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The Danish Medicines Council

issues new principles for use of unpublished data

The Danish Medicines Council recently issued a new set of principles for unpublished data, setting out when and how such data may be used in the Council's evaluations, recommendations and guidelines.

The principles replace the "Criteria paper on the use of unpublished data" (February 2020) and provide a greatly welcomed clarification for industry stakeholders by adding additional guidance on the Council's use of unpublished data and, as something completely new, of confidential data.

The new principles were issued in February 2021 and apply to all future applications for evaluations, irrespective of whether the applications adhere to the Council's prior procedure for the process and method for evaluations or the new QALY-procedure, which came into effect as of 1 January 2021. The new principles for unpublished data are retrievable (in Danish) here.

The Danish Medicines Council is an independent Council providing evaluations, recommendations and guidelines on medicinal products to the five regions of Denmark. The evaluations and recommendations mainly concern whether new medicinal products (or extensions of therapeutic indications) should be recommended as possible standard treatments at Danish hospitals. The Council also provides the regions with joint therapeutic instructions (guidelines) comparing several medicines for a specific disease.

To conduct evaluations, recommendations and guidelines, the Council assesses data, mainly provided by pharmaceutical companies. In 2019, Danish Regions (the interest organisation of the five regions in Denmark) allowed the Council to use unpublished data for this type of assessments, provided the Council established specific criteria for the determination of when such use is appropriate. Such criteria were initially created in February 2020 and have now been replaced.

Types of data and attention to the general principles of *expertise* and *transparency*

The Council distinguishes between three types of data:

1. **Published and peer-reviewed data:** Data from scientific peer-reviewed journals, data from the European Medicines Agency (EMA) and the agency's European Public Assessment Report (APAR), data from the US Food and Drug Administration (FDA) and reports from internationally recognised Health Technology Assessment (HTA) agencies such as NICE, EUnet HTA, FINOSE and IQWIG.
2. **Published data not peer-reviewed:** E.g., data published in abstract format or which in other ways are publicly accessible but which has not been peer-reviewed.
3. **Unpublished (and potentially confidential) data:** Typically, aggregated data from companies (data on file) or collected in clinical practices.

As follows from the Danish Parliament's 7 principles for prioritising hospital medicines, and as also stated in the new criteria, the Council values transparency and expertise in its evaluations, recommendations and guidelines. Accordingly, data used by the Council shall therefore be published, accessible and peer-reviewed to the greatest extent possible.

Although only published and peer-reviewed data will generally suffice as documentation in the Council's work, unpublished data may be relied upon where published, peer-reviewed articles and reports are deemed insufficient. Unpublished data may further be necessary in the analysis of cost effectiveness and since some data may be subject to confidentiality (e.g. price agreements, information protected by patents, etc.).

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Principles for submission and use of unpublished, possibly confidential, data

Following an assumption that pharmaceutical companies submitting data are not interested in unpublished data being published by the Council, the Council has drawn up a set of principles for pharmaceutical companies' *submission* of unpublished data and for the Council's subsequent *use* of same.

A. Principles for submission of unpublished data in connection with new medicinal products and expansions of indications:

To provide the Council with sufficient knowledge on the methodical foundation for studies, pharmaceutical companies must:

- ensure the highest degree of data transparency possible;
- provide, as a minimum, information on study design and execution following the principles for reporting on randomised clinical studies in the so-called CONSORT Statement;
- conduct an analysis of the sensitiveness of the implications of in- or exclusion of unpublished data in connection with the health economic analysis;
- follow Council's request to submit additional data or, if not possible, present the grounds for not submitting additional data; and
- account for whether confidential information is expected to be published by the pharmaceutical company and when.

Generally, a justification is required if a submitting pharmaceutical company marks information as confidential, so as to enable the Council to assess whether information is covered by the rules of confidentiality as follows from the Council's policy on confidentiality.

B. Principles for submission of unpublished data for use in preparation of guidelines

In the preparation of guidelines, data are primarily collected by the Council itself and not the pharmaceutical companies. Nonetheless, companies may submit (un)published data in accordance with the Council's protocol for guidelines in which case the following principles will be applied:

- unpublished data will only be included in guidelines, if the submitting company accepts that data will be published along with the guideline; and
- it must explicitly appear from the unpublished data what published and peer-reviewed main study the patients were originally part of.

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C. Principles for the use of unpublished data

The Council has further presented the following six principles on how it will handle unpublished, potentially confidential, data:

1. The Council's expert committees and secretariat will ensure that pharmaceutical companies providing data have supplied sufficient information on data, studies and the statistical analyses behind;
2. The expert committees and secretariat will conduct a critical assessment of data validity;
3. The implications of in- and excluded unpublished data in health economic analysis will be covered and described in evaluation reports when relevant and possible;
4. At the Council's discretion, it will be decided to what degree unpublished data may influence the collective evaluation and recommendation of a medicinal product;
5. It will appear from evaluation reports and guidelines when unpublished data have been used; and
6. In cases where unpublished data cannot be published by the Council (i.e., because of confidentiality), the Council will seek to describe the implications of such data in evaluations and guidelines.

To ensure transparency, the Council will expect all data to be publishable within 12 months of the Council's evaluation or guidance. Therefore, the council will conduct an assessment one year following the issuing of evaluation or guidance in contemplation of publishing unpublished data. During such assessment, the Council states to consult the pharmaceutical company who submitted the data to make sure confidential information will continue to be treated as such (in accordance with the Council's policy on confidential information).

Accura comments

The original criteria paper on the use of unpublished data from February 2020 was warmly welcomed by the industry because it provided the Council with the opportunity to rely on the latest knowledge in the field.

The new and updated principles provide additional guidance and clarifications for pharmaceutical companies and other industry stakeholders on the Council's assessment of different types of data. Further, the principles make the important and much needed clarification that confidential data are submittable, and that confidentiality will be adhered to, to the extent possible – also subsequent to one year from the issued evaluation or guideline.

Amendments to the Danish Copyright Act on the way:

Enhanced liability for tech companies

The European Directive (20199/790) on Copyright in the Digital Single Market (the DSM Directive) entails rules on enhanced liability for tech companies that must be implemented in national law no later than 7 June 2021. In Denmark, the Danish Ministry of Culture recently announced that a legislative proposal amending the Danish Copyright Act by implementing the two provisions of the DSM Directive is proceeding with expected passing in June 2021.

Implementation of the two provisions in question (Articles 15 and 17) will entail a more rigorous responsibility regime for tech companies behind online con-tent sharing platforms (such as YouTube, Facebook, Instagram etc.) that store and provide access to copyrighted material uploaded by various users.

The DSM Directive is intended to be a game-changer from what applies to the tech companies today in terms of their responsibility for copyright infringements on their platforms. Currently, platforms have been exempted from liability for users' infringing uploaded material by virtue of Article 14 of the Electronic Commerce Directive when the providers of the platforms have been unaware of the infringement and have reacted immediately after receiving notification of illegal content from the rights holders.

With the proposed amendments of the Copyright Act, this may change. Article 17 of the DSM Directive stipulates that a provider of an online content sharing platform performs an act pro-tected by copyright when the platform provides public access to the copyrighted material uploaded by users. I.e., when the provider of an online content sharing platform allows users to upload copyright protected material (e.g., parts of a movie or a song) without prior consent from the rights holders, the platform can be held liable for allowing such material to be uploaded to the public without precautions.

Consent from rights holders

With the expected implementation of the DSM Directive, providers of online content platforms must have consent from the rights holder, if a rights holder's copyright protected material occurs on the platform. In other words, the platform must obtain a consent or license from the relevant rights holder that also extends to the users of the platform.

It is stated in the legislative proposal that consents can be obtained from the rights holders individually or through collective management organisations such as Koda and Copydan. Given the large amounts of copyrighted material, the platforms will presumably tend to enter into agreements with the collective management organisations.

If a platform has not entered into agreements with the rights holders, the platform may under certain circumstances still be exempted from liability provided the platform i) has done its best to ensure that protected material is not made available on the platform and ii) has immediately blocked or deleted the infringing content when notified thereof by the rights holder.

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Stricter requirements for tech companies

It is expected that the new DSM Directive will generally impose stricter requirements on the providers of online content sharing platforms with respect to their responsibilities for users' copyright infringements.

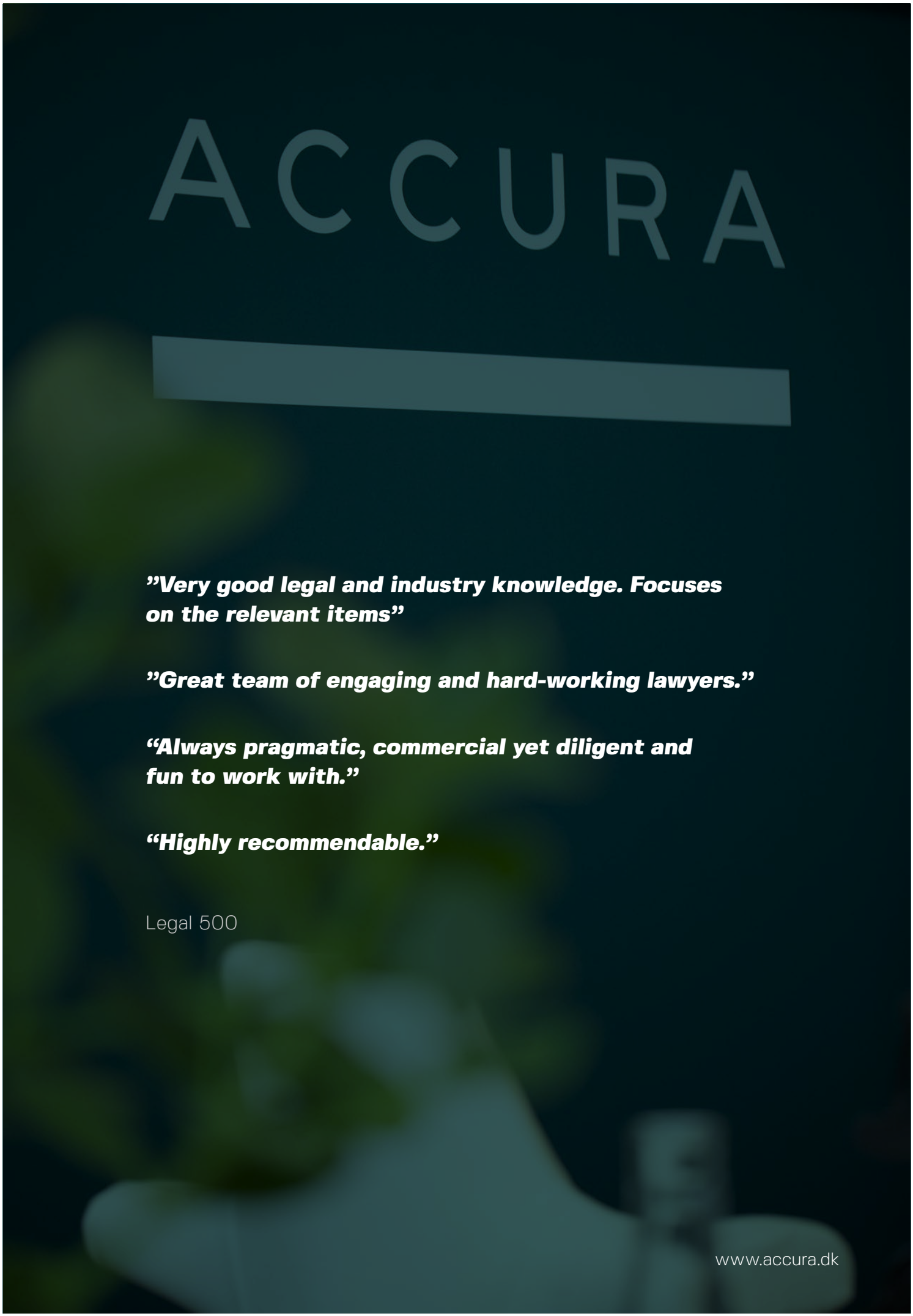
The detailed content of such requirements is to be determined in an on-going collaboration with the rights holders. As of now, the Danish Ministry of Culture has specifically pointed out in the legislative proposal that the platforms *"should initiate the necessary IT-developments"* to be able to comply with the stricter, new requirements. However, it is yet to be determined what the platforms are required to do more precisely, or how active they need to be in order to be exempted from liability.

In this regard, the European Commission is obliged to publish guidelines on the provisions after a dialogue with the online content sharing platforms, rights holders, user organisations and other relevant industry stakeholders, as stated in the DSM Directive article 17(10).

Our IP & Life Science team will keep a close eye on the developments of the implementation of the DSM Directive and the potential amendments to the Danish Copyright Act.

Key takeaways on how copyrighted material is further protected with the DSM Directive:

- The online content sharing platforms must obtain consent from all rights holders of copyright protected material, individually or via collective management organisations.
- Necessary technical measures must be implemented to comply with the DSM Directive's requirement to act and ensure that illegal material is not made available via the platform.
- A complaint system must be offered to the users, enabling the users to file complaints regarding the platform's potential blocking of copyright protected material if in fact the material was uploaded legally, e.g. by virtue of the exclusions in the Copyright Act, including the right to quote.



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