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IP & Life Science News

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Proposed overhaul of regulation of pharmaceuticals in the EU

On 26 April 2023, the EU Commission published its awaited proposals to reform the regulation of pharmaceuticals in the EU. The reform aims to increase the availability, accessibility and affordability of medicinal products throughout the EU while also striving to support innovation and boost competitiveness within the pharmaceutical sector – a balance of interests that is difficult to achieve.

The reform in its nutshell

The reform's objectives

The challenges facing the current pharmaceutical system in the EU are manifold and the objectives of the reform seek to balance the interests of the relevant stakeholders being patients and the pharmaceutical industry as well as authorities.

Challenges include medicine shortages and patients across EU not having same access to medicinal products as well as regulators experiencing limits of current legislation when facing the changing technological environment and the pharmaceutical industry's need of operating in a system nurturing innovation.

On this basis, the EU Commission has proclaimed the reform's main objectives to be the following:

- To ensure that patients across EU all have timely and reasonable access to safe, effective and affordable medicinal products;
- To enhance the supply and availability of medicinal products for all patients across EU;
- To continue presenting an attractive and innovative-welcoming environment for research, development and manufacture of medicinal products in the EU;
- To reduce the processing times for the authorization of medicinal products, so they reach patients faster;
- To make medicinal products environmentally more sustainable; and
- To address antimicrobial resistance.

The proposals and their key elements

The reform includes proposals for both a new EU Directive and EU Regulation to revise and replace the current legislation. Simply put, the Directive contains the requirements for authorization, monitoring, labelling and regulatory protection and placing on the market for all medicinal products authorized at both EU and national level. The Regulation includes specific rules (in addition to those of the Directive) for medicinal products authorized at EU level, while also setting out the rules on management of critical medicine shortages and rules governing the European Medicines Agency (EMA).

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Some of the key elements of the proposals are:

- The regulatory framework is proposed simplified with faster authorisations of new medicinal products. Especially, the EMA will have 180 days compared to the current 210 days to conducts its scientific evaluation, and the time between the opinion of the CHMP and final decision on the application for marketing authorisation shall not extend beyond 46 days compared to the current 67 days. For medicinal products of major public health interest, the EMA shall only have 150 days to conducts its scientific evaluation.
- New requirements are introduced for monitoring medicine shortages by national authorities, the EMA and companies. These requirements entail that companies are to report shortages and withdrawals of medicinal products earlier than today and that shortage mitigation plans are to be prepared by companies. Also, a new list of critical medicinal products will be drawn up with pertinent supply chain vulnerability assessments with recommendations for measures to be taken by companies.
- The current standard data exclusivity period of 8 years will be reduced to a period of 6 years, while the standard market exclusivity period of an additional 2 years will remain. There will, however, be incentivized ways to prolong the data exclusivity period to a maximum of 12 years. Such additional period of protection can be obtained if companies launch the medicinal product in all EU member states (+2 years), if the product addresses an unmet medical need (+1/2 year), if comparative clinical trials are conducted (+1/2 year) or if the product can treat other disease(s) as well (+1 year). Medicinal products for rare diseases enjoy a slightly longer period of protection of 9 years (with a maximum of 13 years).

Next steps

The legislative proposals (being the EU Regulation and Directive) have been submitted to the European Parliament and the Council for their discussion. The timing for final adoption of the proposals is unpredictable at this point in time.

Accura comments

While faster processing times for the authorisation of medicinal products will be welcomed by most stakeholders in the pharmaceutical industry, other parts of the proposed reform have been greeted differently. Notably, the reduction of the standard data exclusivity period from 8 to 6 years can be argued to conflict with one of the reform's main objectives to provide an attractive and innovation nurturing environment for research, development and manufacture of medicinal products. For similar reasons, the proposed reform has overall received no more than a somewhat lukewarm welcome by the originators of the pharmaceutical industry.

If you want to hear more about the proposed reform of the pharmaceutical regulation, feel free to reach out to Accura's dedicated team of legal life science specialists.

The Danish Supreme Court eases the standard of proof for financial losses in product imitation cases

On 22 March 2023, the Danish Supreme Court handed down its decision in a long-pending case between Danish ceramist Anne Black against Danish retailer Salling Group and import company Ronald A/S. The case, which was initially submitted by Anne Black in 2015, concerned whether Salling and Ronald had violated Anne Black's copyrights and marketing rights to three designs (a hanging flowerpot, a vase and a jar) by way of their marketing of products resembling Anne Black's designs.

Before the Danish Maritime and Commercial High Court, all three products were found to enjoy copyright protection. However, the Supreme Court, agreeing with the Eastern High Court, found that only one of the three creations were protected by copyright, whereas all three creations were found to enjoy protection under the Danish Marketing Act based on their market presence and position.

The Supreme Court found that the products marketed by the respondents infringed Anne Black's rights under the Copyright Act, respectively the Marketing Act as the products under the given circumstances were proved to be intrusive imitations of the protected designs.

The respondents were therefore ordered to compensate the financial losses that Anne Black had suffered as a consequence of the infringements.

Throughout the proceedings, Anne Black had claimed DKK 3.000.000 in financial compensation for the alleged infringements. Before the Maritime and Commercial High Court, Anne Black was awarded DKK 1.500.000 which was subsequently reduced to DKK 300.000 by the Eastern High Court.

The gravity of the infringement can influence the infringed party's burden of evidence

Before the Supreme Court, the respondents argued that Anne Black had not sufficiently documented her financial losses and that the conditions for awarding compensation under the Copyright Act and the Marketing Act were therefore not fulfilled. However, and of particular interest in this case, the Supreme Court reasoned that the gravity of the respondents' infringements gave cause to lower the evidentiary standards which Anne

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Black needed to provide to prove the financial losses suffered because of the infringements.

Further, the Supreme Court referenced a financial statement reflecting Anne Black's significant drop in sales during the infringement period alongside an expert's opinion stating that it was plausible (but not certain) that the loss of sales was caused by the infringement, and that the marketing of the infringing products at significant lower prices than the original products could create the impression that Anne Black's brand was under dissolution thereby risking all future sales towards Anne Black's relevant clientele. The Supreme Court accordingly seems to have attached significant importance to the fact that a large player on the market is able to dilute the brands of smaller players by marketing infringing products at a very low price (as so called "loss leaders") to attract new customers.

On this reasoning, the Supreme Court finally awarded DKK 1.000.000 in compensation.

Accura comments

The Supreme Court's decision will undoubtedly set a precedent regarding the fixation of compensation in future product imitation cases as it establishes a general principle that the severity of an infringement may affect the requirements regarding the amount of evidence which a rightsholder must provide to prove their financial losses caused by an infringement.

Although being good news for the creative businesses which can now expect larger compensations in infringement cases, there might still be a long way to go in properly securing right holders' satisfactory compensation for the loss and damages suffered on both brand value and sales in these cases. Even though the Supreme Court increased the compensation, Anne Black was ultimately only awarded one-third of her initial claim.

If you have any questions about infringements of intellectual property rights, please do not hesitate to contact Accura's team of IP experts.

Revision of ENLI's Guidance on the Promotion Code

The Danish Ethical Committee for the Pharmaceutical Industry (ENLI) has issued a revised version of its Guidance on the Promotion Code (the Guidance) reflecting recent decisions from ENLI's Appeals Board and including other various clarifications and changes. Below, we highlight the most material updates. The updated guidance can be retrieved in English here.

The fine line between informative material and promotion

Considering a recent decision from ENLI's Appeals Board on the distinction between information about health and disease and promotional material, new comments referencing the decision has been added to clarify the scope of the disease and health exemption (under the Promotion Code's article 2 (2) (c) (5)).

The Appeals Board upheld a decision from ENLI's Investigator's Panel declining a pharmaceutical company's request for pre-approval of certain material on treatment of a specific disease, which the company wished to provide to health care professionals (HCPs) for educational purposes. The Appeals Board reasoned that the material was aimed at indirectly promoting the company's products, because the material selected by the company from a guideline contained an illustration recommending one of the company's own products and further because the material as a whole was centered on disease treatment rather than information about the disease. In this regard, the board stressed that the exemption provision exempts information about diseases but not the treatment hereof, and that no references – whether direct or indirect – can be made to specific medicines.

Extracts from the decision has consequently been added to the Guidance.

The referenced decision is available in Danish here.

Compulsory information in dynamic banner advertisements

In advertising for medicinal products towards HCPs, certain so-called compulsory information about the product shall be included. New comments to the Promotion Code's article 5 (2) clarify how such information is best provided when advertising via dynamic banner advertisements (i.e. advertisements spanning multiple pages running in a loop, where all pages are not visible simultaneously). Notably, it must be considered whether such an advertisement is perceived by the viewer as a single, coherent advertisement, in which case it will suffice with only one banner containing the compulsory information. To make sure that the dynamic banner is perceived as one coherent ad, ENLI recommends that each individual banner of the advertisement is marked with the pertinent number (e.g., 1/3 on the first banner page) to ensure coherence between the banners. The consequence of the banners being perceived as separate advertisements is that all banner pages as a starting point must visibly include the compulsory information.

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Use of environmental and climate claims in comparative advertisements

When comparing medicinal products in advertisements, it is possible to factor in a product's environmental and climate profile. New comments to article 8 (1) in the ENLI Guidance clarify the conditions to be fulfilled in this regard, namely that the environmental/climate claims cannot be the primary comparative or differentiating element in the comparative advertisement as the comparison must always be based primarily on the efficacy of the product, including its safety profile. Further, reference to the practice of the Danish Consumer Ombudsman is included, highlighting the strict rules on the prohibition of greenwashing, which pharmaceutical companies must also respect.

The update follows previous clarifications made by ENLI following a decision from the Appeals Board in the Fall of 2022, which we covered in our November 2022 newsletter.

The requirement for professionalism encompasses a product's environmental consequences

Under article 13 of the Promotion Code, pharmaceutical companies may offer HCPs training and professional information in the form of i.a. payment of direct expenses in connection with the HCPs' participation in professional relevant courses, provided that the event includes pharmaceutical information or other professional relevant information of relevance to the participant. Continuing the broader influence of environment and climate in the Guidance, the scope of "professional information" has been broadened to also cover environmental consequences of the use of medicinal products as "focus on sustainability and climate friendly solutions must be expected to become a necessary and integral part of the daily life of HCPs".

In order for a presentation to be seen as professional relevant information, 1) the primary purpose of the presentation shall be to provide HCPs with relevant facts for a better understanding of the impact of climate change on healthcare, 2) the presentation includes no mentioning of specific medicinal products and 3) the presentation of other environmental issues must not directly or indirectly be in the nature of or be perceived as advertising for medicinal products.

The update follows a decision from the Appeals Board covered in our March 2023 newsletter.

Accura comments

The Guidance is continuously updated in accordance with the developments of the practice from ENLI's Investigator's Panel and Appeals Board. It is important to be aware of these developments when dealing with promotional activities towards HCPs. Accura's team of legal life science specialists follow decisions, updates and developments from ENLI, so feel free to reach out if you have questions to the above updates or ENLI's Promotion Code and pertinent Guidance in general.

Blurring the line between real and fake in advertising

The rise of AI-generated portrayals, including deepfake advertising, has permeated popular platforms like Instagram and TikTok, raising ethical, legal and commercial questions. While this technology can amplify the spread of deceptive information and pose significant concerns, it also presents commercial opportunities when used responsibly and in accordance with the law.

Challenges and concerns of deepfake advertising

Deepfakes specifically involve digitally manipulated visuals and audio that portray individuals doing or saying things they never actually did or said, often with the intent to deceive or manipulate. Examples include deepfake portrayals of well-known figures such as Joe Rogan and Elon Musk seemingly endorsing products.

The creation of deepfake content often infringes upon intellectual property rights and privacy rights. Furthermore, deepfake advertisements created without consent will also often constitute misleading and false advertising, violating marketing laws and privacy rights while potentially also causing reputational damage to the individuals portrayed.

Danish case law, such as the Supreme Court judgment U 1965.126 H (Buster Larsen case), have previously grappled with unauthorized use of celebrities in advertising and established boundaries to prevent misuse, asserting that utilizing a photography's advertising value without the depicted person's consent is illegal. This principle has since been reinforced in other cases. It is crucial to address misuse in deepfake advertising to protect rights and maintain ethical standards in the digital world.

Potential opportunities in responsible deepfake and AI-generated portrayals

Despite the ethical and legal concerns surrounding deepfakes, responsible use of deepfake technology, as well as the broader realm of AI-generated portrayals, can present commercial opportunities. Companies can leverage AI technology creatively to produce innovative advertisements that engage consumers and generate buzz on social media platforms, as demonstrated by the recent viral social media advertisement by design brand Jacquemus, which featured AI-generated bus-sized leather bags cruising the streets of Paris on wheels.

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Accura comments

The rapid advancement of AI and technology has given rise to various legal challenges (see previous Accura articles here and here), including the emergence of deepfakes in marketing. These deepfakes are challenging for consumers to identify due to their incredibly realistic and persuasive visuals. As a result, deepfake marketing can mislead consumers and raise privacy concerns for the individuals represented in the deceptive content, posing a significant threat to consumer protection.

In response to this issue, consumer protection agencies, such as the Danish Consumer Ombudsman, might consider implementing regulations that require companies to clearly disclose when they have manipulated a piece of content and indicate that AI has been used. This would be similar to requirements in some jurisdictions to label retouched photos on social media, ensuring that consumers are aware of modifications made to any content.

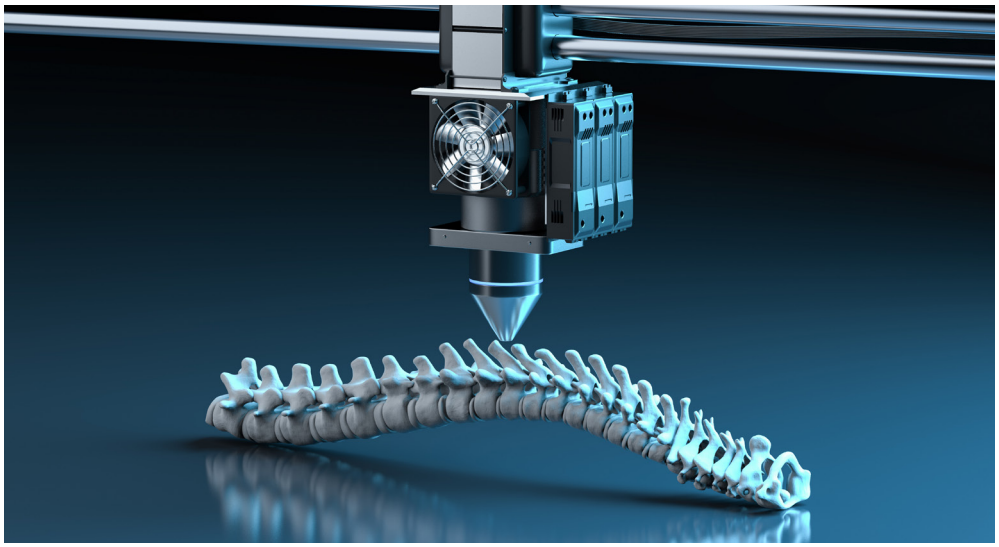
Despite the challenges, the underlying technology also presents commercial opportunities. As the technology continues to advance, it is vital for businesses to remain aware of the legal and ethical implications while exploring the commercial opportunities it offers.

To harness the commercial potential of deepfake technology and AI-generated portrayals, businesses should adhere to relevant legal and ethical guidelines, including obtaining proper consent and respecting intellectual property rights and privacy concerns. By working within the confines of the law, companies can capitalize on the potential of the technology to create innovative marketing campaigns that engage with consumers on a deeper level and differentiate themselves in the competitive advertising landscape.

We will continue to monitor further developments in this area.

Network meetings – 3D printing and MedTech in a legal context

On the 19th of April 2023, Accura held its first of two network meetings about 3D printing, also known as additive manufacturing (AM), and MedTech in a legal context in collaboration with the business foundation for the additive manufacturing industry Danish AM Hub.



In front of a broad range of professionals within the AM industry, Melissa Tronier Kapper, attorney-at-law in Accura's IP & Life Science team, gave an introduction to the main legal issues which may arise with respect to intellectual property rights when using 3D print technology, including the risk of infringing existing third-party rights. Melissa also spoke about protection and enforcement of IP rights with special focus on design and patent rights in the context of 3D printing of medical devices.

Focus was further brought to the essential matter of product liability, which has particular relevance for 3D printing as a production technology with numerous actors in the production chain, who potentially can be held liable for defective products.

In the second half of the network meeting, the recently adopted medical device regulatory framework ("MDR" and "IVDR") was covered with a particular focus on the numerous and difficult regulatory requirements that any manufacturer of medical devices must comply with, including manufacturers using 3D print technology. The presentation gave rise to many questions from the participants, who debated the legal requirements amongst themselves while sharing their experiences on how to best ensure compliance with the rules in practice.

Highlight of the day was the panel talk with two representatives from the Danish companies Exo360 and Snapform that are both relying on AM technologies in the production of their medical devices, which

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include 3D printed casts and prosthetics. Melissa was moderator and asked questions on how the companies incorporated the new regulatory framework into their daily operation to ensure compliance and whether the panelists viewed the new regulations as actual barriers.

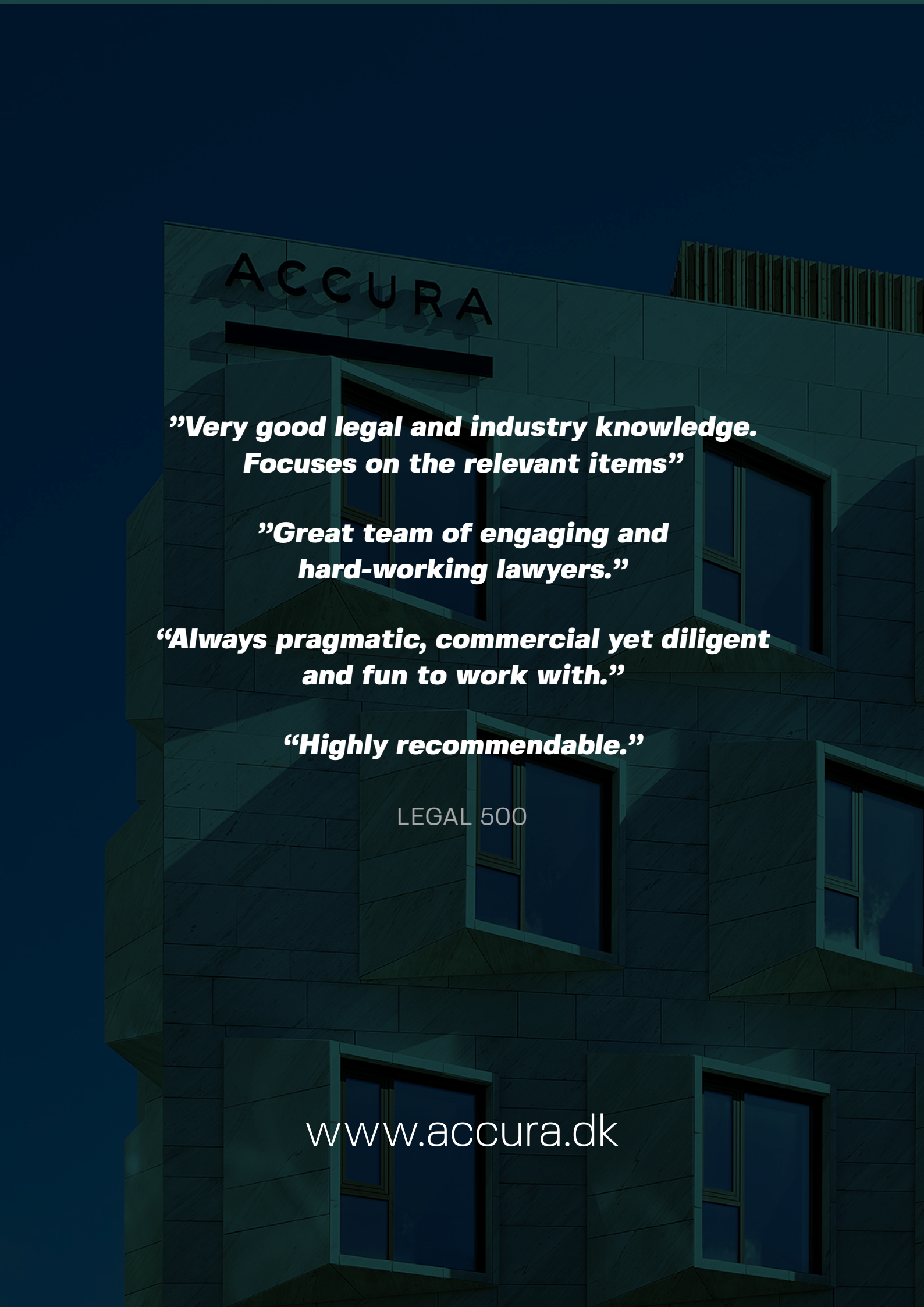
The main key takeaways from the network meeting were that any company that considers – or is in the process of - manufacturing medical devices must think and lay down its compliance strategy from the very beginning. Complying with the regulations on medical devices already starts when innovating the products as the classification of a product is essential to determine whether the product can ultimately be approved by the notified bodies. Therefore, the right counseling and legal advice can be crucial in order to guide one through the difficult regulatory landscape of medical devices.

- Is there a risk that a 3D printed medical device is infringing existing IP rights?
- How do I know if my medical device must be CE marked?
- How do I ensure that my invention does not infringe existing patent rights?
- Can a patented technology infringe a copyright and vice versa?
- As a manufacturer using 3D print technology, how do I ensure that I cannot be held liable for defect products?

These were just a few of the many questions that arose on our insightful networking event, which focused on 3D printing and MedTech in a legal context.

If you missed out on this network meeting, fear not! We are continuing the roadshow in Aarhus, where we once again will shed light on the various legal issues when 3D printing medical devices.

The next network meeting will be held in Accura's office in Aarhus on 24th of May 2023. Register here.



”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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