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June 2026

IP & Life Science News

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What's the latest in Danish Life Science: Medicines Council, MFN and a new four-party government

As of early June 2026, Denmark has a new four-party "Clover" Government and a fresh coalition platform. We have examined the coalition's platform's high level life science priorities. In this article, we highlight this and other developments of interest to life science companies, namely the forthcoming evaluation of the Danish Medicines Council (Medicinrådet) and the MFN Task Force.

Independent evaluation of the Medicines Council

The Danish Regions (Danske Regioner) has decided to commission an external, independent evaluation of the Danish Medicines Council, which is to run in the second half of 2026. The evaluation is part of the Danish Regions' ongoing evaluation, and the intention is to benchmark the Danish practices against other countries, review methods, and assess transparency and patient involvement, specifically looking at whether medicinal products are approved more or less often in Denmark than in comparable countries.

Lastly, the evaluation will specifically investigate how other countries approach the evaluation of medicinal products aimed at small patient populations with rare diseases. The aim of the evaluation is to identify strengths and weaknesses of the Medicines Council, and to allow continuous adjustment in its approach to evaluation of new medicinal products.

While the evaluation will assess topics that have already been raised in the public debate, the general aim is for the evaluation to serve as the starting point for a qualified debate on how medicinal products should be assessed in the future.

The outcome of this evaluation is expected in the second half of 2026. We look forward to sharing its conclusions.

The MFN Task Force

The "Most Favoured Nation" (MFN) concept is a US policy aimed at bringing down pricing on medicinal products in the US market. This is done by identifying the lowest price that a medicinal product is sold at from a selected group of countries (the most favoured nation) and requiring that the medicinal product is sold at the same price in the US. With Denmark having the doubtful honour of being selected as a reference country, we saw the first product withdrawn from the Danish market early this year referencing global impact on pricing caused by the MFN policy.

SØREN CHR. S. ANDERSEN
PARTNER, ATTORNEY-AT-LAW
IP & LIFE SCIENCE

SOA@ACCURA.DK

ARMIN SARVAN
DIRECTOR, ATTORNEY-AT-LAW
IP & LIFE SCIENCE

ARS@ACCURA.DK

DAVID LOMBORG SØRENSEN
ASSISTANT ATTORNEY
IP & LIFE SCIENCE

DLS@ACCURA.DK

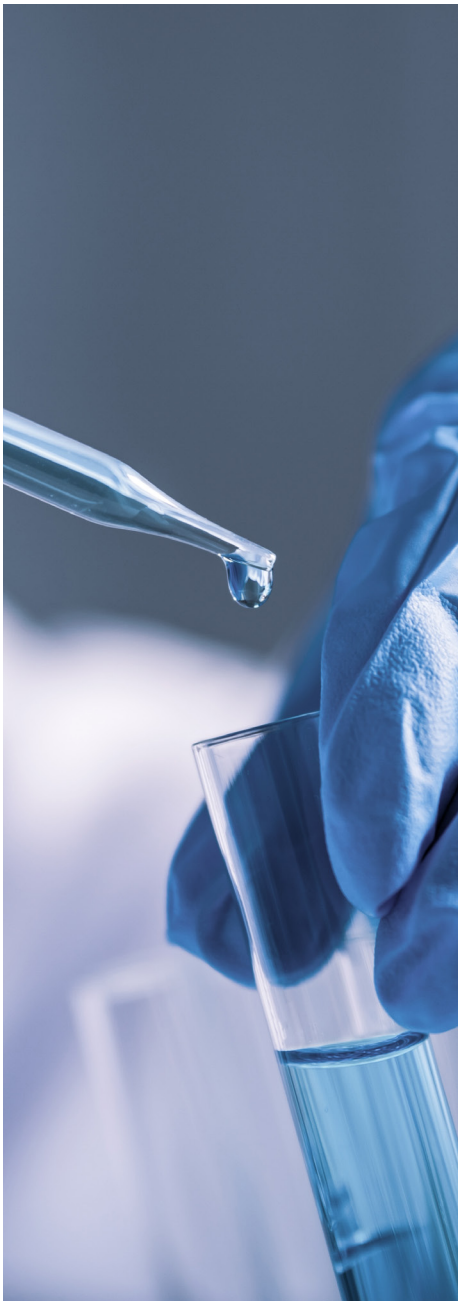
The consequences of the MFN policy are significant to both the public and the Danish life science industry, as it may cause medicinal products or treatments to not be marketed in Denmark or to be marketed later than they would have been; it may cause a reduction in the number of clinical trials run; and further down the line we risk fewer investments in our life science industry reducing exports, workforce and general growth of the industry.

The former Danish government established an MFN Task Force to investigate the consequences of this. We are happy to see that the new government's coalition platform directly mentions the task force, and the aim of ensuring that Denmark and the life science industry are equipped to handle the issue. Needless to say, Accura will follow developments in this area closely.

The coalition platform and government attention on Life Science

The coalition platform expressly recognizes the Danish life science industry and sketches an updated life science strategy to align access to treatment, clinical trials, commercialisation, export and consent based use of health data. It also signals prevention focus, and a national "digital health assistant" developed in public private collaboration.

We note several positives for the life science sector: the platform emphasises research, clinical trials and data enabled care. At the same time, affordability and value for money remain central. While these objectives need not be mutually exclusive, we look forward to following to what extent and how the government manages to implement these in the coming years.



Faster access to new medicinal products – extended timelines for alternative pricing agreements

Uncertain clinical efficacy and budget-impact are recurring themes in the Danish Medicines Council's (Medicinrådet) decisions not to recommend a medicine as standard care available to Danish hospitals. In an attempt to increase use of alternative pricing agreements for new high price and/or limited evidence medicinal products, the Danish Medicines Council and Amgros have extended the timelines for proposing alternative pricing agreements stating an intention not to delay the timing of planned meetings or the expected decision date. As such, going forward companies will be allowed to submit the alternative pricing agreement until and including week six of the evaluation-process. The hope is that this will help accelerate patient access to new medicines.

What are alternative pricing agreements

Alternative pricing agreements are used to propose mitigations of uncertainties related to clinical efficacy and/or costs of new medicinal products. As such, it is a risk-mitigation measure enabling a positive recommendation where a standard pricing set-up would not suffice for a positive recommendation. These can be utilized to mitigate potential budget impact of high-priced medicinal products, and/or medicinal products where knowledge on efficacy is insufficient, this could e.g. be by a price-volume model, where pricing decreases as sales-volumes go up, or an effect-based model where payment is tied to relevant (measurable) clinical endpoints.

Pricing of the medicinal product – regardless of whether this is based on regular or alternative pricing models – are negotiated by Amgros on behalf of the Danish regions; ultimately the Medicines Council will make their recommendation based on an evaluation of whether there is a reasonable balance between price, effect and risks.

What has changed – and why it matters

As indicated, the concept of alternative pricing agreements is not new, but sponsors may now submit the alternative agreement up to and including week six from their initial submission. And as a starting point, the intention is that such later submissions should not affect the timing of already planned meetings or the expected decision date.

SØREN CHR. S. ANDERSEN
PARTNER, ATTORNEY-AT-LAW
IP & LIFE SCIENCE

SOA@ACCURA.DK

DAVID LOMBORG SØRENSEN
ASSISTANT ATTORNEY
IP & LIFE SCIENCE

DLS@ACCURA.DK

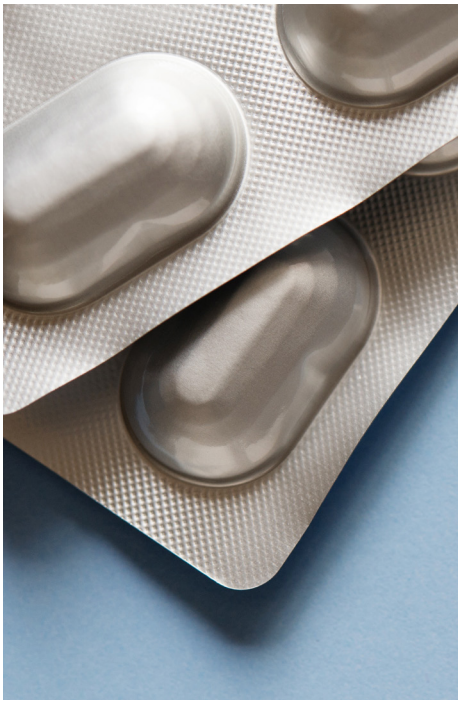
Applicants should be aware that the alternative pricing agreement as a main rule should be described in their initial submission to the Medicines Council. However, this is not set in stones, and later submissions of alternative pricing agreements may be made for the first six weeks following alignment between the Medicines Council and the applicant.

At the outset, it is the intention of the Medicines Council that alternative pricing agreements submitted after the initial request for assessment will not cause clock-stops, or cause meetings and decision timelines to be postponed. However, applicants should be aware that clock stops remain a possibility in case of alternative pricing agreements submitted within those six weeks, and introducing complex pricing models. The net effect of this to applicants is clear, as this paves the way for adjusting or adding an alternative pricing agreement early in the process where this could improve the likelihood of a positive recommendation.

Accura's comments

The new six-week window adds welcome flexibility, and could lead to more "file-early, refine-by-week-six" strategies. But this is not a carte blanche to secure an early assessment and fill gaps later. Any late or complex alternative may still prompt a clock-stop and push subsequent milestones. Used well, the new flexibility will allow applicants to start the assessment and then table a targeted alternative within six weeks if value or effect concerns crystallise. Used poorly, it risks avoidable delay: submissions that are incomplete, methodologically complex, or operationally vague may still stall the process. The Medicines Council's evidentiary standards are unchanged; flexibility widens the timing options but does not lower the bar.

If you want to know more about the different options for setting up alternative pricing agreements or anything related to this, please do not hesitate to reach out to our team of experts in Accura IP & Life Science.



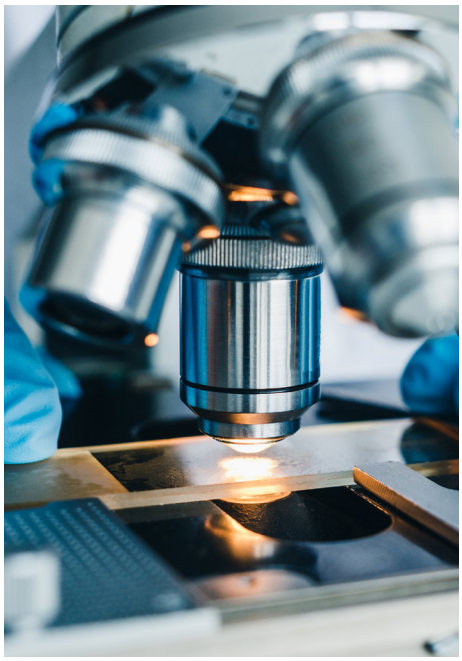
The Pharma Package further unwrapped

In December 2025, we covered the new EU Pharma Package addressing major changes with commercial impact. Following the provisional political agreement of 11 December 2025, the pharma package is moving towards formal adoption with the draft directive and regulation published in March 2026. While we will not know the final wording until publication in the Official Journal, we now have a good starting point for assessing the changes. In this update we focus on the operational business effects: namely the shorter regulatory timelines for marketing authorizations, and the shift to risk based pharmacovigilance and electronic product information (ePI).

Pre-authorization: Shorter authorization timelines and stronger environmental risk assessment requirements

The Pharma Package introduces several changes to the marketing authorization process, including perhaps one of the most immediate and impactful changes brought about by the Pharma Package – that is a reduction in the evaluation timeline for centralized marketing authorization applications, meaning that the Committee for Medicinal Products for Human Use ("CHMP") will have 180 days to issue their scientific opinion, which is a 30 day reduction from the current 210 days. This is further supplemented by a reduction in the timeline for the subsequent Commission Implementing Decisions which the Commission at the moment has 67 days to complete. After implementation of the Pharma Package, these Implementing Decisions will be completed within 46 days of release of the CHMP's scientific opinion. In line with this, the timelines for approval of medicines of major interest to public health have also been reduced, and marketing authorisation applications of such will be evaluated in 150 days.

The upside is clear: faster access to the market. Yet, the trade off is proportionally bigger: any clock stop can push you past a CHMP meeting cycle and erase the 30 day gain. Accordingly, companies would be well advised to prepare for the Pharma Package by revising and optimizing internal processes to QC and increase the scientific output and decrease procedural bottlenecks.



Separately from timelines, but under the topic of marketing authorization applications, applicants will also face a reinforced environmental risk assessment (ERA) obligation. It will be mandatory for applicants of marketing authorizations to include an environmental risk assessment in their application. In this, the applicant is required to evaluate the environmental impact of the product as well as risk mitigation measures taken. This requirement continues through-out the life cycle of the product and companies will be required to update this if new information arise that alter conclusions of the original assessment.

ARMIN SARVAN
DIRECTOR, ATTORNEY-AT-LAW
IP & LIFE SCIENCE
ARS@ACCURA.DK

CHRISTINE QVIST BRANDT
LEGAL TRAINEE
IP & LIFE SCIENCE
CQB@ACCURA.DK

Post-authorization: risk-based pharmacovigilance and electronic product information

To match faster pre authorisation timelines, the Pharma Package streamlines post authorisation oversight. The direction of travel is clear: fewer routine processes and more risk based oversight anchored in EU level procedures and digital tools. Going forward, only two of EMA's current five committees for human medicines will continue. The direction is a shift away from one-size-fits-all routine updates towards targeted, risk-based oversight.

At a first glance the changes at the marketing authorization holder-level largely result in the same situation; thus, core duties concerning PSUR, PSMF and QPPV requirements persist. The material change is in how these are run: going forward, EU coordinated procedures, shared repositories and digital infrastructure will take the center stage, improving data quality, shortening response times and enabling single assessments implemented uniformly across Member States

Practically, the risk management plan (RMP) becomes a living steering document. Like it is today, RMP updates can drive changes to product information; what changes is the speed and consistency of those updates across the EU, and the governance and resourcing MAHs will need to operate to that cadence.

The move towards use of electronic product information (ePI) underpins this shift. Authorized product information will have to be made available in structured electronic form alongside certain paper materials, supporting faster, uniform product information updates throughout the EU.

The move towards electronic product information sits alongside the broader EU level process and IT changes intended to speed up and harmonise post authorisation updates, including safety related changes to product information. The proposals emphasise EU coordinated procedures and digital tools rather than MAH or national level implementation of relevant updates; the operational effect of the updates is thus that once the new framework is in force, changes should flow through the EU system in a more uniform and timely way.

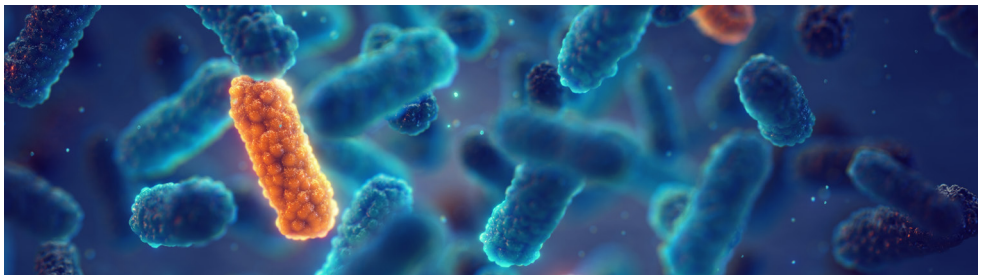
Accura's comments

Being in the final stages before the expected implementation of the new Pharma Package and with only minor changes to the wording of the two documents expected, companies are well advised to start preparing for the new legislation. Accordingly, we are at a bridging point allowing businesses an opportunity to get a head start on preparing for capturing shorter timelines while running PV/ePI at EU cadence.

If you want to know more about the reform and its implications, please do not hesitate to reach out to Accura's team of specialists in IP & Life Science.

Transferable regulatory incentives: a new currency in Life Science?

In our newsletter in December 2025, we briefly covered the introduction of Transferable Exclusivity Vouchers (”TEV”s) in the EU. This is a topic gaining increasing interest, fuelled by news flashes that cover stories about sales of the similar US Pediatric Disease Priority Vouchers (PRV). In their Q1 2026 financial statement, Ascendis Pharma has disclosed the sale of such a voucher for USD 187,5 million. In view of this and previous sales it is evident that such vouchers hold significant potential value to both buyers and sellers. In this article, we will look further into the new rules on TEVs and how companies may gain the most of them.



A brief look at PRVs

A PRV is granted by the FDA to pharmaceutical companies for the development and approval of medicines for the treatment of neglected tropical or rare paediatric diseases. The voucher is transferable and grants the holder expedited FDA review of marketing authorization applications, thereby providing for significantly faster access to the US market. Considering the size of the US market, it is not surprising that PRVs are sold for such high prices.

TEVs in summary

TEVs are intended for antimicrobials. The hope is that TEVs, among others, will mitigate the conflicting interests between the developer companies' interest in selling their products, and health authorities' interest in limiting use of antimicrobials to combat antimicrobial resistance. TEVs will thus play the role of a carrot at the end of a stick, trying to incentivise companies to chase and catch it via development of new antimicrobials. If companies catch it, companies will be granted a voucher which may be transferred to another company (and only one) – it is valid for five years, and it can be exchanged for 12 months of additional data exclusivity for any centrally authorized product. However, catching this carrot will require companies to complete a track fraught with obstacles without losing balance.

Qualifying for TEVs

First obstacle is developing a *priority antimicrobial* which, in plain terms, means an antimicrobial targeting a multi-drug resistant organism that demonstrates significant clinical benefit against antimicrobial resistance and which either employ (a) a new mechanism of action, or (b) a new active ingredient (alone or combined with other active substances) which targets serious or life threatening infections.

Next, the applicant must 1) be able to demonstrate that it has the capacity to supply the expected needs of the EU market, 2) provide public information on direct financial support received to develop the antimicrobial, and 3) demonstrate that the MA-application was first sent to the EMA, or, alternatively, that it was a least sent to the EMA within 180 days of submission to a competent authority of a country outside the EU. Finally, applicants need to accompany their MA application for the new antimicrobial with a request for a TEV.

DAN ERMOSE
ASSOCIATE PARTNER,
ATTORNEY-AT-LAW
IT & OUTSOURCING

DER@ACCURA.DK

DAVID LOMBORG SØRENSEN
ASSISTANT ATTORNEY
IP & LIFE SCIENCE

DLS@ACCURA.DK

TEV restrictions

Importantly, even when all hoops have been jumped through satisfactorily and the TEV has been granted, companies should be mindful of a number of restrictions:

1. In line with the goal of the TEV-scheme, the antimicrobial can only be used in humans during the first 10 years after grant of the MA to decrease the risk of organisms developing resistance to the new antimicrobial.
2. Further to this, TEVs may be revoked if the MA holder is unable fulfil a request for supply of the priority antimicrobial, unless it has already been transferred to another MA holder.
3. A TEV can only be used to extend the regulatory data protection period of a product if gross sales of that product have not exceeded EUR 490 million in either of the four years after grant of the MA.
4. The 12 months data protection extension period can only be utilised in the fifth or sixth year of the regulatory data protection period.
5. The TEV will expire if it has not been used within 5 years of being granted or if the MA of the priority antimicrobial has been withdrawn.

TEVs vs. PRVs

These limits will likely reduce flexibility and therefore impact the expected willingness to pay of would-be-buyers of TEVs, relative to PRVs. TEVs also interact with Europe's fragmented pricing/HTA environment, meaning the marginal value of an extra year of data protection will vary widely by product and Member State. On the other hand, where a buyer has an EU authorised product with weaker patent/SPC cover and sub blockbuster sales, a well timed TEV could still command meaningful value; the ceiling will simply be lower and more case specific than in the US PRV market.

Next steps

This article is based on the provisional political agreement on the EU "Pharma Package" announced on 11 December 2025 and on the draft regulation and directive published in March 2026. We are following developments closely and await adoption of the final legal text. Specific parameters (e.g. timing of use, sales based conditions for TEVs etc.) should be verified against the final adopted instruments.

Accura's comments

TEVs are the shiny new but fairly specific tool joining the existing tools in the EU regulatory and IP toolbox. TEVs hold real potential value, but companies should carefully examine how they can be utilized alongside the existing rules on data and market protection, supplementary protection certificates and paediatric extensions, investigating where an extra year of data protection yields real marginal value. Where patent/SPC cover is short, narrow or uncertain, a well timed TEV can materially strengthen early to mid revenue years; where robust patent/SPC protection already spans the commercial peak, the incremental value may be lower. In addition, the broadened Bolar safe harbour of the Pharma Package underscores why timing matters: deployment of the TEV in the permitted window should be modelled against when follow on entrants could otherwise capitalise on data access milestones. In short, TEVs should be regarded as a precision instrument to close protection gaps in the product's lifecycle rather than as a generic extension.

If you are assessing eligibility for EU TEVs or considering how to deploy them alongside data/market protection, orphan exclusivity, SPCs and paediatric extensions, Accura's IP & Life Science team can help you build the right lifecycle model. If you are more interested in the monetisation or transfer mechanics, we work seamlessly with our Corporate and M&A colleagues to structure and execute transactions aligned with disclosure and governance expectations.

Five-star venues vs. ENLI's "reasonable hospitality" standard

In Denmark – and in the rest of the EU – events aimed at health care professionals (HCPs) and sponsored by pharmaceutical companies are strictly regulated. Activities by pharmaceutical companies directed at or involving healthcare professionals are, furthermore, subject to the codes and rulings of the industry body, ENLI – the Danish Ethical Committee for the Pharmaceutical Industry. In a recent ruling by ENLI, it was reaffirmed that five-star accommodation is extravagant by default and that exceptions allowing use of such must be justified and documented up front.

ENLI at a glance – scope and supervisory approach

ENLI is established by the Danish pharmaceutical industry, and ENLI's codes and rulings apply only to the members of ENLI. This is at least the formal truth; the practise of ENLI can be persuasive when applying the generally applicable rules of the Danish Medicines Act and associated administrative orders.

Under the promotion code, members are allowed to pay HCPs' direct expenses related to the HCPs' participation in courses, conferences and training sessions. As such, all forms of hospitality offered by pharmaceutical companies to HCPs must be kept at a reasonable level, and, as a general rule, members should not offer accommodation at venues known for being extravagant and luxurious.

ENLI interprets this restrictively. As a starting point, a five-star hotel is, in the public opinion, regarded as extravagant or luxurious, and thus not suitable as accommodation for HCPs. Accordingly, ENLI will take account not only of the official star-classification, but also of the general public opinion of the hotel, and exceptions may be made if it is documented that exceptional circumstances such as logistics, specific facilities or if no other alternatives are available, necessitate use of the hotel.

In making this assessment, ENLI will review official ratings of the hotel at booking sites, and they may include specific user ratings. But even in situations of discrepancy between an official five-star rating and lower user ratings, which could cast doubt on the general public opinion of a specific hotel, ENLI's restrictive approach will lead to the conclusion that any five-star hotel is unsuitable for accommodation of HCPs.

Members are required to register e.g. (co-)arranged or sponsored activities, incl. meetings, courses and conferences, directly or indirectly involving HCPs with ENLI. ENLI may at its discretion conduct spot checks of registered events to check their compliance with ENLI's promotion code.

DAVID LOMBORG SØRENSEN
ASSISTANT ATTORNEY
IP & LIFE SCIENCE
DLS@ACCURA.DK

ENLI's assessment of use of a five-star hotel

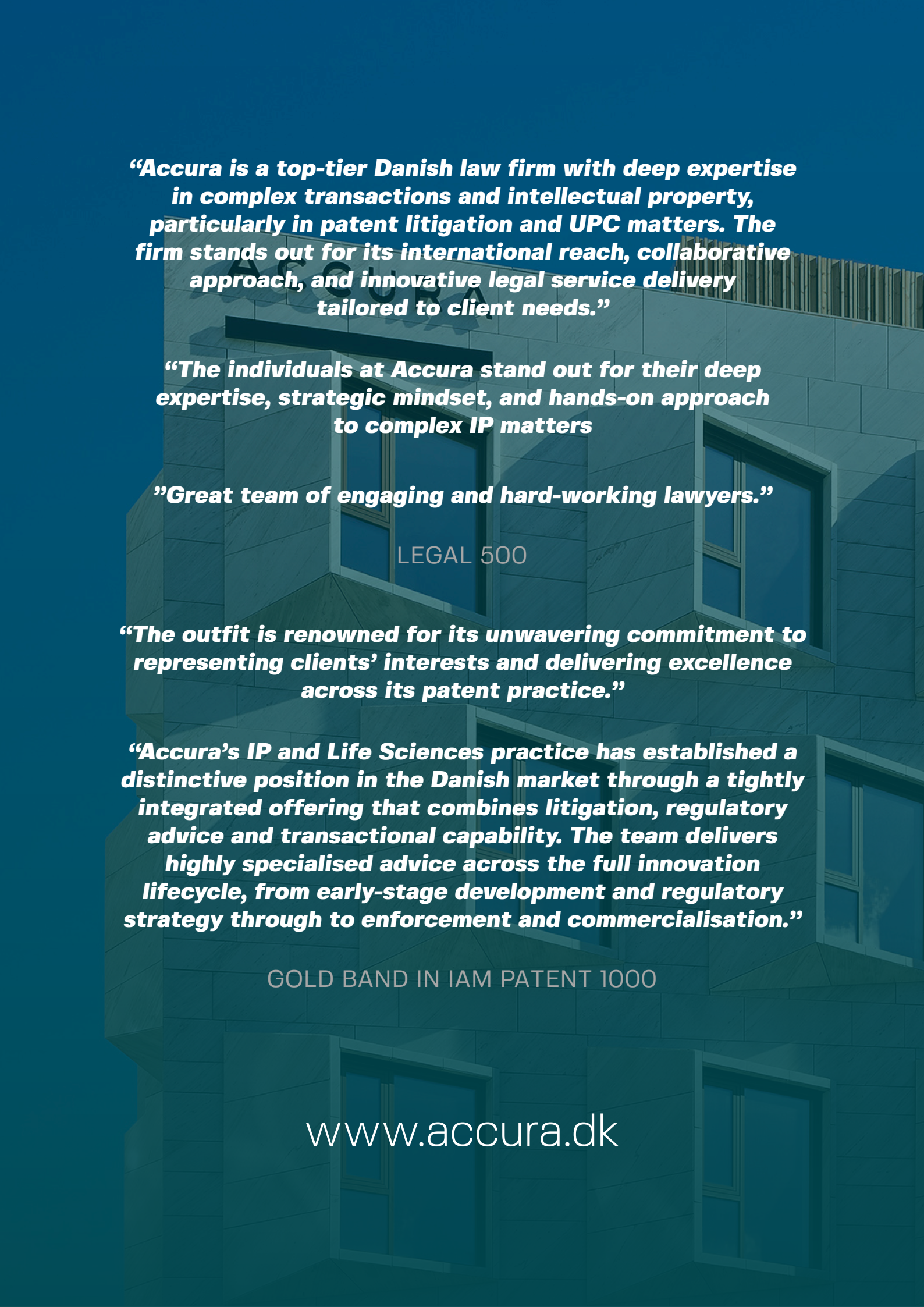
In a recent spot check, ENLI investigated the use of a five-star hotel chosen by a member for accommodation of HCPs. As just established, five-star hotels are considered extravagant or luxurious at the outset and thus was at its outset incompatible with the promotion code, and only exceptional circumstances would permit use of the hotel. In a response to ENLI, the company clarified that the hotel had been chosen due to ease of transportation from the hotel to the venue of the meeting and further clarified that a final decision on which hotel to book was not yet taken and that it would find a more suitable option.

Despite this, and in line with its procedural rules, ENLI based its assessment on the documentation provided at registration of the activity. Accordingly, the explanation provided did not change ENLI's assessment as the exceptional circumstances necessitating use of a five-star hotel must be provided and documented at registration of the event. In its decision, ENLI reiterates that companies cannot rely on spot-checks as a second chance to assess registrations and to bring them within the established framework. In the referenced decision, ENLI ordered the arrangement to be changed or cancelled and imposed a fine of DKK 75.000 on the company.

Accura's comments

For pharmaceutical companies operating in Denmark, the practical takeaway is to plan for the Danish standard screening and to have all documentation ready and included in the registration.

If you are planning to organize or sponsor an event involving HCPs and have questions on how to operate within the boundaries of the promotion code, please do not hesitate to reach out to our team of specialists in IP & Life Science.



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