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IP & Life Science News

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New guidance for applications to the Danish Medicines Council based on alternative contract models

In collaboration with Amgros and Lif (the Danish Association of the Pharmaceutical Industry), the Danish Medicines Council has prepared and recently published a new guidance on the integration of alternative contract models in applications to the Council.

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.

Amgros

Amgros is the central entity purchasing medicinal products (and certain other goods) for the Danish hospital sector by organising and conducting tenders and procurement for the Danish Regions.

The new guidance is titled "Guidance for Application with Alternative Contract Models to the Medicines Council" (retrievable here (in Danish only)) and is supplementary to the Danish Medicines Council 's guidance for applications for the Council's assessment of new medicinal products with respect to whether such are recommendable as standard treatment at the Danish hospitals. The purpose of the new guidance is to simplify and standardize the application process for companies applying to the Danish Medicines Council for assessment of a new medicinal product (or an extension of indication), which are based on an alternative contract model.

Alternative contract models

Unlike standard contract models, which are typically characterized by a fixed price for a specific period, alternative contract models provide a dynamic approach by tying pricing to specific outcomes, thereby incentivizing providers to provide for high-quality and cost-efficient treatment.

These alternative contract models can be based upon an economic- or effect-based contract model or a combination. The effect-based model can be relevant if the clinical effect of the medicinal product is deemed to be less certain, making the pricing dependent on whether the patients receive the expected results from the treatment. The economic-based model can be relevant if there is uncertainty about the quantity of patients requiring a specific treatment, making the pricing dependent on the consumption (i.e. administration and use) of the medicinal products in question.

The guidance applies to the various alternative contract models described in Amgros' overview (overview and details of each alternative contract model can be retrieved here (only available in Danish)), including i.a. the Price-Volume model, the Budget-Ceiling model, the Subscription model, the Market Share model, the Added Value model, the Combination-Based Pricing model, the Indication-Based model, the Patient Initiation model, the Maintenance model, the Installment Pricing model and the Pricing Upon Effect model as well as the Conditional Recommendation model.

The new guidance and the process for assessment of an alternative contract model

The guidance defines the requirements for how to incorporate alternative contract models in the application for assessment as well as the prerequisites that must be met for the Danish Medicines Council to assess a medicinal product in light of an alternative contract model.

To go with the guidance, a special request form for alternative contract models has been prepared by the Council to be filled in by the applicant and submitted to the Council together with the standard application form for the assessment of a medicinal product. The new request form can be retrieved here (only available in Danish).

To prompt the assessment of an alternative contract model, applicants are to fill in the mentioned new request form together with the Council's standard application form and submit these to the Danish Medicines Council and Amgros. On this basis, the Council and Amgros assess whether the alternative contract model is suitable to address the most significant uncertainties connected to the Council's assessment of the medicinal product in question and, if so, both the standard (i.e. fixed price) contract model and the alternative contract model will form part of the Council's assessment of whether to recommend the medicinal product in question, and Amgros and the applicant will negotiate a price based on standard pricing as well as based on the alternative contract model. It is the Council's discretion whether a recommendation is ultimately based on a standard (i.e. fixed price) contract model or the alternative contract.

The new request form for alternative contract models

The request form as such consists of a fact sheet to be filled in with information about the applicant, the medicinal product in question and expected patient population in Denmark (with details of both incidence and prevalence) as well as the current and future predicted competition in the market for the following three years.

Additionally, the desired type of alternative contract model shall be specified together with a description of the purpose of going for the intended alternative contract model and how it may solve the given issue. Further, it is possible to suggest a combination of alternative contract models as well as making proposals for the duration of the contract and what is to happen upon contract expiration.

Specifically for the effect-based alternative contract models, it must be stated who will measure and assess the effect in clinical practice, who will analyse the data collection and who will collect and report the data to Amgros.

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With respect to preparation of the application as such, it is emphasized in the new guidance that applicants, as part of the application, are to describe the key aspects of the alternative contract model, including assumptions, results, sensitivity analyses and budget impact analyses. It is specifically highlighted that the chosen alternative contract model forming part of the application shall be included in a health economic model by similar means as the standard analysis, and, in case of deviations from the standard contract model's structure and assumptions, the applicant must therefore describe the differences and also provide a model diagram.

Applicants are further required to include the result of the alternative contract model in both the health economic model and in the application itself with highlighting of the differences in results.

For each suggested alternative contract model, the applicant is to conduct sensitivity analyses based on the given model's input parameters. Such analyses can be either deterministic or probabilistic and shall be completed for both the standard and alternative contract models.

The guidance also contains a specific section on reassessments (i.e. the Council's reassessment of a medicinal product previously having failed to obtain recommendation from the Council) relevant for situations where the applicant's original application did not contain an alternative contract model or where the applicant now wishes to change an existing alternative contract model. In both cases, the applicant is to complete and submit the referenced new request form to the Council and Amgros. If the Council and Amgros make the assessment that the alternative contract model is suitable, the applicant is to submit a revised application with the integration of the suitable alternative contract model to the Council.

As the Danish Medicines Council and Amgros can choose to exclude the alternative contract model and carry out the assessment based on the standard contract model, it is important that the application is thoroughly prepared and supplements the general application for assessment of the medicinal product in question.

Accura comments

The formal integration of alternative contract models in the process for the assessment of new medicinal products is a new development for both companies and the Danish Medicines Council and Amgros, and the new guidance provides a welcomed contribution to how to best incorporate suggested alternative contract models as part of applications to the Danish Medicines Council.

Please reach out to Accura's IP & Life Science team for more information about alternative contract models and the new guidance from the Council.

Eight influencers reported to the Danish Consumer Ombudsmand

Minister encourages influencers to "*familiarise themselves with the rules*".

The Danish consumer rights organisation TÆNK recently reported eight influencers to the Danish Consumer Ombudsman for alleged violations of the Danish Marketing Practices Act. The complaint has once again shed light on Danish influencer practices' compatibility (or lack of same) with the Danish Marketing Practices Act. The points of critique from TÆNK include covert advertisement, inappropriate content targeted towards children or adolescents and aggressive marketing tactics and have caused the Danish Minister for Industry, Business and Financial Affairs to publicly encourage influencers to "*familiarise themselves with the rules*". To assist with the familiarisation, we highlight some of the pitfalls which influencers and bureaus may experience and should be aware of.

Covert advertising and commercial intents

It is a fundamental principle in the Marketing Practices Act that the commercial intents with all "*trading practices*" (including advertisements) must be clearly stated. To put it in other words; covert advertising is not allowed. One of the fundamental principles underlying this rule is that consumers must be able to clearly recognise advertisements as such – a distinction that can sometimes be blurry on social media.

If a company has engaged an influencer to post content (e.g. an Instagram post or a YouTube video) containing a promo of a product, it must be clearly stated that there is a commercial intent behind the post. It is important to note that both verbal and tacit agreements may be sufficient to demonstrate a collaboration between the company and the influencer, even when the influencer is not paid in cash but instead via e.g. presents, discounts or other benefits from the company. When a company unilaterally sends a product to an influencer in the hope that the company or product will gain positive publicity in a later post, such post can subsequently be considered advertisement, thereby triggering the obligation to clearly specify this.

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There are no specific rules in the Marketing Practices Act as to what constitutes a clear specification of a commercial intent. However, guidance may be found with the Consumer Ombudsman according to which a post clearly marked with the word ”advertisement”, ”paid content” or similar is sufficient. The main goal should be to make the viewers and followers aware of the commercial intent behind the post. Conversely, words or phrasings such as ”ad”, ”spons”, ”in collaboration with” or merely tagging the company or product are *not* sufficient. ”Post” is to be understood in a broad sense, and also includes stories, reels, etc.

However, when an influencer unilaterally decides to post a photo of a certain company or product without the company being involved in the post, no commercial intent is behind the post and no mandatory information needs to accompany it.

We have previously covered covert advertising on social media. Click the link for an in-depth review of the rules.

Content directed at children or adolescents

The report to the Consumer Ombudsman further concerns the alleged violation of rules on trading practices directed at children and adolescents. When engaging in such practices, companies and influencers should be extra attentive as there are additional rules to be aware of when targeting young consumers.

Notably, it is important to be aware that trading practices on social media directed at children and adolescents under 18 may not be performed through social media profiles that belong to (or appear to belong to) children under 15 and may further not display children under 15 unless the appearance happens in a natural way or to illustrate a product. Lastly, such posts may not mention, refer to or display alcohol, drugs or other substances or products not suited for minors. The rules are based on the assertion that children and adolescents are more susceptible to and less critical of the messages found in marketing practices.

The question is, of course, when a post on social media can be said to be directed at young people. For influencers under the age of 18, there is a presumption that their content is generally targeted at other minors. For older influencers, the assessment depends on factors such as the appearance, content, displayed products and whether children or adolescents appear in the video. A good indicator is also the age of the influencer’s followers. Not surprisingly, when a significant part of the influencer’s followers are under 18, there is a general presumption that the posts are targeted at this (young) audience.

When posting to a younger audience, influencers should also be aware of not using aggressive tactics when posting. Directly encouraging children to either purchase or try to persuade their parents to purchase a product is per se seen as aggressive marketing, and therefore not allowed.

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What are the consequences?

Following the complaint, two obvious questions present themselves: Who is responsible, and what are the consequences?

As a starting point, it is the company's responsibility to ensure that the commercial intent of the commercial practice is clearly indicated by the influencer. If the company can demonstrate that it has made reasonable efforts to ensure compliance, the company will normally not be held liable. Further, the influencer contributing to the violation by posting the content may be liable and subject to a fine.

On 1 January 2022, a model for determining the fine for companies violating the above-mentioned prohibitions came into effect. The model operates with three penalty levels (low, normal and high) which are to be seen in combination with the company's annual turnover. For a company with an annual turnover between DKK 5 and 10 million, a violation categorised as ”normal” (i.e. where no mitigating nor aggravating circumstances are present) will result in a fine between DKK 40,000 and 99,000 depending on the specific circumstances. The described model is only applicable to legal entities and therefore not applicable to private influencers who do not operate through a legal entity.

Accura comments

Accura welcome the continued focus on social media posts' compliance with the Danish Marketing Practices Act, especially in posts directed at children and adolescents. It is always advisable for companies and influencers to clearly agree on the contents of the specific posts as well as the clear disclosure of the commercial intent to avoid any potential violations.

Tips to avoid covert advertising

Companies using influencers must ensure that the commercial intent of the influencer marketing is sufficiently clear, namely:

- Very specific instructions on how to properly mark all social media or blog posts containing any commercial content as advertising must be provided to any influencer receiving gifts, payment or other advantages from the company.
- The instructions can be provided to influencers in standardised social media guidelines, but it is pivotal that these instructions are clear and very specific and in compliance with the requirements under Danish law.
- The company must on a continuous basis review whether the influencer(s) associated with the company are in fact complying with the applicable rules, and if not, act on it.
- As long as the company is able to show that all that is possible has been done to ensure that its influencer marketing is properly marked as advertising/commercial content, the company will not be held liable for an influencer's breach of the rules.

Employees in marketing material: A legal risk

A company's marketing material can be a powerful branding tool, and who better to play the role of an employee than an actual employee of the company? Although casting employees may contribute to a more honest feeling, companies should consider the risk of employees withdrawing their consent, and instead opt-in for the use of paid actors.

It is a firm principle in copyright law that the creator of an original work is also the owner thereof. Besides protecting an original work from unauthorised use and exploitation by third parties, copyrights also provide the rights holder with the right to display the work to the public. As the copyright holder to specially developed marketing material, a company will therefore be able to use the marketing material as it sees fit and use it for branding purposes on websites, social media, etc.

However, when a company uses its own employees in the marketing material by way of obtaining consent hereto and assignment of rights to make use of their personal image rights, copyrights are no longer the only legal aspect to consider.

The reason being a decision rendered by the Danish Data Protection Agency (DPA) in 2020 referencing "the right to be forgotten" and the General Data Protection Regulation's (GDPR) article 17 (1) (b) implying that employees are always entitled to withdraw their consent to appear in marketing material.

As the case demonstrates, an employee withdrawing a consent to appear in marketing material over which a company holds copyright may hinder the company in using the sequences starring the employee.

The facts in short

An employee filed a complaint with the DPA in September 2019 following his resignation from his employer. During the employment, the employee had consented to – and participated in – a series of marketing videos for the company. The employee had signed a written declaration in 2018 which allowed the company to use the videos on the company's website, in brochures, newsletters and other externally targeted informative material for marketing purposes.

Following the employee's resignation in 2019, the employee requested that the company deleted the videos he appeared in. The company confirmed to do so without objection. In September 2019, the employee was informed by the company that he had been removed from all marketing material on the company's websites and other media. Despite this information, the employee continued to appear in the company's marketing material on YouTube as well as on the company's website as of 11 December 2019. As the company had not complied with the employee's request, the employee filed a complaint with the DPA.

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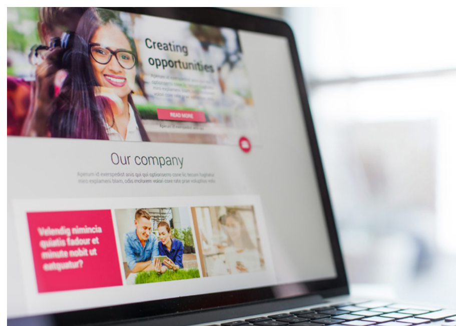
DPA's decision

Following the complaint, the DPA ruled that the company had violated the GDPR by failing to remove the employee from the marketing material and thereby erase his personal data without undue delay. The DPA further found that the company had failed to properly inform the employee about its data processing activities and its handling of collected personal data. In this respect, the DPA noted that the employee had withdrawn his consent to the processing of his data, which included his appearance in published marketing material. The DPA further concluded that the company did not have another legal basis for processing personal data belonging to the employee.

The DPA did not attach importance to the company's copyright to the marketing material which was specifically developed for and by the company. This is relevant because the decision hereby demonstrates that the copyright holder's right to use the parts of the marketing material showing the employee is overruled by the employee's right to withdraw consent and request the erasure of personal data.

Employees who appear in company marketing material may therefore always withdraw their consent to the participation and further request that marketing material in which the employee appears is deleted regardless of the company having the copyright to the marketing material.



Accura's comment

Accura recommend that companies consider the risk of employees withdrawing their consent when using employees in marketing material. This risk is not trivial as the development of marketing material can be a time-consuming and resource-intensive process. Furthermore, companies may incur fines from the DPA if the employees' rights under the GDPR are infringed.

One way for companies to eliminate the risk of having to subsequently edit or delete their marketing material is to utilise paid actors instead of employees. Hiring actors on a contractual basis ensures that the company has an additional basis for utilising the marketing material. As a result, the company retains the ongoing right to utilise the marketing material featuring the actor, even if the actor's consent has been withdrawn.

As the case from the DPA illustrates, the same does not apply with respect to written and signed declarations from employees, as such declarations solely rely on the employee's consent. While utilising actors on a contractual basis may be the most appropriate solution in an ideal scenario, e.g., to minimise the risk of marketing materials becoming unusable due to employee consent withdrawal, this solution is certainly also more costly and may be a less personal reflection of the brand.

In this case, Accura recommend that companies design and develop their marketing material in a way which allows for the removal of an employee's presence without rendering the rest of the material unusable in the event of a consent withdrawal.

Contact Accura's IP & Life Science team if you have questions about your company's strategy for using employees or actors in marketing material.

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Flash news from the IP Prosecution team

EU design reform in progress

The EU Council and European Parliament have recently reached a provisional agreement on the legal protection system of designs within the EU. This is a first step for updates to the directive and the regulation.

The changes inter alia include the renaming of RCD to EUCD, changes to the definition of a design, changes to the fees and the introduction of a registered design symbol. The revised directive will also include a new repair clause. The repair clause excludes replacement parts for a complex product from design protection if they are used to restore its original appearance. It only applies for repair purposes and if the replacement part looks exactly like the original piece. The aim is to liberalise the spare parts market and ensure that more accessible spare parts for repairs are available to consumers. The transition period will be eight years.

The agreement will now have to be endorsed and formally adopted by the Council and Parliament and at Accura we welcome the proposal for changes to the design system.

Apostille Convention officially takes effect in China

As of 7 November 2023, China has officially joined the Hague Convention, and therefore also the Apostille Convention.

The Apostille Convention removes the requirement of legalization for foreign public documents. With the accession to The Hague Convention, document legalization procedures between China and approximately 125 contracting states will be significantly simplified, as foreign public documents for use in China will no longer have to be validated by different authorities. It should be noted, however that only public documents issued by an authority or official associated with the contracting states are covered by the Apostille Convention.

”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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