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IP & Life Science News

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European Commission proposes new Critical Medicines Act

On 11 March 2025, the European Commission presented a proposal for a new regulation, the Critical Medicines Act (CMA), aimed at strengthening the security of supply and availability of critical medicinal products within the EU. The initiative responds to repeated challenges with serious medicine shortages within the EU in recent years and seeks to build a more resilient and coordinated European Health Union.

The proposal in a nutshell

To counter the risk connected to medicinal products and ingredients being sourced primarily from few suppliers, some of whom may be based outside the EU, the proposal aims not only to ensure uninterrupted access to critical medicinal products but to also boost EU-based manufacturing and reduce dependency on countries outside of the EU.

The proposal introduces several concrete measures that can be divided into five overall features:

First, a list of critical medicinal products will be established forming the basis for identifying products subject to special monitoring and support measures.

Secondly, the proposal defines "strategic projects" covering projects that may be eligible to benefit from facilitated access to both financing from the EU and its Member States and accelerated administrative regulatory procedures. A designated authority within each Member State shall be tasked with assessing whether a project meets the criteria for being a strategic project, which include – but is not limited to – projects that create or increase manufacturing capacity for one or more critical medicinal products or for collecting or manufacturing their active pharmaceutical substances.

Thirdly, a core element is the introduction of voluntary, collaborative procurement schemes aimed at providing more coordinated and secure access to critical medicinal products across EU Member States. This includes cross-border procurement facilitated by the European Commission, European Commission procurement on behalf of or in the name of EU Member States and joint procurement between the European Commission and EU Member States.

Fourthly, the proposal encourages international partnerships with likeminded third countries to reduce dependency on a few suppliers.

Lastly, Member States will receive guidance on how to provide financial support to manufacturing projects within the framework of EU state aid rules.

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Timeline and next steps

Following the European Commission's presentation on 11 March 2025, the proposal will now proceed to deliberation in the European Parliament and Council. Due to the European Commission's emphasis on quickly strengthening the security of supply and availability of critical medicinal products within the EU, the negotiations may be carried out in shorter time than usual. As per the proposal, the adoption of the regulation is expected for the end of 2025 with implementation starting in 2026.

Accura comments

As described in our previous newsletter from January 2025 (retrievable here), some Member States, including Denmark, have already taken legislative steps on a national level to improve supply security of critical medicinal products. The new Danish act on stockpiling of critical medicinal products that took effect last year requires certain pharmaceutical companies to maintain mandatory national safety stocks equivalent to six weeks of expected sales.

With the European Commission's new CMA proposal, questions arise as to how local Member States' laws such as the Danish rules on stockpiling of critical medicinal products will align with the forthcoming EU regulatory framework. While the Danish approach is focused on stockpiling at a national level, the EU proposal takes a broader view, encompassing international cooperation, strategic investments and joint procurement.

At Accura, we are closely monitoring the developments within this area of security of supply and availability of critical medicinal products. Please contact us if you have questions about the upcoming EU regulation or the current Danish rules.

Status on the EU design reform

The new reform of the EU legislation regarding protection of designs is on its way. The reform includes a new directive and regulation amending the current legislation - first part of the reform (and most of the changes) follow from the regulation and will apply from 1 May 2025.

Changes from 1 May 2025

The regulation will bring changes to the fees for design registration. While application fees will remain at 350 EUR, renewal fees for registered EU designs will increase significantly; ranging from 150 EUR per design to 700 EUR per design depending on how many times the design has already been renewed.

The process for filing multiple designs will be simplified, as it will be possible to combine up to 50 designs in one application. Each design contained in the application will require payment of an additional fee of 125 EUR.

The application may pertain to designs from different classes, and therefore, the application process will become significantly easier and cheaper.

A new registration symbol "D" in a circle is introduced - similar to respectively "R" and "C" in circles used by trademark and copyright holders. The purpose of the symbol is to facilitate the marketing of design-protected products, in particular by SMEs and individual designers, and to increase awareness of the design registration regimes existing both at Union and national levels.

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What's next?

While most changes will enter into force with this first roll-out of the regulation, certain articles that require implementation through secondary legislation will apply from 1 July 2026. The directive does not apply until 9 December 2027. Therefore, some initiatives have yet to enter into force. Relevant changes are:

1. The definition of products eligible for design protection will be broadened by wider definitions to include virtual goods. Going forward, "designs" will include the movement, transition or any other sort of animation of the design features, while "products" will include items materialized in a non-physical form. A modernisation of the current legislation was needed to consider new opportunities to produce digital products and copy designs through digital means.

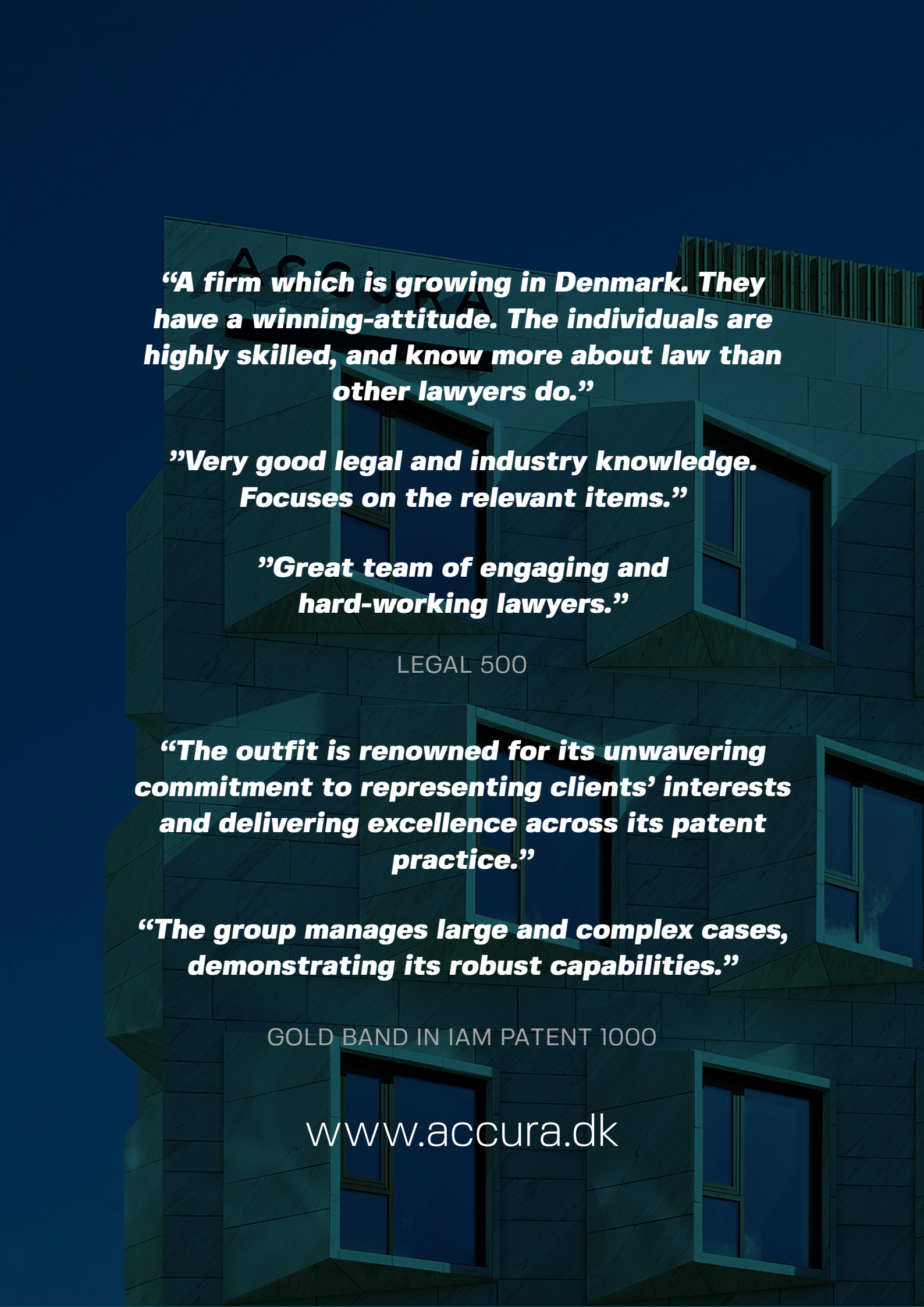
2. A new repair clause will exclude components of a complex product from design protection if the component is used for the sole purpose of repairing the complex product to restore its original appearance. The manufacturer or seller of the component will, however, be obliged to inform consumers about the commercial origin of the product and identity of the manufacturer. However, existing registrations will still be in force until 9 December 2032.

3. A simpler process for invalidity proceedings where the grounds of invalidity or the relief sought are not contested will be implemented. The details for this process will be established by the Commission.

Accura comments

The EU design reform gives a needed boost to the current legal protection of designs within the EU. The new regulation expands the scope of design protection and makes design protection more accessible. On the contrary the increase in renewal fees secures that the system will not clog with inactive designs. Accura's IP specialists will continue to monitor the implementation of the EU design reform and will be happy to discuss how the changes may impact your design strategy going forward.

Read more about this in our previous newsletter from December 2023 here.



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“The group manages large and complex cases, demonstrating its robust capabilities.”

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