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IP & Life Science News

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New initiatives to bring down processing times at the Danish Medicines Council

During the past year, the Danish Medicines Council has implemented 16 new initiatives to cut down the processing times and ensure robust and transparent processes for the Council's assessment of new medicinal products.

The Danish Medicines Council

The Danish Medicines Council is an independent council assessing whether new medicinal products (and indication extensions) are recommendable as standard treatments at the Danish hospitals.

The initiatives are based on an analysis of the Council's work from early 2023, which lead to a recommendation from Danish Regions to make improvements with respect to both processing times and the effectiveness of processes within the Council. All 16 initiatives are fully applicable from 1 April 2024, but a certain "transitional period" may still be expected to get everything up-to-speed, including making available certain process documents in English.

Read more below, where we highlight the key new initiatives:

- **New targets for case processing times**

  The Medicines Council has implemented differentiated processing times for applications incoming 1 April 2024 or later. The new processing times are 14, 16 and 18 weeks dependent on the complexity of the assessment (see below). Previously, one processing time (16 weeks) applied to all applications.

  - 14 weeks track: A fast track for PD-L1 inhibitors for monotherapy or for use in combination with non-patented medicinal products and for extension of indication to also cover children.
  - 16 weeks track: To be used for direct classification in treatment guidelines of a medicinal product in an existing treatment guideline and for reassessment of medicinal products where new prices are fixed.
  - 18 weeks track: To be used for assessments of new medicinal products (which do not fall within the scope of the 14- or 16-week tracks) or reassessments of medicinal products required due to new data being available.

A significant improvement of the Council's processing time was already spotted from 2022 to 2023, increasing the number of applications being completed within the processing times from 24% to 56%, which you may read about in our newsletter from earlier this year (to be retrieved here).

As for ongoing applications, the Medicines Council has announced that the applications will be adapted to the new processes. According to the Council, a period of tests and adaption is still ongoing, which likely entails that processing times for a while may still be expected to be somewhat longer than the 14, 16 and 18 weeks respectively.

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- **Applications by appointment**

  As something completely new, applicants must schedule a date for filing its application(s) with the Council's Secretariat. The purpose is to time applications with Council and expert committee meetings. As a result, the Council will be able to disclose, at an earlier stage than previously, when recommendations will be made available. This will ensure added transparency for applicants. However, whilst the processing times may be reduced as explained above, the actual time frame between an applicant being ready to file its application and the recommendation being complete might not be shortened. All ongoing assessments are published at the Council's website available here.

- **Technical validation of applications**

  When the Medicines Council receives an application, a technical validation process of 10 working days is initiated to ensure that formal requirements regarding the application's length, format, cross-indexing etc. are observed. If not, the Council will schedule a new application deadline, which prolongs the process of assessing the medicinal product. To ease applicants' task with ensuring that formal requirements are observed, a new checklist has been drafted by the Council. The checklist is not yet available in English but can be retrieved in Danish here.

As a result of the new initiatives related to the processes at the Medicines Council, the Council's Process Guide has been updated accordingly (the updated version is not yet available in English but can be retrieved in Danish here).

The CJEU clarifies the rules on online retail supply of non-prescription medicinal products

The European Court of Justice (CJEU) recently issued a preliminary ruling (in case C-606/21) that clarifies the conditions under which companies acting as online intermediaries between pharmacists and customers may engage in the online retail supply of non-prescription/over-the-counter (OTC) medicinal products.

Facts of the case

The case giving rise to the preliminary ruling concerned the company Doctipharma which operated ("designed and managed") an online platform where consumers could purchase medical products from pharmacy websites. The platform was arranged so that the consumers' orders were sent to the pharmacies offering the OTC medicinal products for sale. Payments were processed through a separate payment system.
The French pharmacy union, Union des groupements de pharmaciens, challenged this setup, claiming that Doctipharma was involved in the online sale of OTC medicinal products without having status as a pharmacist as required under French law.

According to the EU Medicines Directive article 85c (2), Member States must ensure that OTC medicinal products are offered for sale at a distance to the public by means of information society services subject to certain specific conditions only, and Member States may impose additional conditions for the retail supply of such medicinal products if this is justified on grounds of public health protection.

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The dispute led the Paris Court of Appeal to submit a set of preliminary questions to the CJEU on the interpretation of the EU Medicines Directive. In essence, the CJEU was asked to clarify when Member States may, by way of the Medicines Directive article 85c, prohibit companies that are not authorised pharmacists (in this case online service intermediaries) from connecting pharmacists and consumers through a website for the sale of OTC medicinal products.

CJEU ruling

The CJEU ruled that to determine whether Member States may prohibit online service intermediaries from connecting pharmacists and consumers for the sale of OTC medicinal products involves an assessment of whether

1. the service intermediary merely connects sellers (pharmacists) and consumers, or
2. if the service intermediary is itself providing the actual sale.

In this assessment, the "specific features" of the service provided must be taken into consideration and specifically whether the online service intermediary provides "a service of its own distinct from selling".

Accura comments

The CJEU ruling contributes towards clarifying when online intermediaries without authorisation to supply OTC medicinal products may nonetheless be associated with the online retail supply of such products, but it is also made clear that online intermediaries cannot assume the role of pharmacists.

New Institute merges the Danish Health Technology Council and RKKP

A new institute will assume the current responsibilities of the Danish Health Technology Council (Behandlingsrådet) and the Danish Clinical Quality Program – National Clinical Registries (Regionernes Kliniske Kvalitetsudviklingsprogram) ("RKKP").

On 8 April 2024, the Danish Regions announced its plans to merge the Danish Health Technology Council and RKKP into a new institute called the Danish Healthcare Quality Institute (Sundhedsvæsnets Kvalitetsinstitut) ("*the new Institute*").

The aim of the new Institute is to promote synergy and a unified approach to enhancing and prioritising quality within the Danish healthcare system.

Which functions will the new Institute take over?

Danish Health Technology Council:

The Danish Health Technology Council's main responsibility has been to provide the best value for money within medical equipment and other healthcare technologies. This is done through either *evaluation* of specific medical equipment's effect and costs or through overall *analysis* of e.g. treatment regimens or organisational approaches.

With the formation of the new Institute, the Danish Health Technology Council will transfer its tasks, including both its evaluation and analysis competences, to the new Institute. As is currently the case with the Danish Health Technology Council, evaluations of medical equipment or other healthcare technologies can be submitted by hospital managements, the Danish regions, or private companies.

Accura has in a previous newsletter provided a comprehensive overview of Danish Health Technology Council, including its responsibilities and structure.

This newsletter can be accessed here.

RKKP:

RKKP oversees 85 national clinical quality databases that collect healthcare data. This healthcare data is important for continuously monitoring and improving the Danish healthcare system. RKKP further contributes to advancing health science by providing health data to research projects. The new Institute will also take over RKKP's responsibilities and continue to work to improve the quality of healthcare in Denmark.

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The new Institute: Purpose and expected impact

Currently, the Danish Health Technology Council and RKKP operate independently. By merging the tasks and expertise of the Danish Health Technology Council and RKKP into a Danish Healthcare Quality Institute, the Danish Regions expects to create a synergy, improve clinical work quality, establish a more patient-centred and efficient healthcare system, and ultimately, reduce resource waste.

Additionally, it has been decided together with the Danish Medical Association (Lægeforeningen) and the organisation of Danish Medical Societies (De Lægevidenskabelige Selskaber) that the new Institute will be responsible for ensuring that the medical specialties develop national clinical guidelines, thereby setting treatment standards in Denmark.

The Danish Regions has announced that the new Institute will begin its operations in the beginning of 2025.

Accura comments

The plan to merge the Danish Health Technology Council and RKKP is still in its early stages and details on the formation of the new Institute are still being finalised.

Accura's IP & Life Science specialists will be keeping a close eye on the development.

Another update on the continuous challenge of greenwashing

In terms of greenwashing, 2024 got off to a particularly eventful start. In January, the Danish Consumer Ombudsman reported two companies to the police for misleading marketing practices regarding environmental claims. In February, the Consumer Ombudsman, accompanied by the European Commission and the authorities responsible for consumer protection in Norway, Sweden and Germany, came to a final solution in a long-lasting case concerning the environmental claims of an online retailer. And in March, the Consumer Ombudsman decided in a case regarding online platform providers' liability for misleading green claims. In addition to the Consumer Ombudsman cases, the Western High Court rendered its decision in the first Danish all-greenwashing case (read about that decision here). Below, we highlight the most essential aspects of the four Consumer Ombudsman cases together with key focal points for companies engaging in green marketing.

Better than others does not necessarily mean green

The first company reported in January had marketed its wood-burning stoves by claiming that the use of such stoves was environmentally friendly. In addition, the company had claimed that its stoves were certified with the Nordic Swan Ecolabel ("*Svanemærket*"), although the stoves had not been officially certified by the label's supervisory body *Miljømærkning Danmark*.

Though one might argue that wood-burning stoves have a minor environmental impact than other heating sources, such stoves emit various pollutive articles that are damaging to the environment. In fact, the Danish Environmental Protection Agency has found – in the context of the case before the Consumer Ombudsman – wood-burning stoves to be the largest source of particle pollution in Denmark. Due to these various environmentally damaging aspects of using wood-burning stoves, it is misleading to claim that the use of such stoves is good for the environment – even when the stoves are less damaging to the environment than other heating sources.

The use of general terms such as "*environmentally friendly*", "*CO2 neutral*", etc. in marketing often violates the prohibition of misleading commercial practices in the Danish Marketing Practices Act as companies have a hard time substantiating the claims. It is therefore advisable to use specific claims instead. Naturally, a company must also refrain from marketing its products under a labelling scheme if neither the company nor the product has been certified in accordance with the criteria of the scheme. Such a commercial practice is expressly listed as misleading in the Marketing Practices Act.

The Ombudsman's decision is available (in Danish) here.

Documentation is the key

The second company reported to the police in January had claimed that its swimwear was made from 78% recycled plastic from the oceans. Furthermore, the company had marketed its swimwear under terms such as "*made from ocean waste*" and "*saving the ocean one product at a time*".

Although this is an example of using *specific claims* (instead of general claims as described above) and although the swimwear was in fact made from 78% Econyl – a product consisting of both pre- and post-consumer waste – the documentation provided by the company to substantiate the claims established that only a smaller part of the product consisted of plastic waste from the ocean. The Consumer Ombudsman therefore found the company's claims to be misleading. The claims may give consumers the incorrect impression that the swimwear contributed to saving the planet's oceans to a greater extent than what was the case.

The Ombudsman's decision is available (in Danish) here.

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A symbol needs an explanation

The third case from February concerns the environmental claims of an international online retailer of clothing. On its website, the retailer used symbols like trees and leaves in connection with some of its marketed products to indicate the environmentally friendly features of these products, e.g. the percentage of ecologic or recycled materials. The retailer had also marketed some of the products under specific environmental claims without providing an explanation in connection with each claim.

Following a long-lasting dialogue with the authorities involved, the retailer committed to remove the symbols and provide information regarding the specific environmental features of a product directly on the product's page. Furthermore, the retailer committed to introducing two new websites where consumers may find information about the product standards as well as the environmentally related initiatives of the retailer.

The Consumer Ombudsman's decision is available (in Danish) here.

Providers of online platforms may be liable for misleading green claims

Lastly, the case from March concerned online platform providers' liability for misleading environmental claims regarding products that are marketed by other traders on the platforms.

Under Article 6 of the Digital Services Act (previously Section 16 of the Danish E-Commerce Act), an online platform provider (or a so-called "*information society service*") is exempted from liability if the provider plays only a passive role in the communication to the public of the illegal content.

The Consumer Ombudsman, however, found that two Danish providers of online platforms could not rely on the exemption in the DSA as the providers had taken an active part in the optimisation and promotion of sales of the concerned products on the platforms. Therefore, the providers of the platforms were subject to the requirements of the Danish Marketing Practices Act, including the documentation requirement.

As the two providers were not able to substantiate the environmental claims regarding the concerned products by providing sufficient documentation, the Consumer Ombudsman found that the providers had violated the prohibition of misleading commercial practices.

The Consumer Ombudsman's decision is available (in Danish) here.

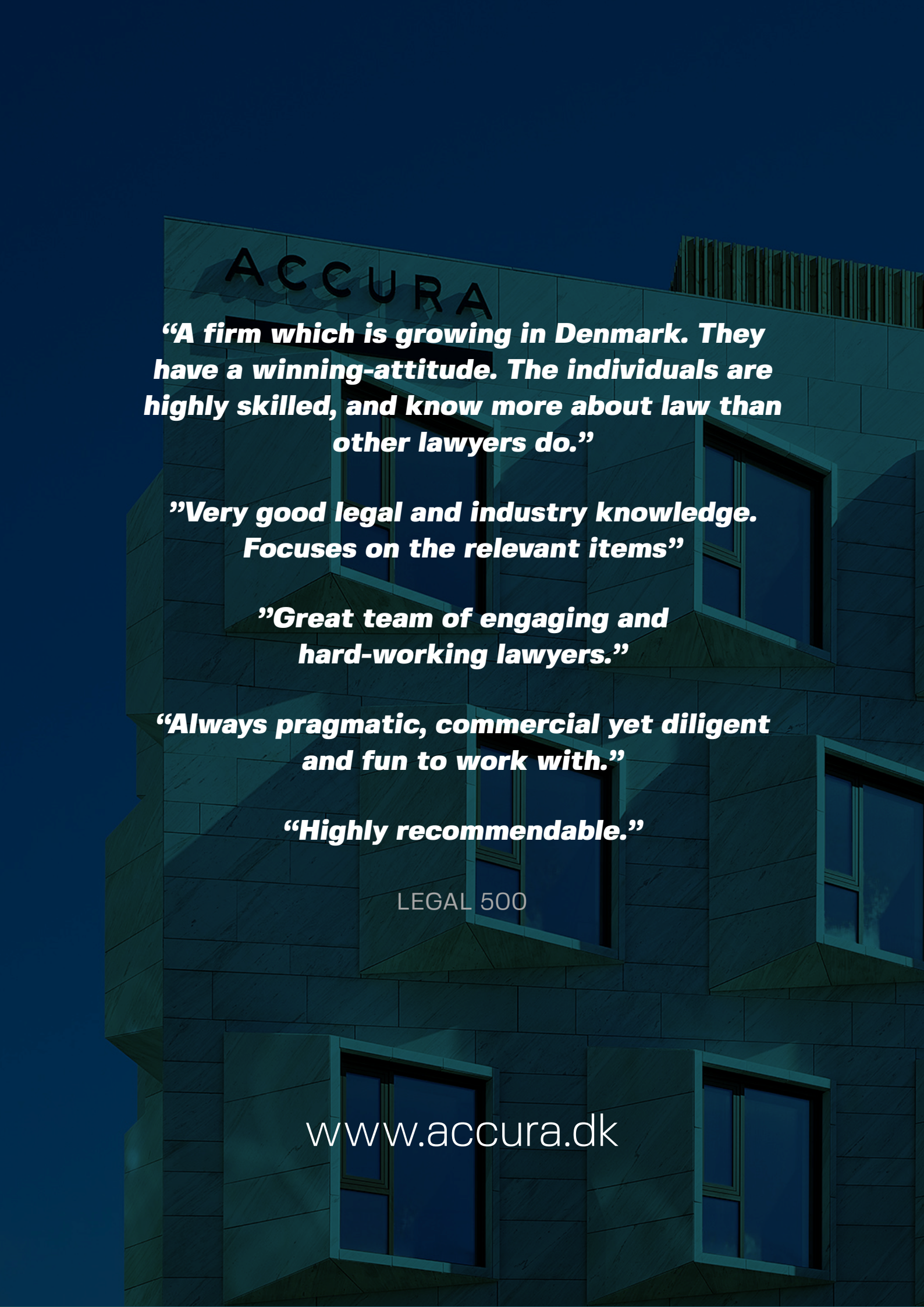
Accura comments

According to an article published by the Danish newspaper Børsen at the beginning of this year, the number of annual complaints about greenwashing lodged with the Consumer Ombudsman has increased from 16 complaints in 2019 to 146 in 2023.

The steadily growing number of complaints also seems to reflect that a company's actions matter more to the Danish consumers than a company's promises. Consumers are demanding products and services that have an *actual* and *proven* impact on the green transition.

The increase in consumer awareness combined with the obligation for companies to substantiate their environmental claims (whether specific or general) means that companies should be careful when preparing their marketing campaigns. Avoiding general claims like "*environmentally friendly*" and instead highlighting only *specific* positive environmental aspects of a product or service makes it easier to substantiate the claim and decreases the risks of misinterpretations or confusion. Further, honest communication supports brand reliability and ultimately consumer loyalty.

If you have any questions regarding marketing, greenwashing or a specific campaign for your company, please feel free to reach out to Accura's team of marketing experts.



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

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

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