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January 2025

IP & Life Science News

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A new year in Danish life science law: Red carpets, mandatory stocks and a brand new strategy – what to expect?

The recent turn of the year marks a good opportunity to look at the legislative initiatives and changes impacting Danish life science law in 2025.

Legislative changes with effect from 1 January 2025 pertain to a) the economic model for pharmacists, b) mandatory emergency stocks of critical medicinal products and c) reprocessing of single-use medical devices. See the box on the right for further details on these subjects.

In the following sections, we dive into these topics:

- The Danish Government's life science strategy towards 2030 with a particular focus on the recently concluded political agreement on the strategy for 2024-2027;
- The establishment of a "red carpet" for manufacturing companies as per a recently concluded political agreement;
- The European Parliament's recent call on the European Commission to revise the EU regulations on medical devices; and
- A brief status on the much discussed reform of the pharmaceutical legislative framework in the EU.

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Legislative changes 2025

The new year was off to a busy start in Danish life science law with the following new rules and requirements coming into effect on 1 January 2025:

A The economic model for pharmacists was modified with the amendments of the Danish Pharmacy Act of 4 June 2024 by introducing known, fixed fee income for dispensing and advising on prescription medicinal products to ensure that pharmacists will not suffer loss of profits from sales of prescription medicinal products because of the limits of the gross profit agreement. The amendments of the Pharmacy Act, including the modifications to the economic model, were described in our newsletter from June 2024 (to be retrieved here).

B The new rules from 2024 on mandatory emergency stocks of critical medicinal products introduced an obligation for pharmaceutical companies to establish an emergency stock for critical medicinal products corresponding to six weeks of sale of the respective medicinal product in question. No later than by 1 January 2025, emergency stocks for 263 critical medicinal products should have been established, and emergency stocks of a further 318 medicinal products shall be established by 1 July 2025. It is worth noting that it is possible for companies to apply the Danish Medicines Agency for exemption(s) from the emergency stock obligation for one or more critical medicinal products.

C The introduction of Section 15a of the Administrative Order (no. 837 of 20 June 2023) on medical devices, which places obligations on the natural or legal person reprocessing single-use medical devices for the purpose of further use similar to those applicable to a manufacturer of medical devices under the medical device regulation.

The first stage of the life science strategy towards 2030

On 1 November 2024, the Danish Government presented its life science strategy towards 2030.

The strategy, which is developed with stakeholders within the life science sector, including the Danish Life Science Council, addresses solutions to secure economic growth and face future challenges in the life science industry.

In close proximity to the presentation of the 2030-strategy, a broad coalition including the Danish Government and five political parties from the Danish Parliament reached an agreement on 21 November 2024 on a life science strategy for 2024-2027. The agreement can be retrieved here (in the Danish language).

From 2024 to 2027, an annual amount of DKK 100 million is reserved for support of the life science strategy.

The 2024-2027 strategy revolves around the following seven strategic beacons reflecting the vision of positioning Denmark as a leading life science nation in Europe:

1. *A stronger growth layer*: Denmark shall support new, viable companies within life science to a greater extent.
2. *Strengthened research and better use of health data*: Through a strengthened research and IT infrastructure, Denmark shall translate its unique health data into ground-breaking research, the spread of artificial intelligence and increased innovation for the benefit of better patient treatment.
3. *Better uptake of innovation in the healthcare system*: Denmark shall promote access to innovative, effective and workforce-free health solutions and innovative medicinal products to create better health for citizens and future-proof the healthcare system.

4. *Attractive framework conditions and a "red carpet" for manufacturing companies*: Denmark must support attractive framework conditions to attract more life science manufacturing and additional foreign investments.
5. *Life science can foster growth and employment in all of Denmark*: Denmark shall take advantage of the opportunities to foster growth and employment in all of Denmark on the basis of the life science sector.
6. *International cooperation and health diplomacy*: Denmark shall continue to play an active international role to solve global health challenges and support the export of Danish health solutions.
7. *A strengthening of the handling of Danish interests in the EU*: Denmark shall be a strong actor in the EU to support Europe as an attractive life science region and to ensure a competitive regulatory framework for Denmark's life science sector.

The plan for implementation of the 2024-2027 life science strategy will be presented to the parties to the agreement in the beginning of 2025.

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Implementation of the "red carpet" for manufacturing companies

In alignment with the life science strategy for 2024-2027, the same coalition reached an agreement in November 2024 on establishing a so-called "red carpet" for manufacturing companies, including those operating within the life science sector. The agreement can be retrieved here (in the Danish language).

The "red carpet"-agreement involves the following four initiatives:

1. The establishment of a so-called "*one-stop-shop*" to ensure a faster and more flexible process for obtaining the relevant public authorities' approvals when certain manufacturing companies wish to establish or expand manufacturing facilities in Denmark.
2. Reservation of several *industrial parks for the manufacturing industry*. The industrial parks will be designated in suitable geographical areas with access to necessary commercial infrastructure such as transportation, water, electricity and wastewater drainage.
3. The setup of a *business panel* consisting of representatives from companies and business organisations with the task, among others, to support the implementation of the referenced "one-stop-shop".
4. The initiation of dialogue between the Danish Government and the interest organisation of the 98 Danish municipalities, Local Government Denmark, to enhance the cooperation of *faster and more flexible handling of applications* across municipal and state authorities.

A plan for the implementation of the "red carpet" agreement will be presented to the parties to the agreement in the beginning of 2025.

Revision and evaluation of the EU regulations on medical devices

On 23 October 2024, the European Parliament passed a resolution addressing the urgent need for a revision of the Medical Devices Regulation (2017/745 - "*MDR*") and the In Vitro Devices Regulation (2017/746 – "*IVDR*").

With the resolution, the European Parliament calls on the European Commission to propose revisions that tackle the most pressing challenges and bottlenecks in the implementation of the two regulations. According to the European Parliament, these challenges and bottlenecks constitute a risk for shortages of medical devices and, thus, lack of access to medical devices in the EU.

The European Parliament has called on the European Commission to propose its revisions by the end of Q1 2025.

In addition to the above, the European Commission initiated a targeted evaluation of the MDR and the IVDR in December 2024 with the purpose of assessing the effectiveness, efficiency and proportionality of the two regulations. As part of the evaluation, relevant national stakeholders (in Denmark being the industry association *Medicoindustrien*) have been invited to provide their feedback on the two regulations by 21 March 2025.

The European Commission will conclude its evaluation in Q4 2025.

Brief status on the reform of the EU pharmaceutical regulation

The European Commission adopted its proposal for a reform of the EU pharmaceutical regulation on 26 April 2023, which we discussed in our April 2023 newsletter (to be retrieved here). Approximately one year later, the European Parliament adopted its position on the European Commission's proposal on 10 April 2024. Notably, the Parliament's position and amendments extend – in comparison with the Commission's proposal – the base period for regulatory data protection from six years to seven-and-a-half years and bring changes to the conditions, under which base protection can be prolonged.

Presently, the European Council's review of the European Parliaments position is awaited. It is not known when the European Council will form and adopt its position, but it is certain that the discussions on the reform continue in 2025.

Accura comments

With the above in mind, there is no doubt that 2025 will be an eventful year within Danish life science law.

Accura's IP & Life Science specialists will closely monitor the developments and provide updates in upcoming newsletters.

Legislative proposal: Confidential pricing of medicinal products in the Danish reimbursement system

The Ministry of the Interior and Health of Denmark sent a new legislative proposal with amendment of the Danish Health Act for consultation in December 2024. The proposal introduces the possibility for the Danish Medicines Agency (DMA) to grant reimbursement to selected medicinal products on the basis of so-called negotiated, confidential medicinal product prices.

The proposal in a nutshell

The proposed scheme provides Amgros with the possibility to negotiate confidential discounts on medicinal products with pharmaceutical companies, which the DMA may then subsequently consider when deciding whether to grant reimbursement for the respective medicinal products or not. The pharmaceutical companies may be interested in offering such negotiated confidential discounts for medicinal products, which would not otherwise meet the reimbursement criteria because of e.g. high price points.

As the purpose of the legislative proposal is to reduce the Danish regions' reimbursement costs, the difference between the lower, negotiated price and the public list price will in practice be paid to the Danish regions by the pharmaceutical company marketing the medicinal product in question. Accordingly, any negotiated, confidential discounts will not result in direct cost savings for the patients but may lead to reimbursement for medicinal products, which would not otherwise have been given reimbursement status.

Amgros, an organisation owned by the five Danish regions, is responsible for the **procurement and tendering procedures** of medicinal products for the Danish public hospital sector.

Therefore, Amgros **purchases medicinal products for the public hospitals** in Denmark.

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The scheme will be relevant for the following medicinal products:

1. New medicinal products with high price points, where the company has applied for general reimbursement;
2. Medicinal products where the DMA is reassessing their status as eligible for reimbursement; and
3. Medicinal products where the treatment of a disease area is being transferred to the primary (medical practice) sector from the secondary (hospital) sector.

The proposal will soon be presented to the Danish Parliament in the beginning of 2025 and is proposed to enter into force on 1 July 2025 and run for three years until June 2028.

Accura comments

A scheme providing the possibility for confidential discounts has been requested by the pharmaceutical industry for a while, but the first draft has gotten a mixed reception. The Danish Association of the Pharmaceutical Industry (Lif) has criticised that it as per the current proposal will be a requirement for concluding agreements that the total expenses to reimbursements are lowered for the Danish regions, which may limit companies' incentives to make use of the proposed scheme for confidential pricing.

Also worth noting is that companies as a starting point will have to refund the price difference for packages distributed in Denmark both by the company itself and for parallel imported packages. This may, however, be an element in the company's negotiations with Amgros as companies may require more favourable terms, e.g. only partial refunds for parallel imported packages.

Feel free to reach out to the life science experts at Accura for more information regarding the proposal or other aspects relating to eligibility of reimbursement for a medicinal product.

Contemplated advantages

For the regions
The purpose of the scheme with confidential prices is to reduce the regions' expenses.

For the patients
The patients will not experience change in the cost of medicinal products, but they may get better access to new, expensive medicinal products through the reimbursement system.

For the companies
Companies have a better opportunity to place innovative medicinal products on the Danish market through the reimbursement system without compromising sales potential abroad, because the lower prices will be confidential.

A helping hand to assist micro-enterprises with their IP rights

The Danish Patent and Trademark Office (DKPTO) has released a proposal for a new executive order for an "IP fast track" scheme for public hearing, which can help Danish micro-enterprises in protecting their intellectual property rights.

Key features of the proposal

The proposal for the executive order aims at supporting micro-enterprises in their efforts to protect their trademark and design rights by allowing applications for so-called "IP starter packs" as well as providing grants to cover expenses related to micro-enterprises' applications for registering their design and trademark rights.

The starter packs are separated into a design and a trademark right starter pack with each starter pack including access to dialogue-based guidance and dedicated searches from the DKPTO as well as access to financing of the registration fees associated with applying for a registered trademark or design right. Relevant for the trademark starter pack, this includes registration in up to three classes and further access to market surveillance by the DKPTO for two years.

In addition to the starter pack, eligible companies may also apply for a grant which can be used to finance access to private consultancy services related to the application process. The grant will make up 50 % of the qualified funds with a maximum of DKK 10,000 per grant to be used by the company for private counselling. Such assistance may, for example, be relevant to companies in situations where the DKPTO's search reports show potential hindrances for the registration of a company's trademark application and where third-party counselling therefore can be necessary. Companies should note that assistance in the prosecution of registered rights falls outside the scope of the funding.

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Who may apply?

Only micro-enterprises (defined as businesses with fewer than ten employees and an annual turnover or balance sheet total of less than EUR 2 million) that are registered as active in the Central Business Register (CVR) may receive funding under the scheme. Companies undergoing bankruptcy proceedings are not eligible.

Applications for IP starter packs and grants must be submitted digitally via Business Hub Northern Denmark's application module. Companies should note that applications are processed on a "first-come first-served basis" and that funds will be granted until the allocated budget for the application round is exhausted. If the budget is not exhausted, surplus funds may be redistributed to future application rounds. A grant will be valid for 12 months from the date of issuance.

The importance of IP rights

Micro-enterprises or start-up companies may not necessarily recognise the potential value associated with a registered trademark or design and registration and protection of such rights are therefore very often not a priority for these companies. Instead, companies may often try to rely on their use-based rights but will often find that such rights are difficult to enforce in practice.

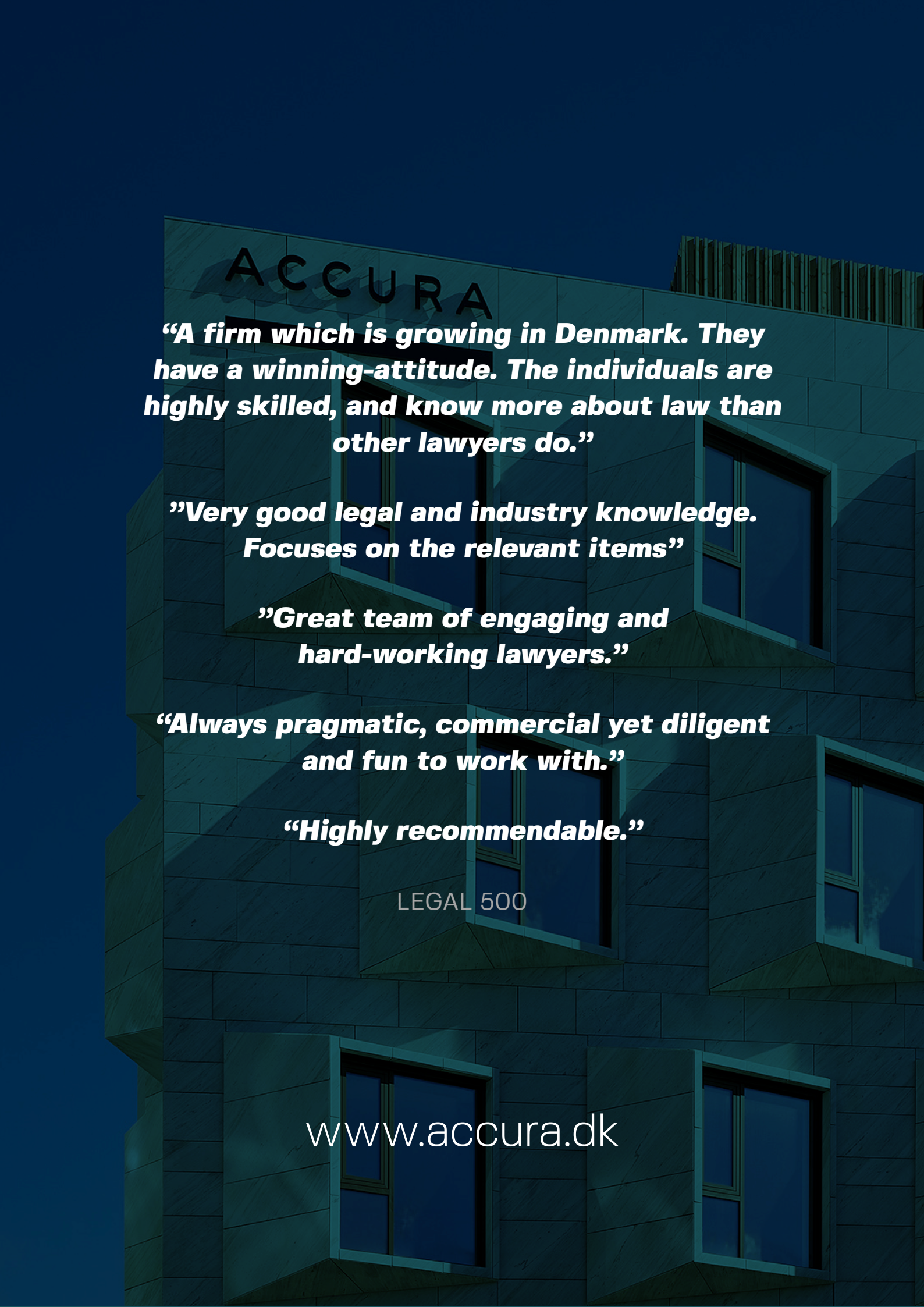
Conversely, a trademark registration covering, for example, a company's name or logo is easy to enforce and is therefore a very effective way to protect the company's brand value. It will further enable the company to prohibit a competitors' use of confusingly similar names and logos. Similarly, a registered design may cover the appearance of the whole or a part of a product and therefore offers further protection in addition to, e.g., copyrights or rights established under the Danish Marketing Practices Act.

Accura Comments

Registered IP rights may constitute an important yet often overlooked asset for micro-enterprises and other newly founded companies. Focusing on registering your company's relevant IP rights early in the process may ensure a solid foundation for the company's freedom-to-operate, investment potential and future growth. Accura therefore welcomes the initiative.

If you have any questions about the IP fast track scheme or your company's IP rights and how to best protect these, please feel free to reach out to Accura's team of IP experts.

The executive order is expected to enter into force on 1 April 2025 and is available (in Danish) on the Danish portal for public consultations here.



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