an arbitral tribunal, a decision issued by the Design Board can be presented in any subsequent court case between the parties, where it may carry weight in the court's further assessment of a creative work or a dispute.



**Accura comments**

Decisions from the Danish Design Board are a valuable alternative to ordinary litigation proceedings before the courts, both from a time and a cost perspective. The degree of extensive expertise and capabilities of the members of the Board further speaks to the quality of the Board's decisions. The decisions rendered so far indicate very high quality also in the grounds, as these are more detailed than in regular court decisions and therefore provide a better understanding of the decisions and the scope of protection of a work.

Consequently, we strongly recommend that the Danish Design Board is considered as a choice of venue, when drafting contracts, especially, when a contract relates strictly to creation, licensing, and exploitation of copyrights and designs.

If you want to know more about bringing a dispute before the Danish Design Board or drafting agreements where designs and copyrights are relevant, please feel free to

# EU expands geographical indication protection: A new era for craft and industrial products

**The regulation on the protection of geographical indications for craft and industrial products (Regulation (EU) 2023/2411) entered into force on 23 October 2023 and took effect from 16 November 2023. As of 24 November 2025, the Regulation has been harmonised into Danish law through Executive Order No. 1392, marking a significant expansion of geographical indication protection within the EU.**

## Purpose and objectives

This new framework aims to increase consumer awareness of authentic goods, strengthen the competitiveness of micro, small, and medium-sized enterprises, and promote employment and tourism in rural and less developed regions. Until now, EU geographical indication rules applied only to agricultural products, foodstuffs, wines, and spirits. The Regulation now extends protection to a wide range of craft and industrial products, such as natural stone, woodwork, jewelry, textiles, cutlery, and glassware<sup>1</sup>. This change is expected to benefit traditional industries and regional craftsmanship across Europe.

For the purpose of this Regulation, “craft and industrial products” are defined as products either produced entirely by hand or with the aid of manual or digital tools, or by mechanical means whenever manual contribution is an important component of the finished product. The definition also includes products produced in a standardised way, including serial production using machines<sup>2</sup>. This broad definition ensures that both traditional craftsmanship and modern industrial production can benefit from geographical indication protection

## In brief, about the regulation:

From a legal perspective, the Regulation introduces a harmonised EU-wide system for protecting geographical indications for craft and industrial products.

<sup>1</sup>Article 3

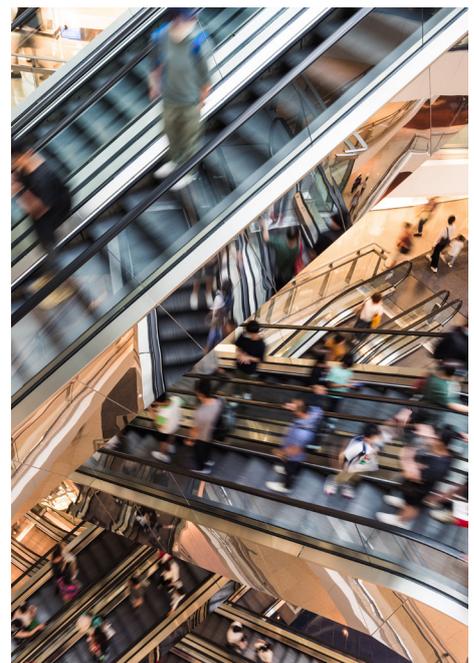
<sup>2</sup>Article 4(1)

<sup>3</sup>Article 6(1)

<sup>4</sup>Article 9

This means that producers who secure protection will enjoy exclusive rights to use the registered name throughout the EU, and will be able to prevent misuse, imitation, or misleading practices. Enforcement will be strengthened as public authorities are empowered to act against infringements, including online misuse. The Regulation also provides legal certainty by defining clear eligibility criteria: products must i) originate from a specific place, region or country, ii) have qualities or reputation linked to that origin, iii) and include at least one production step in the defined geographical area<sup>3</sup>. Applications must include a detailed product specification demonstrating compliance with these requirements<sup>4</sup>.

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EU member states may grant temporary national protection to a geographical indication, with effect from the date on which an application is submitted to the Office. Existing national geographical indication protections for craft and industrial products must be transitioned to the EU system by December 2026, which will require businesses to review and update their registrations. For Danish producers, this represents both an opportunity and a legal obligation: securing EU-wide recognition can strengthen brand value and market position, but it also demands compliance with the new procedural and substantive requirements.

In short, the Regulation not only protects cultural heritage and craftsmanship but also creates a robust intellectual property framework that will influence branding strategies, enforcement actions, and cross-border trade for years to come.

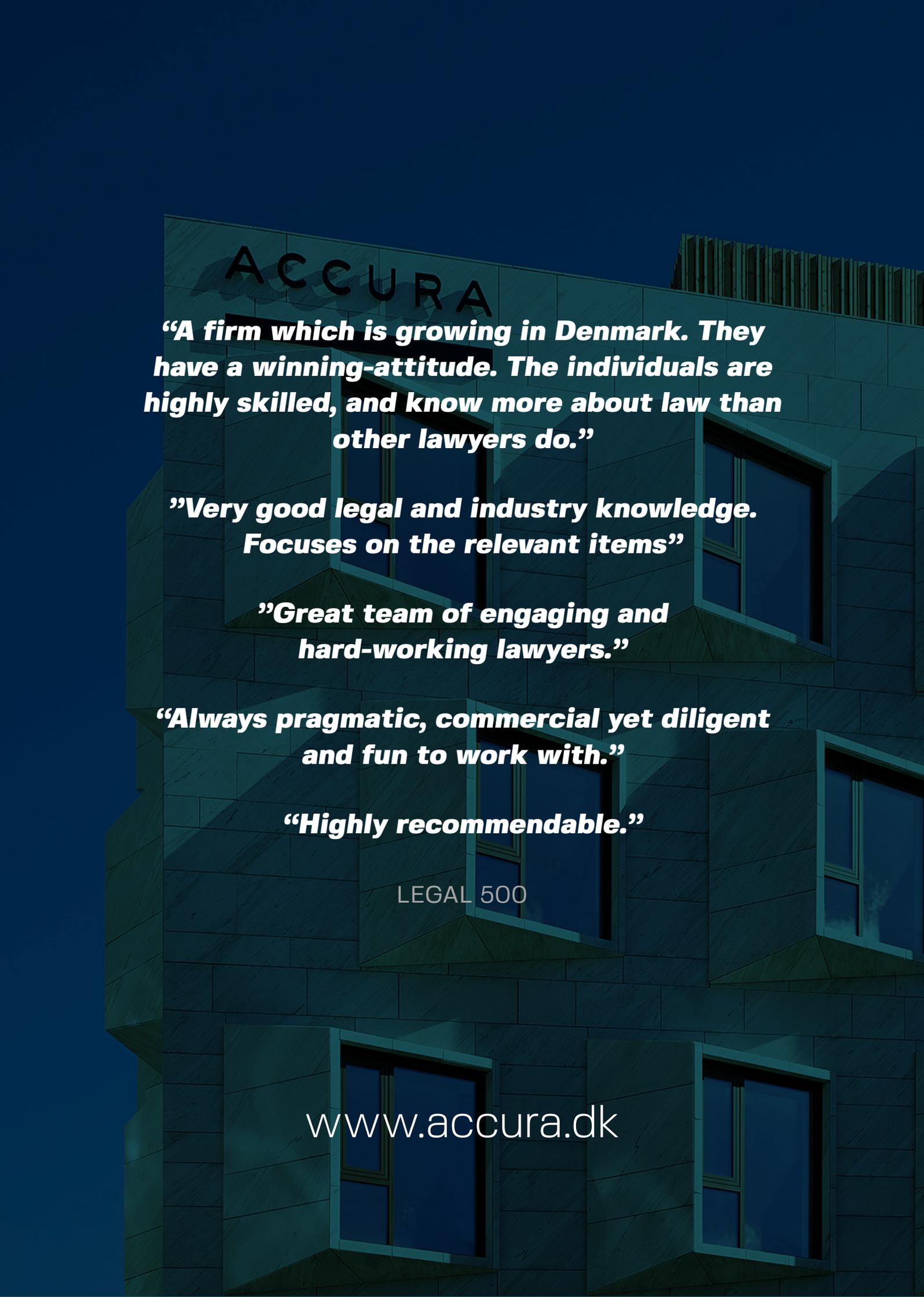
**Registration procedure**

As of 1 December 2025, it will be possible to apply for EU-wide protection for geographical indications for craft and industrial products through a single application process, filed either with the national authorities (Standard procedure) or the EUIPO (Direct procedure) depending on the applicable rules. A single registration grants a non-expirable protection across the EU.

To boost awareness and consumer recognition, the implementing regulation introduces a Union symbol and abbreviation, along with clear rules for their use, thus aligning CIGIs with other GI schemes.

Want to know more about geographical indication protection? Get in touch with our IP team at Accura!





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***“A firm which is growing in Denmark. They have a winning-attitude. The individuals are highly skilled, and know more about law than other lawyers do.”***

***”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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