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IPR & Life Science News

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New Danish Health Technology Council to recommend health technologies

– Get the full overview here

In recent months, the new Danish Health Technology Council (the "Council") (in Danish: *Behandlingsrådet*) has been put in place on the initiative of Danish Regions.

The new Danish Health Technology Council will be evaluating and making recommendations on the use within the Danish health sector of selected health technologies, including medical devices, treatments, diagnostics, and more. The technologies and products will be selected on the basis of incoming proposals from companies, hospitals and the 5 regions of Denmark. Additionally, the Council will annually analyse a limited number of more fundamental treatment regimens and approaches.

The Council can be seen as the counterparty to the Danish Medicines Council (recommending medicinal products) and is, accordingly, likely to get a powerful say in which health technologies, medical devices and treatment regimens to use in the Danish health sector going forward.

The Council is expected to accept proposals for evaluations as of next month (June 2021), however initial dialogue with the Secretariat initiated by parties wishing to submit proposals has already commenced.

The Council consists of a Board, temporary specialist committees and a Secretariat, and will operate independently of the political system (arm's length) on the basis of a procedural handbook and method guidelines (currently undergoing final review and only available in Danish)[1].

Framework and Organisation

The Board constitutes the top management of the Council. Based on the temporary specialists committees' evaluations, the board is responsible for the final recommendations.

The Board consists of 15 members:

- A chairman appointed by Danish Regions
- Five members from hospital managements appointed by each of the 5 regions
- Two members from the Organisation of Danish Medical Societies
- One member from Danish Patients
- One member from Disabled People's Organisations
- One member from the Danish Nurses Organisation
- Two health economists
- Two expert representatives

The appointed members are chosen for the first 3 years of operation. After this period, 1/3 of the members will be replaced or re-appointed every year.

Further 3 observers are appointed:

- One observer appointed by the Danish Health Authority
- One observer appointed by the Danish Medicines Agency
- One observer appointed by the life science industry (MedTech Denmark)

The observers may attend the Board's meetings but without voting rights.

The members of the temporary specialist committees are appointed on a case-by-case basis by the secretariat.

The committees will carry out the individual evaluations and prepare the basis for the Council's decision (recommendation).

The committees will consist of:

- Professionals with expert knowledge (doctors, nurses, physiotherapists, engineers, etc.)
- Patients experienced with the particular technology subject to evaluation
- Health economists and persons skilled with public procurement
- Municipalities and general practitioners

The Secretariat appoints the temporary specialist committees and ensures progress in the individual committee's work.

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[1] The procedural handbook and method guidelines are expected to be finalised in the beginning of June 2021

Evaluations and recommendations

The Council's evaluations of new and existing treatment technologies (covering *inter alia* medical devices, treatments, diagnostics, rehabilitation, and prevention) will result in either recommendations for

1) use;

2) no use, or;

3) knowledge acquisition.

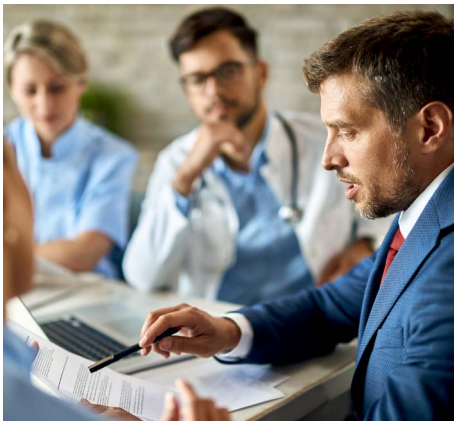
No. 3) means that the technology is recommended for use in one or a few hospital(s) to collect more knowledge on the effect and expenses related to the technology. This may be recommended if there is deemed to be considerable uncertainty regarding the technology's value to the health system.

Proposals

As mentioned, the technologies to be evaluated will be selected on the basis of incoming proposals from companies, hospitals and the 5 regions of Denmark. To be noted that private companies' proposals must render probable that the given technology will not cause additional expenses for or lower the quality of the healthcare system.

Selection process

Based on incoming proposals, the Board decides which technologies to evaluate, which will be made public on the Council's website. The specialist committee is then put together by the Council's Secretariat to evaluate the technology and prepare the basis for the final recommendation from the board.



The evaluation

Each evaluation will contain factual descriptions of the technology, the disease area and the target group together with an evaluation of the effects, expenses, implementation, and organisation of the technology. The effects and expenses of new technologies must be compared to actual and current alternatives.

Evaluations will be based on existing documentation, such as literature, manufacturer documentation, expert opinions, and information from patients. Consequently, as a starting point, no research projects will be launched by the Council as part of its evaluation process.

The evaluation process is expected to take between 5 to 8 months depending on the complexity of the matter.

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The recommendation

The final recommendations will be aimed at Danish Regions and the hospitals. Although the recommendations from the Council are not binding upon the Danish Regions and the hospitals, it is the expectation that recommendations will be followed in the majority of cases.

Recommendations cannot be appealed but the technologies in question may be reevaluated upon request and in case of changed circumstances (e.g. a lowered price or additional documentation) after 3 months from date of decision on whether to recommend or not. The Council may also set an expiry date on the recommendations, e.g. if new and competing technologies are preceding.

Analyses

The Council will also carry out 2 to 3 larger analyses relating to fundamental issues such as treatment regimens and organisation of treatments.

Danish hospital managements and regions as well as the Council itself may propose topics for these larger analyses. Based on the incoming proposals, Danish Regions will choose the topics to be analysed. The analyses will be conducted following the same method as the evaluations of single technologies resulting in recommendations from the Board. An analysis is expected to take up to 12 months.

Accura comments

Recommendations made by the new Council are expected to have a significant impact on which health technologies and medical devices to use in the Danish health sector going forward. Manufacturers and distributors of medicinal devices and other health technologies on the Danish market should therefore consider and keep themselves updated on the work of the Council.

Accura's IPR & Life Science experts will continue to follow the work of the Danish Health Technology Council. Feel free to reach out to us if you have questions regarding the new Council.

Internal preservation of evidence

– A key initial step when suspecting IP infringements

If you discover or suspect that someone is making unauthorised use of your IP rights, it is crucial to carefully consider your enforcement strategy.

Most IP disputes are decided by the facts of the given case. Therefore, securing evidence is key. Before reacting to the potential infringement, it is important to make certain that you possess the IP rights that you believe a third party is infringing upon and that the rights are enforceable against such third party's actions. In this regard, be sure to keep documentation of your IP rights (registration documents, statements of creation, mentions and coverage of use of unregistered IP rights, etc.) at all times.

Once you have made certain that you hold the IP rights enforceable against the infringing party, it is crucial to secure evidence of the infringements discovered. Ideally, this step should be carried out immediately and before taking any further actions to prevent that the infringing party has anticipated your discovery and therefore stalled sales or in other ways tried to conceal the infringing acts. Below, we have prepared a *non-exhaustive* checklist for preserving evidence when suspecting infringement.

Identify the infringer

Find out who is carrying out the infringing acts. Inspect the Central Business Register and look up any information on the legal and natural person(s) behind the infringing activities. Such information could be names, addresses and other information that you deem relevant such as owners of domain names, trademarks, etc.

Determine the scope of the infringement

You may have discovered the infringing activities occurring on a single distribution channel, but make sure to determine whether the activities are confined to this singular distribution channel or whether the activities are also taking place elsewhere. E.g., if you discover unauthorised use of your IP rights in a physical retail store, you should investigate whether these activities are also occurring online and vice versa.

Document the suspected infringement(s)

Save relevant web addresses and take dated screenshots and/or photographs of relevant marketing; advertisements, brochures, websites, and social media platforms displaying the infringing activities and the time thereof.

Preserve correspondence

Save (e.g. by screenshots) correspondence with the potential infringer, if any. Also be sure to save any correspondence or documentation in which third parties, such as consumers or co-operating partners, comment on the infringement or in which it is clear that such parties confuse the infringer's product with yours.

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Secure product samples

If relevant to the specific infringing activities, purchase samples of products sold by the potential infringer for the purpose of evidencing the infringing act. Check whether the products are sold through both physical retail stores and web shops and make sure to purchase samples from each distribution channel to document that the product has been sold through more than one distribution channel. Remember to keep a receipt for your purchase.

Social media coverage and presence

Take screenshots showing the number of followers on social media platforms if the infringing activities occur on Instagram, Facebook, etc. Make sure the screenshots contain the date on which the screenshot was taken.

The checklist for preservation of evidence is meant as a helpful tool but cannot and should not substitute seeking legal advice. We always take all relevant information into consideration when we advise our clients on enforcement of intellectual property rights in Denmark and abroad. Consequently, our advice on how to proceed against a possible infringement is based on a specific assessment of the client's business, product and the specific market in which the client operates as well as the evidence at our disposal.

Extension of the Pilot Programme on Medicinal Cannabis

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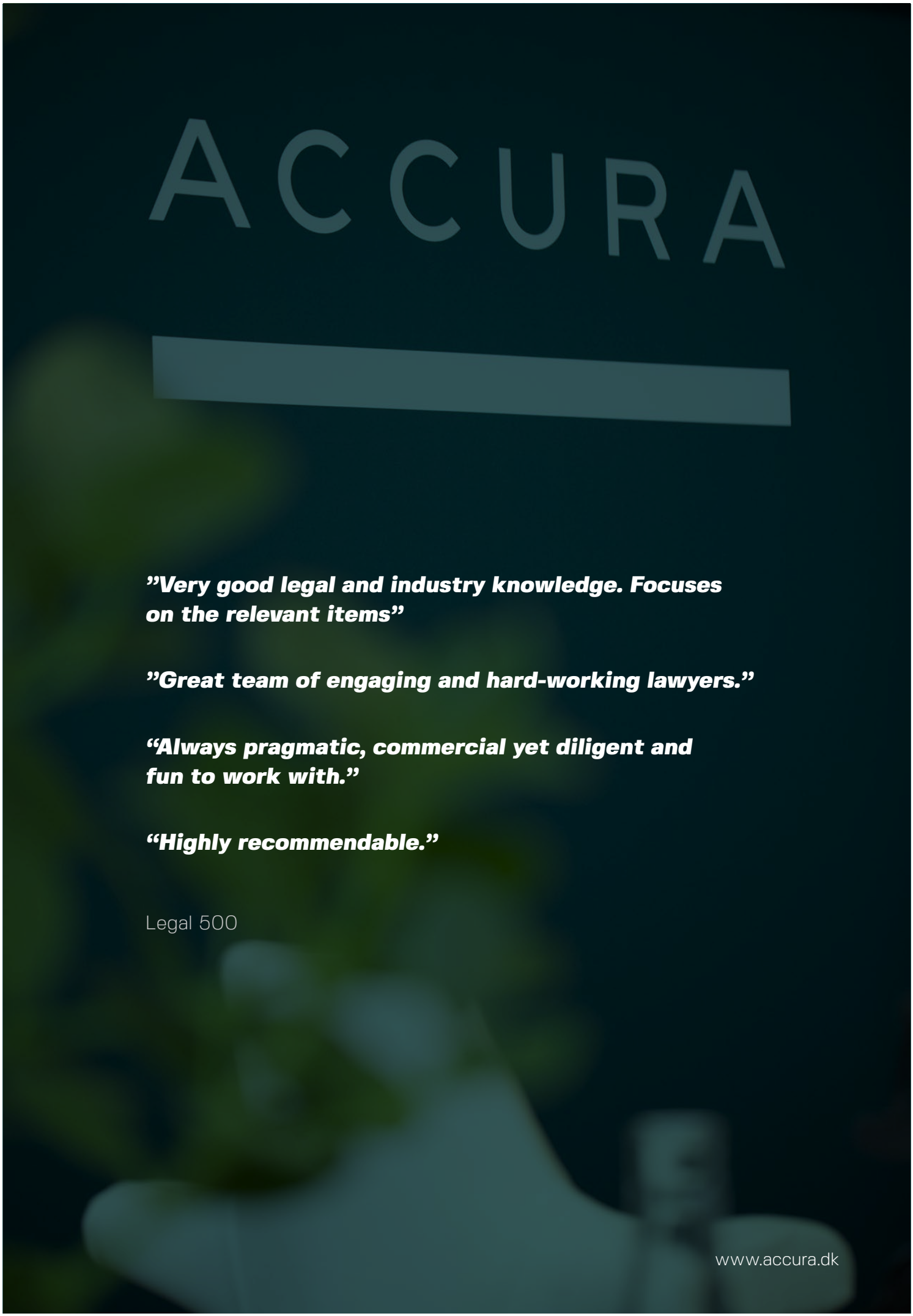
On 25 May, a majority of the Danish Parliament agreed to extend the statutory pilot programme on medicinal cannabis, which was originally set to expire by the end of 2021. While one part of the programme is made permanent, the other part has been prolonged until the end of 2025.

The Danish pilot programme on medicinal cannabis first entered into force in January 2018 with the purpose of establishing a safe framework for the use of medicinal cannabis in the Danish healthcare system. Revisit our newsletters from February 2018 and 2019 with details on the pilot programme here and here. You can also read what we wrote about DMA's recommendations for medicinal cannabis companies in April 2021 here.

The political agreement extends physicians' possibility of prescribing cannabis-based products for medicinal use in specific cases with 4 four years. To provide clarity for companies investing in medicinal cannabis, the pilot programme concerning cultivation of medicinal cannabis is given permanent status.

The medicinal cannabis treatment of patients in pain will continue to be subject to a prescription from a physician, following guidelines from the Danish Medicines Agency (the "DMA"). Further, physicians prescribing medicinal cannabis must continue to takeresponsibility for the prescription as the product has not been authorised by the DMA.

A legislative proposal to formally extend the pilot programme will be introduced by the Danish Government in the Fall of 2021. The parties of the agreement have all agreed to vote in favor of the legislative proposal.



”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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