Pharma Report

Retrospective view of legal developments in Norway

Winter 2025

Introduction

Dear reader

As legal advisors with a passion for the pharmaceutical sector, Haavind has for several years published Pharma Report, providing an overview of some of the legal developments in the pharmaceutical sector in Norway. In this report, we are happy to present a summary of some of the most significant cases occurring in 2024.

In this edition, you can read about whether parody concerning medicinal products is considered as advertisement, as well as the outcome on the complaint of a large violation fine for breaches of the rules of pharmaceutical advertising. You can also read about the Norwegian appeal in the apixaban case, which concerns plausibility.

As a leading law firm on healthcare and life science in Norway, our team continuously and closely monitors legal developments relevant to the pharmaceutical sector. If you wish to discuss how your business can meet the legal challenges of this innovative and highly regulated sector, you are always welcome to contact us.

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A tale of two influencers and advertising.

Two recent decisions on mentioning medicinal products in social media accounts highlight the problematic aspects of an infamous CJEU decision from the past.

The first decision

On 24 September 2024, the Norwegian Medical Product Agency (NOMA) rendered a decision against the company of one of the most famous Norwegian influencers based on statements made in a video published on her Snapchat account concerning the product Lonolox (minoxidil). Lonolox contains the active ingredient minoxidil, which in addition to stimulating hair growth is a potent vasodilator with a pronounced antihypertensive effect. In Norway, minoxidil is only available as a liniment for application to the scalp to prevent hair loss and stimulate hair growth in people with alopecia andregentica (hereditary hair loss). Lonolox does not have a valid marketing authorization in Norway and must therefore be prescribed by the so-called "approved exemption procedure".

The observations made by NOMA referred to in the decisions are:

- *"Medicine for hair loss - update"*
- *But here it is - it's called Lonolox! (The doctor who is an expert on hair loss in Norway is called [...] and works at [...])"*
- *"And yes, the hair starts to grow on the WHOLE body. I don't think any medicine can make you ONLY get better hair on your head, and not otherwise"*
- *"So here it is! I've been using it since the end of April and beginning of May, and I'm now noticing a real difference. Remember to take a screenshot, because the questions come daily"*

NOMA considered that these statements were in violation of the rules for pharmaceutical advertising. It was clear that the statements made on Snapchat constituted an activity that would technically be considered as advertising. However, in order for there to be an advertisement, this is not sufficient. It is also required that the activity must have an intent to promote prescribing, dispensing, sale or use of the medicinal product.

If the statements came from someone with a financial interest related to the sale or use of the medicinal product, this requirement would naturally be fulfilled. However, in this case, the influencer in question had no such connection to either the manufacturer or other parties related to this medicine.

However, that was not sufficient for NOMA. With reference to the CJEU ruling C-421/07 *Frede Damgaard*, NOMA pointed out that if a third party provides information about the curative or preventive properties of a medicinal product, it may be regarded as advertising, even if this is completely independent of the manufacturer or seller of the medicinal product.

NOMA was of the opinion that the video appears to be clearly promotional through the use of claims of medical effect. The video was also proactively distributed to followers who had not requested information about which medicine the influencer had been treated with for her hair loss.

On the latter point, NOMA referred to further practice from the CJEU, namely C-316/09 *MSD*. Citing parts of para 47, NOMA highlighted the following from the decision:

> *"That means of communicating information with the assistance of a passive presentation platform is not, in principle, intrusive and does not impose itself unexpectedly on the general public, such a situation thus distinguishing itself from that of 'push' services, in which an internet user is confronted, without searching for it, with that kind of content by means of intrusive windows called 'pop-ups,' which appear spontaneously on the screen, from which situation a strong presumption of advertising must, by contrast, be inferred."*

NOMA also pointed out that the fact that the videos distributed via Snapchat were unavailable for the recipient shortly after being opened, was of no consequence in this regard.

One interesting aspect was that the influencer had alleged that the information provided was not promotional but came as a result of a question concerning which medicinal product the influencer had used, in a personal note which also included negative aspects, and that the video came as a result of an exchange of arguments with the followers. NOMA in this regard stated that the situation prior to the distribution could be of importance on whether the information should be considered as advertisement. However, this requires that the question to be answered has not been constructed by providing information which is suitable to provoke questions on the medicinal product, and that the answer to a question shall only be directed to those who asked the question. In this regard, NOMA had requested further information from the influencer concerning these posts, but the influencer had stated that due to the nature of Snapchat's functionality, it was not possible to recreate earlier posts.

Consequently, NOMA concluded that the posts on Snapchat were unlawful advertising of a medicinal product.

The second decision

The second decision was rendered on 20 September 2024 and directed towards an influencer who from the media is also a well-known comedian. The medicinal product in question was one of Norway's most famous brands for the analgesic agent paracetamol ("Paracet").

The violation in question occurred by a video posted on the personal TikTok account of the comedian in August, and the decision is also directed towards her personally.

The video, titled "When the influencer forces her boyfriend into an advertising partnership", contained the following statements:

- *"...I've been struggling with a really bad headache for a very, very long time. It's just a throbbing, throbbing sensation all the time...", and*
- *"...I get so tired".*
- *"That's why, in collaboration with Paracet, I'm going to show you how to get rid of that headache!",*

followed by a demonstration of how to take 2 tablets of Paracet 500 mg. The video ended with

- *"...and then you're ready to have a nice day without having a headache because your girlfriend is nagging you so much".*

Similarly to the first decision, the crucial question was whether the criteria of intent to prescribing, dispensing, sale or use of the medicinal product was fulfilled. It was clear that the comedian and influencer had no ties or other relationship with the manufacturer

of the medicinal product or other parties related to the medicinal product.

Again, NOMA referred to the Frede Damgaard decision with regard to the issue of third-party dissemination of information and advertising. Referring to the individual claims, NOMA stated that the properties of the medicines are not presented objectively, as the results of the effect are guaranteed. Furthermore, NOMA also stated that the post lacked any of the mandatory information required by advertisements, including information for necessary use and important precautions etc. An item of concern was also that the post disclosed use of a dosage of 1000 mg (two tablets), whereas the summary of product characteristics recommends using the lowest effective dose necessary to achieve efficacy.

On the crucial points highlighted by the influencer, namely that this was a sketch and that the comedian had not been paid by the manufacturer of the medicinal product, NOMA took note that there was indeed no collaboration between the comedian and the manufacturer (despite the statement of sponsorship). However, NOMA then stated:

> *"NOMA cannot emphasize that the video contains incorrect information or that it was actually intended as a funny sketch but must assess the video as it appears. In NOMA's opinion the video is, on the basis of the factors described above, likely to promote prescribing, dispensing, sale or use of Paracet. The fact that [name of comedian] is a comedian by profession does not change this assessment."*

Consequently, NOMA concluded that the posts on TikTok constituted unlawful advertising of medicinal products.

Comments

In the latter years, there have been many examples of advertising on social media accounts involving medicinal products, which is a sign of the times we are living in. However, decisions where the parties do not have a financial interest in promoting the medicinal product are rarer, and these two decisions are therefore interesting examples on how NOMA evaluates the rules on advertising in such scenarios.

For anyone working with pharmaceutical advertising, the Frede Damgaard case from CJEU is well known. The principle outlined by the CJEU in that case has been used in several decisions by NOMA in the past. The decision is controversial, since it runs contrary to the freedom of speech. However, this was also addressed in the decision, where CJEU in para 26 stated the following:

> *"Whilst the principle of freedom of expression is expressly recognised by Article 10 of the European Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950, and constitutes one of the fundamental pillars of a democratic society, it nevertheless follows from the wording of Article 10(2) that freedom of expression is also subject to certain limitations justified by objectives in the public interest, in so far as those derogations are in accordance with the law, motivated by one or more of the legitimate aims under that provision and necessary in a democratic society, that is to say justified by a pressing social need and, in particular, proportionate to the legitimate aim pursued (...)"*

The legitimate concern in this scenario is the fact that wrongful advertisements of medicinal products can be a harm to the public health. However, it also follows from the Damgaard case that it is necessary to strike a balance between freedom of expression and

this objective, and that the justification on the freedom of expression depends on the nature of the activities in question. In other words, there is a requirement both of reasonableness and proportionality in implementing such restrictions.

In this regard, NOMA's reaction in the first decision is understandable. The statements are clearly promotional when viewed with an objective point of view. The influencer in question is also known to be a sought-after influencer for companies wanting to promote various products, and her audience is well aware of this.

The second decision is more problematic. While some of the claims when viewed in isolation could be perceived as promotional, it should be clear for the viewers based both on the context and the communicator that the message is not promotional, but a comedic expression. It is highly problematic that NOMA in this decision simply applies the "Damgaard" principle without any further subsumptions of the facts. In particular, the statement from the decision that NOMA cannot emphasize that the intention of the video is to make a funny sketch and the fact that the communicator is a well-known comedian is highly problematic from a freedom of speech perspective. In the opinion of this author, it is also wrongful application of law. It is also unlikely that NOMA's decision in this case would pass the proportionality test with regard to balancing the need for freedom of expression with the need for protection of the public health.

Unfortunately, the decision was not appealed to the Ministry of Health and Care by the comedian, which could have provided much needed clarity on NOMA's practice. Irrespective of this, the two decisions demonstrate the clear pitfalls of mentioning medicinal products in social media, and once more demonstrates the controversial consequences in practice of CJEU's decision from nearly 15 years ago, at a time when social media accounts were much less common than today.

Plausibility round two – a summary of the Norwegian appeal on the apixaban-case.

In the patent landscape, the active substance apixaban has been synonymous with the rather elusive concept “plausibility”. What is the Norwegian take on this concept in light of Enlarged Board of Appeal’s decision G-2/21?

Introduction

The pharmaceutical company Bristol Myers-Squibb (BMS) is the holder of Norwegian Patent 328 558 (NO'558), which concerns the active ingredient apixaban. Apixaban is an anticoagulant drug primarily used to treat and prevent blood clots and to prevent stroke in people with nonvalvular atrial fibrillation through directly inhibiting factor Xa. BMS markets apixaban under the brand name Eliquis. In addition to NO'558, BMS also holds a supplementary protection certificate (SPC 2011021) for apixaban. BMS has also applied for a pediatric extension of this SPC.

In June 2022, the pharmaceutical company Teva initiated a legal action against BMS at Oslo District Court, claiming that NO'558 and the SPC were invalid. In addition, Teva requested that the court issued a declaratory judgement that Teva's generic medicinal product containing apixaban did not infringe the patent and the SPC, with reference to the invalidity of the patent and the SPC.

In May 2023, Oslo District Court ruled in favor of BMS, which were acquitted. A summary of that ruling can be found in our previous edition of Pharma Report. Teva appealed the case to Borgarting Court of Appeal.

A key aspect of the case was going to be the interpretation of the Enlarged Board of Appeal's decision G-2/21, which was rendered in March 2023. This decision was published after the oral hearing in the District Court case, but the District Court allowed for supplementary pleadings prior to reaching its decision.

The parties' arguments

Teva's arguments before the Court of Appeal was slightly less extensive than those before the District Court, focusing solely on the inventive step argument, more specifically whether the technical effect of apixaban was plausibly substantiated in the patent application. With reference to earlier decisions from the Technical Board of Appeal prior to G2 /21, Teva argued that with regard to new chemical compounds, the selection must be «justified by at hitherto unknown technical effect which is caused by those structural features which distinguish the claim compounds from the numerous other compounds», and that from the patent application it had to be «at least plausible that a solution was found to the problem which was purportedly solved»

With regard to G-2/21, Teva argued that this decision did not result in any changes in practice. The standard to be relied on was summarized in the decision to be that "«a patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would consider said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention». Teva also argued that the decision from EPO post G-2/21 and that a requirement of plausible substantiation of technical effect in the application still applied in relation to the assessment of inventive step.

Teva argued that the skilled person would not be able to deduce from the patent application that the large number of active compounds in the application, including apixaban, would be an effective and selective Xa-inhibitor which would be therapeutically useful. The application did not contain any technical teaching, just an allegation related to all the compounds described. There was no data

which highlighted apixaban over any other compounds, and no data which highlighted apixaban over others with regard to potency. The skilled person would not be able to deduce that apixaban was a selective inhibitor of factor Xa, as the application stated that some compounds were inhibitors of another enzyme, thrombin. Furthermore, there was no data concerning oral bioavailability. In summary, Teva argued that there was nothing in the application that made the skilled person able to deduce that apixaban was an effective, selective and therapeutically useful factor Xa-inhibitor.

BMS argued that the technical problem solved by the invention was to produce an effective factor Xa-inhibitor for the treatment of thromboembolic diseases, with improved properties, which was described in the application, and also documented by subsequent comparative data, where apixaban was compared to the structurally most similar compounds in the patent application which was considered as the closest prior art.

BMS alleged that the requirement for documenting technical effect is rather low, and that it is not necessary for the application to contain experimental data, unless there is doubt about the technical affect that can be achieved by the invention. BMS argued that both prior to and after G-2/21, the assessment of technical effect was subject to a specific assessment of the evidence, and that it was incorrect not to include evidence of technical effect just because these were not publicly available at the time the patent application was submitted. What was relevant was what the skilled person could deduce from the patent application at the time of the submission, based on the prior art.

BMS argued that the skilled person would consider the technical effect of apixaban «as being encompassed by the technical teaching» and «embodied by the same originally disclosed invention», which G-2/21 requires. The technical effect was described expressly in the

application, and the skilled person would have no reason to doubt this. Apixaban was identified as a preferred embodiment in a patent claim, and the synthesis of apixaban was described in an example. The skilled person would also understand that apixaban has several structural similarities with factor Xa-inhibitors which were included in the prior art. BMS also argued that apixaban had been produced in a larger amount than any of the other exemplified compounds. Based on this, the skilled person would deduce that apixaban had provided promising results in initial tests as an effective Xa-inhibitor and chosen for further studies as the most promising compound.

Apixaban was also a technical contribution over the closest prior art, and thus a valid selection invention.

The Court of Appeal's reasoning

The Court began with a rather lengthy description on the requirement of inventive step, citing relevant legal sources. This was also reiterated with the part concerning the requirement of technical effect, citing inter alia the preparatory works of the Norwegian Patent Act, as well as legal theory and relevant case law from the EPO. On EPO, the court stated that EPO in practice seems to make a specific assessment on whether the technical effect claimed is sufficiently substantiated in the application, and that EPO had not stated a general requirement on experimental data or test data to be included in the application. Only when there is doubt that the invention has the technical effect claimed is it necessary with such evidence. Furthermore, such evidence for technical effect can, under the circumstances, be considered even if they are supplied after the time of application. However, the condition for doing so seemed to be that the claimed technical effect in a sufficient manner was «plausible... at the effective date of the patent in suit».

The court disagreed with BMS that the requirement of plausibility was lowered by G-2/21. The court referred to the decision, stating that plausibility is not a requirement for patentability but rather a "generic catchword". The relevant criterion was «what the skilled person, with the common general knowledge in mind, would understand at the filing date from the application as originally filed as the technical teaching of the claimed invention» and «the technical effect relied upon, even at a later stage, needs to be encompassed by that technical teaching and to embody the same invention, because such an effect does not change the nature of the claimed invention». The court further referred to the decision stating that "a patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would consider said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention."

The court thus found that the decisive factor for whether a technical effect in relation to inventive step can be substantiated, is whether it at the time of the application, in light of common general knowledge, was plausible for the skilled person (in this case a professional team) that this effect could be achieved.

The court then moved on to what could be derived from the patent application. The parties differed on whether the skilled person would have more information than what followed from the description in the patent application. The court found that this was the case, stating that the team in this case would have information concerning publications on factor Xa-inhibitors beyond what was described in the description.

The court also found that the skilled person would find it plausible that apixaban had the technical effect claimed. The skilled person would note that the patent application concerned factor Xa-inhibitors, and that the goal was to identify such inhibitors which were both potent and specific. The court pointed to this being described several times in the description.

Concerning potency, the court referred to statements in the intro ductory part of the descriptions which concerned all compounds covered by the Markush-formula described. The court found that the totality of information, which included the description of synthesis of apixaban and apixaban being produced in a larger amount, indicated clearly for the skilled person that apixaban had been synthesized and tested for potency by the method described in the patent. Despite that the application did not explicitly state the potency of apixaban, the court found that the skilled person at the priority date based on the application and common general knowledge would find it plausible that apixaban was a highly potent factor Xa-inhibitor. The skilled team knew that several factor Xa-inhibitors had been developed and were potent. There was nothing concerning apixaban which would make the skilled team question the potency. The court summarized its review by stating that it would be plausible for the skilled person that apixaban was a potent and selective factor Xa-inhibitor, and that the application contained more than sufficient information to substantiate the technical effect concerning the assessment of inventive step.

Another aspect of the case was that a closest prior art, a former patent application, included a Markush-formula which included a large number of compounds described as useful factor Xa-inhibitors. Theoretically, apixaban was included by this formula, and the invention of apixaban was therefore a selection invention. In this regard, the court referred to relevant legal sources, including the guidelines of the EPO and the Norwegian Industrial Property Office. In order for a selection invention (in this case apixaban) to fulfil the requirement of inventive step, it is required that the compound demonstrates a "special technical effect", and that nothing in prior art leads the skilled person to specifically choose the compound having this effect. The court here referred to a letter provided by BMS during the prosecution of the parallel patent application

in the EPO, which in the view of the court demonstrated that apixaban showed such an unexpected and special technical effect. The court here referred to the expert witnesses who had described that to arrive at apixaban, a skilled person would have been faced with the task of selecting from an extensive list of options.

Consequently, the court found that the patent was valid in light of the requirement of inventive step, and that the subsequent supplementary protection certificate also was valid.

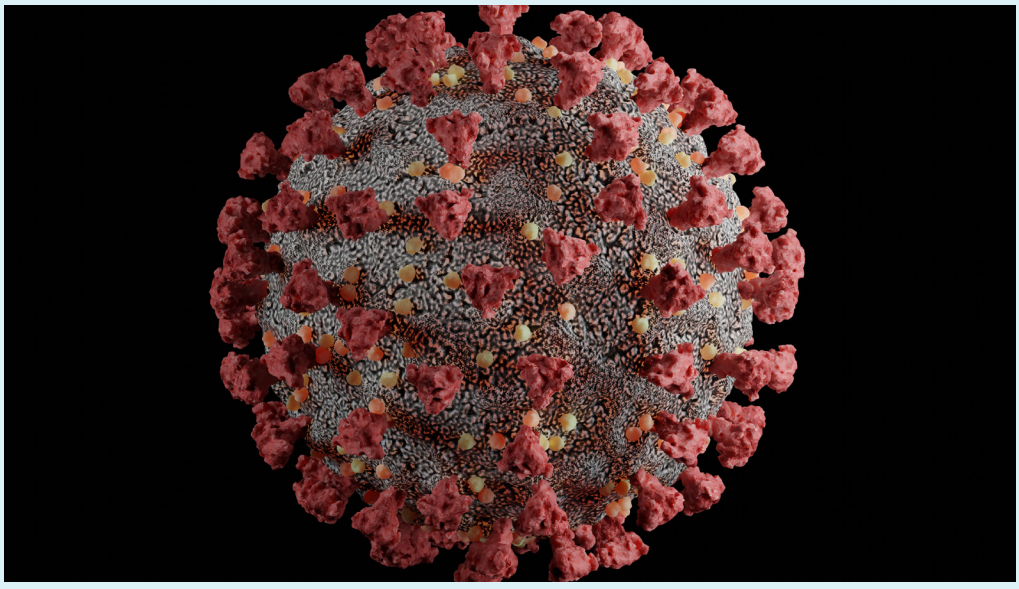
Comments

The decision from the Court of Appeal provides an interesting approach with regard to Norwegian courts' approach to the topic of plausibility. As in 2023, plausibility was a hot topic also in 2024, with several patent cases post G-2/21 in many European jurisdictions. From a Norwegian perspective, the Court of Appeal follows up on the position by the District Court with a rather patent holder friendly view. It is worth to note that the Court of Appeal disagreed on the position that G-2/21 lowered the threshold for plausibility and takes little regard to the subsequent Technical Board of Appeal decision T 116/18, which appears to provide such a lowering. On the other hand, the Court of Appeal also bases its view on Norwegian legal literature which describes that the threshold for plausibility is rather low, and in that regard the position is hardly surprising.

Teva did appeal the Court of Appeal's decision to the Supreme Court, but the Supreme Court refused to admit the case. Consequently, the Court of Appeal's decision is final, and will likely serve as a precedent in Norway for future cases regarding this topic.

Moderna fails to secure key trademark for covid-19 vaccine.

While covid-19 is still very much present in the world, the restrictions from the pandemic are for many a past memory. Unfortunately, the same cannot be said for the restrictive practice on registrations for trademarks in Norway, which Moderna last year became a victim of.



Background

During the pandemic, many were acquainted with names of the manufacturers of covid-19 vaccines, due to mass coverage. The vaccines were often identified with the manufacturer, such as the "Moderna-vaccine" or the "Pfizer-vaccine". However, the names of the actual products were less known.

In June 2023, the Norwegian Industrial Property Office (NIPO) refused Moderna's application for trademark registration of the word mark SPIKEVAX for the category vaccines (NICE Class 5). In the view of NIPO, the trademark was considered as descriptive and lacking the necessary distinctiveness. Moderna complained the refusal to The Norwegian Board of Appeal for Industrial Property Rights (KFIR). KFIR rendered its decision 11 January 2024.

KFIR's reasoning

KFIR pointed out that the question of whether a trademark is devoid of distinctive character or is descriptive must be assessed in relation to the goods or services for which registration is sought, and on the basis of the average consumer's perception of the mark, with reference to the CJEU's decision in case C-273/05 P Celltech. In this case, the average consumer would in particular be professionals in the healthcare sector, such as doctors, nurses, pharmacists or similar, but could also be private end users. With reference to CJEU's decision in case C-210/96 Gut Springenheide, the average consumer shall be deemed to be reasonably well informed, reasonably observant and circumspect. KFIR assumed that the average consumer in this case would have a higher level of attention than normal, because the products have an impact on the user's health.

Having cited relevant case law on the interpretation of distinctiveness, KFIR found that the average consumer will perceive the mark SPIKEVAX as a combination of "SPIKE" and "VAX". "VAX" would be perceived as short for "vaccine", and that the average Norwegian consumer would readily understand VAX as "vaccine". The word SPIKE could have several meanings according to KFIR, but when used in the specific word combination and for vaccines, it was likely that the mark would be perceived as "spike protein". KFIR referred to an article in an online encyclopedia, where it was stated that most vaccines against the coronavirus contain the virus' spike protein. From the same article it also followed that so-called mRNA vaccines, which most Norwegians received during the pandemic, work by stimulating immunity to the virus' spike protein. This would in any case be known to the professionals. KFIR could further not rule out that some private end-users had become aware of this as a result of the extensive media coverage on the corona vaccines during the pandemic. KFIR also referred to that when it comes to vaccines, particular attention was paid to the product's content and mode of action. Against this background, KFIR found that SPIKEVAX would be perceived as a "spike-protein vaccine".

Consequently, when SPIKEVAX is used for the goods in class 5, the average consumer will perceive the mark as information that the vaccines contain spike protein, or that the vaccines function by targeting the spike protein of the virus. The mark is thus descriptive of content and mode of action of the vaccines. The meaning was direct and immediate; the mark will be perceived as descriptive without the consumer having to go through a thought process. That the mark was a newly formed word was not decisive.

Consequently, due to its purely descriptive meaning, SPIKEVAX would not be suitable to distinguish Moderna's goods from those of others. According to KFIR, the average consumer will not be able to

deduce a specific commercial origin from the mark, and it does not fulfill the guarantee-function, which is the main purpose of trademarks.

As an argument for registration, Moderna had referred to a number of registrations in Norway and in the EU that contain the element VAX, such as PUREVAX, STIMUVAX, MABVAX and ZIKAVAX. However, this was not found to be decisive, as KFIR was of the opinion that the decision must be based on a specific assessment of how the word combination would be perceived today. KFIR also noted that for the past three years, the EUIPO has refused to register marks such as ALLERGYVAX, COVIVAXX and STABLEVAX. The fact that SPIKEVAX was registered in other countries was a relevant factor but was not given decisive weight. KFIR also pointed out that the discretionary assessment may be different in different countries, and it is not necessarily a goal to achieve the same results in individual cases, with reference to statements in the Supreme Court's decision HR-2001-1049 GOD MORGON and to the Court of Appeal's decision LB-2022- 64395 Trustshop.

On this basis, KFIR upheld the previous refusal of NIPO.

Comments

Anyone familiar with trademark prosecution in Norway is well aware of the rather strict practice on distinctiveness practiced by NIPO and KFIR on particularly word mark, which often comes as a surprise on applicants which do not face similar challenges when applying via the international system. The result is often that many trademarks that are registered in foreign jurisdictions fail to achieve a registration in Norway. This situation may seem odd for foreign practitioners and lead to the assumption that the requirements are stricter in Norway, which is not the case. However, the discretionary assessment in specific cases often leads to this result.

In this specific scenario, it also appears that the massive press attention concerning covid-19 vaccines and their mode of action has worked against Moderna with regard to use of SPIKEVAX. On one hand, that Moderna was one of the most known suppliers in Norway of covid-19 vaccines is undisputed. On the other hand, the name SPIKEVAX was not very well known. As a result, the product itself was very well known, but not the product name, and as such Moderna could not lean on acquired distinctiveness. On the other hand, the mode of action of covid-19 vaccines was so well described in press media that what would previously likely had been considered as a vague association with a key property of the vaccines resulted in it being, in the view of the NIPO and KIFR, "a direct and immediate" understanding for the average consumer. In that respect, the case is an interesting tale from a pharmaceutical trademark perspective.

All is not doom and gloom for Moderna, which were able to register a combined mark using both figurative elements and the word element "SPIKEVAX".

Pharmaceutical company strikes back against violation fines.

Last year, Novo Nordisk was faced with a violation fine of NOK 1.5 million for alleged breaches of the rules on pharmaceutical advertising. The Danish giant was, however, not going to accept that result without a fight.

Background

In our last edition of Pharma Report, we reported on Novo Nordisk being slapped with violation fines for allegedly misleading advertising of its products Saxenda, Ozempic and Wegovy.

The case began by a letter from the Norwegian Medicines Agency (now Norwegian Medical Product Agency – NOMA) on 15 May 2023, where NOMA issued a warning letter to Novo Nordisk Norwegian affiliate (Novo Nordisk Norway) concerning a breach of the rules of pharmaceutical advertising for various ads for the three products, forecasting both an order to stop the wrongful advertisements and issue corrections on the matters, daily fines of NOK 5,000 if the advertisements are not stopped, as well as a violation fine of NOK 1.5 million.

The alleged breaches were, in summary, that the advertisements either violated the requirements of the Norwegian Regulation on Medicinal Products section 13-3 third paragraph a and b (cf. Article 87(3) of Directive 2001/83/EC) that advertisements should encourage the rational use of the medicinal product by presenting it objectively and without exaggerating its property, and not be misleading. Some of the advertisements were also found to be in violation of the requirement stipulated in the Regulation section 13-8 (cf. Article 92(2) of Directive 2001/83/EC), which states that documentation relating to a medicinal product which is transmitted as part of the promotion has to be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned.

Novo Nordisk replied to the warning letter on 31 May 2023. With one exception, Novo Nordisk rejected the allegations of NOMA. As part of the argumentation, Novo Nordisk also rejected that there were grounds for a violation fine. On 11 October 2023, NOMA

issued its decision, issuing an order in line with the previous warning letter, ordering Novo Nordisk to stop the wrongful advertisements, issue corrections on the matters, imposing daily fines if the advertisements are not stopped within a given deadline, as well as a violation fine of NOK 1.5 million for the alleged breaches.

Novo Nordisk filed an administrative complaint against the decision.

Obtaining a statement from the Norwegian Association of General Practitioners

A rather peculiar aspect occurred after Novo Nordisk had submitted the complaint.

Two of the claims that NOMA had asserted in their decision was that it was not clear to physicians that ceasing to use the products will result in a reversal of the weight loss at the time of the advertising, and that the advertising of Ozempic by Novo Nordic has contributed to off-label prescription. In the complaint, Novo Nordisk had pointed out that NOMA had not presented any factual evidence for these claims.

Prior to sending the complaint to the Ministry of Health and Care Services (the Ministry) for review, NOMA had obtained a statement from the Norwegian Association of General Practitioners (Association). In the letter to the Ministry which forwarded the case documents, it was stated that the Association confirmed that the presentation of the advertisements was suited to promote off-label use of Ozempic, and that the Association confirmed that it generally was not known for physicians that the weight loss is reverted when ceasing to use the products.

Upon closer investigations, it became clear that NOMA had e-mailed the Association and asked whether they could refer to the Association. Noma had even presented a text proposal in the letter and stated that the purpose was to communicate to the Ministry that NOMA had been in contact with a neutral third party to confirm their view. One hour later, the contact at the Association had responded that this was completely fine and completely true.

In a supplementary letter to the Ministry, Novo Nordisk criticized NOMA for this, stating that the evidentiary value of this evidence was null since NOMA had dictated or at least led the Association in their statements. The Association had not been presented with an objective question, nor had it presented any reasoning or even been requested to provide such reasoning. Novo Nordisk also criticized that NOMA misrepresented the statements in the letter to the Ministry compared to the correspondence with the Association and requested that the statement was disregarded in the complaint proceedings.

The Ministry's reasoning

On 7 June 2024, the Ministry decided on the matter, and in a 30-page decision overturned the decision from NOMA.

The Ministry first addressed the situation with the statement from the Association, where it criticized NOMA for the way they had obtained the statement, and in essence dictated the wording from the Association. Furthermore, the Ministry pointed out that Novo Nordisk in any event should have been presented to Novo Nordisk prior to sending the case to the Ministry. In other words, NOMA had failed to ensure the rights of contradiction for Novo Nordisk. Furthermore, since these statements were obtained after NOMA had rendered its decision, it was unclear whether the case could be considered to be clarified as thoroughly as possible, which is a requirement under the Public Administration Act. The Ministry found that NOMA had obtained the "confirmation" from the Association to support the upholding of the original decision and concluded that it supported Novo Nordisk's allegations that this statement had to be disregarded.

The Ministry then turned its attention to the material aspects of the case.

The first reaction NOMA had was towards a poster for the product Saxenda. This poster contained the headline "Saxenda GLP-1 analog – for the treatment of overweight and obesity".

NOMA argued that the poster was suited to give the impression that Saxenda alone could be used for the treatment of overweight and obesity, which is not in line with the approved indications in the summary of products of characteristics for Saxenda. Saxenda is approved as an adjunct to a reduced calorie diet and increased physical activity for weight management in adult patients with either obesity (BMI ≥ 30) or overweight (BMI ≥ 27) in the presence of at least one weight-related comorbidity (e.g. diabetes type 2 or hypertension).

The Ministry agreed that if the advertisement only contained this text, it would be a violation of the rules. However, if the advertise-

ment contains other information in addition, the advertisement as a whole has to be evaluated. The Ministry further stated that in its view, an advertisement where the headline reproduces the use "relatively roughly and generally", and where the indication is otherwise clarified in the advertisement, can be considered to be compliant with the rules. This must be assessed on an assessment of whether the advertisement otherwise contains relevant information, which is complete and in harmony with the SmPC, and is sufficiently detailed so that the recipient is able to make his own opinion of the therapeutic value of the medicinal product. The Ministry concluded that this was the case in this scenario.

Similarly, the second circumstance NOMA had reacted to was the use of this statement in an advertisement in a professional journal. The statement used an emphasized font. NOMA had argued that this phrase was a clear main eyecatcher in the advertising, and that when using the statement in this way it is not sufficient that the clarifications could be found elsewhere in the journal with a lesser font. The Ministry disagreed, and reiterated the same view as above, and that the relevant supplemental information was present in the advertisement. Of particular note, the Ministry expressed that there is no explicit requirement in the Norwegian Medicinal Product Regulation that requires that all information must be given collectively in the same sentence. In the view of the Ministry, the advertisement presented the use of the medicinal product objectively without exaggerating its properties, and that the information complied with the SmPC, and was sufficiently available and adequately detailed for the recipient to form its own opinion of the therapeutic value.

The third circumstance NOMA had reacted towards was an advertisement for Wegovy in a professional journal. This advertisement emphasized the statement "Wegovy (semaglutide) – for weight control – news". The objections from NOMA were similar to the previous use of statements in ads– that when you emphasize "weight

control" in a heading, it needs to be equally clear what the primary treatment is (which is supplementary to a caloric restrictive diet). The Ministry reiterated its view that there is no explicit requirement in the Norwegian Medicinal Product Regulation that requires that all information must be given collectively in the same sentence. The Ministry also pointed out that it was clear from the ad that the indication is treatment of obesity and that the medicinal product is meant as supplementary treatment. The information was otherwise in line with the SmPC and was sufficient for the recipient to form its own opinion of the therapeutic value of the product.

The fourth reaction by NOMA had been concerning an ad for Saxenda, which informed that the product could be used for children above 12 years. The underlying study which concerns children showed that the weight loss in children is reversed when the drugs are separated from use, and this was an important clinical information which NOMA believed should be clearly communicated in the advertisement. Consequently, NOMA was of the opinion that the information was not sufficiently complete for the recipient to form its own opinion on the therapeutic value. The Ministry pointed out that the approved SmPC sets the boundaries for how a medicinal product can be presented. There was no information in the SmPC that the weight loss of children is reversed upon separation of the

product, and as a starting point, the lack of such information could not be considered to be a violation of the requirements for the advertisement. The Ministry then pointed out that it followed from case law that such information could be presented in certain cases (with reference to CJEU's decision C-249/09), stating there was no support that such information had to be provided. The Ministry also pointed out that it is a foreseeable effect of treatment with medicinal products that the effect disappears upon separation of the product. There were no special circumstances in this case that indicated that this was information that had to be provided in the advertisement, and in the event that this was necessary information, the authorities had to ensure that such information had to be provided for in the SmPC. As such, not mentioning the fact that the weight loss of children is reverted upon separating the product did not constitute a violation on the rules for advertising.

The fifth reaction concerned an advertisement for Ozempic, which showed the weight loss effect in a similar manner as the reduction in glucose and effect on cardiovascular events. NOMA pointed out that Ozempic is approved for supplemental treatment of diabetes type 2, and that weight loss is a side effect of the medicinal product and not a part of the indication. NOMA pointed out that at the time the ads were presented, it was generally not clear for neither patients nor practitioners that the weight would increase again after separation of the drug. In such a scenario, Novo Nordisk had a duty to inform that this was the case, especially when the studies they referred to in the ads demonstrated a rapid reversal of the weight loss upon separation.

The Ministry was of a different opinion, stating that Novo Nordisk did not have such a duty, as this was not information mentioned in the SmPC. Otherwise, the Ministry stated that the information in the SmPC about weight loss was not only related to being a side effect of the product, but also an effect. In the view of the Ministry, there was sufficient basis in the SmPC for Ozempic having demon-

demonstrated clinically relevant reduction of body weight for up to two years, and that it was maintained for two years. At the same time, it was clear from the advertisement that Ozempic is not indicated for weight loss. The Ministry pointed out that there are no explicit rules that approved indication and other effects of a medicinal product must be held separated in the advertisement. That weight loss is presented together with information on the reduction of HbA1C could in itself give the impression that weight reduction was part of the indication. However, at the same time it was stated that Ozempic was indicated for the treatment of diabetes type 2 when metformin was insufficient, and the effect was compared with other medicinal products used for the treatment of diabetes. It was also explicitly stated that Ozempic is not indicated for weight loss, and thus the Ministry found that there was no doubt for the recipient that this was a medicinal product indicated for the treatment of diabetes. The Ministry also pointed out that the advertisement was not directed towards the public, and that healthcare personnel are expected to form their own opinion on the therapeutic value. Consequently, there was no breach of the rules on pharmaceutical advertising.

Another argument used by NOMA was that the advertisements in total had made practitioners less able to get a correct understanding of the approved indication of Ozempic, and that the unbalanced advertisement was suited to promote wrongful off-label prescription of Ozempic. In the view of NOMA, it was highly likely that these ads had contributed to off-label prescription of Ozempic. In this regard, reference was made to the high numbers in prescriptions for Ozempic on approved requirements for reimbursement, and from reports by another government agency that off-label use had significantly increased the costs for reimbursed prescriptions. NOMA also referred to significant promotion in social media for Saxenda and Wegovy which provides a distorted view of the therapeutic significance, and that there are abnormally many patients who approach healthcare personnel to try these medicines. In the view of NOMA, this provided Novo Nordisk with a special responsibility to communicate objectively and with sufficient information towards practitioners, as objective and more conclusive presentation of the medicines is particularly important when there is significant unbalanced advertising on social media.

In this regard, the Ministry stated that NOMA had unduly emphasized the reports concerning off-label prescriptions by the other government agency. Furthermore, how the medicines are promoted in social media could not be emphasized in advertisements directed towards healthcare personnel. As stated above, the statements from the Association were also disregarded. In the view of the Ministry, NOMA had emphasized irrelevant considerations in its assessment of the rules and its subsumption.

Since the Ministry had concluded that there was violation of the rules, there was no basis for the violation fine issued by NOMA. Nevertheless, the Ministry took the opportunity to comment on the allegations by Novo Nordisk concerning this issue.

One of the factors in assessing whether a violation fine shall be issued is the severity of the breach. NOMA had highlighted that the advertisement was directed towards the treatment of children. However, this advertisement had not been in use after the rules of violation fines were introduced. Nevertheless, NOMA had argued that the advertisements directed towards treatment of children was still a relevant aspect because the indication for Saxenda was from 12 years. Novo Nordisk had pointed out that the fact that the indication included children from the age of 12 years could not automatically mean that the breach was severe when the advertisement itself was not directed towards the treatment of children. The Ministry agreed with Novo Nordisk that this was not a relevant argument when determining whether violation fines should be issued, and that the advertisement is directed towards healthcare personnel is expected to have a greater level of scientific knowledge compared with the general public (with reference to CJEU's decision C-249/09).

Another aspect in the assessment of whether violation fines should be issued is whether there have been repeated offences. However, according to the preparatory works, such repetition exists where a business previously has received penalties or administrative sanctions. It was clear that Novo Nordisk previously had received various orders from NOMA to correct advertisements, cessation of advertisements and prohibitions of advertisements, and NOMA believed that these could be considered to be repeat offences. The Ministry, however, referred to the fact that these orders where neither administrative sanctions nor penalties, and therefore not relevant concerning whether there were repeat offences. The Ministry highlighted that the assessment of NOMA on whether a stronger reaction should be used should be an assessment of whether other reactions are sufficient to obtain compliance.

In summary, the Ministry also found that the decision of NOMA was disconnected from the rules and based on considerations outside of the requirements prescribed by the Norwegian Medicinal Product Regulation. As such, it was also concluded that NOMA had committed procedural errors that made the decision invalid, as these had been determinative on the decision. Consequently, the Ministry reverted NOMA's decision.

Comments

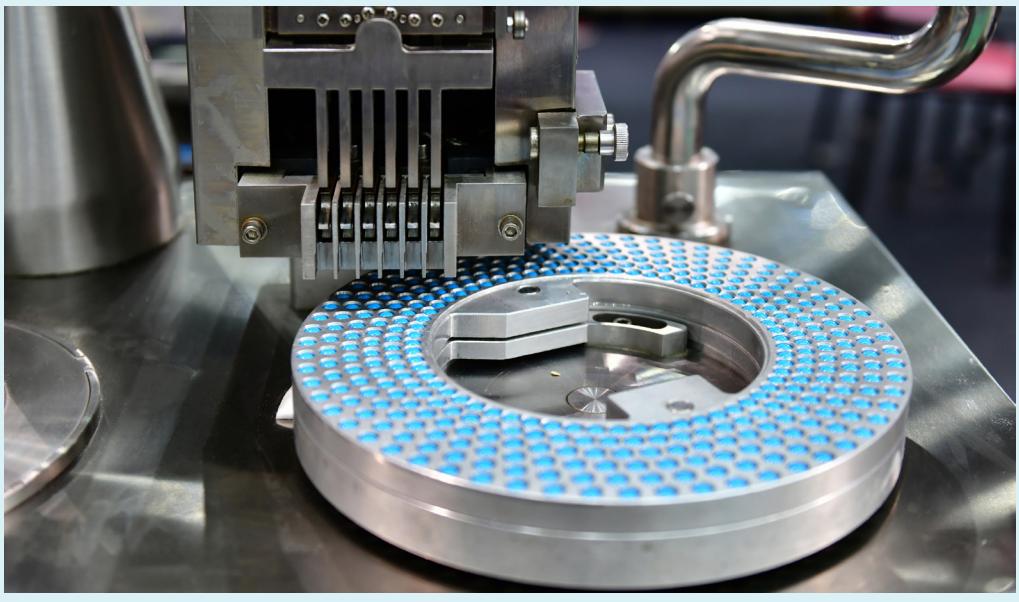
This case is a treasure trove for the understanding of the interpretation of the rules for pharmaceutical advertising in Norway. NOMA is known for a rather strict practice regarding the interpretation of the rules in the Norwegian Medicinal Product Regulation, but in the view of the Ministry went too far with their interpretation of rules that in all fairness are rather flexibly worded, and therefore difficult to manage. The message from the Ministry is also rather harsh – NOMA clearly did not do its job in this case, neither by application of law nor by its procedure.

Of particular concern is the fact that NOMA believed it was a good idea to contact an association of general practitioners to get a statement to verify its own determinative facts after the decision to issue a violation fine had been made. This is a clear (and luckily rare) error in procedure which hopefully is never repeated again. Even more incomprehensible is the fact that NOMA drafted a proposed wording that the association could confirm, and then present it as a statement from said association.

The reversal is a significant loss of prestige for NOMA. The decision was one of the first used to issue violation fines for alleged breaches of pharmaceutical advertising in Norway since the violation fine regime was introduced in 2022, and from a political view, this decision was likely to send a signal to the pharmaceutical industry that breaches of the advertisement rules are not something NOMA considers lightly. But when the case ends with such a spectacular failure both on the application of material and procedural law, the message for the industry is likely another than intended. This is especially true since according to media sources, NOMA had to pay the attorney's fees for assisting Novo Nordisk with the work on the administrative complaint, which amounts to approximately NOK 1 million, i.e. 2/3 of the imposed violation fine.

New rules on rationing and possibility to ban parallel export of medicinal products.

With effect from 1 July 2024, amendments in Norwegian legislation were made which open for rationing of medicinal products and a possible ban on parallel export of medicines from Norway.



The amendments are directed both towards wholesalers and pharmacies, and thus amendments were made both in the Pharmacy Act and in the Norwegian Medicinal Product Act. Furthermore, the amendments are two-folded – they aim to provide a legislative basis for rationing of medicinal products in case of shortages, but also open for a prohibition of parallel export of medicinal products. The amendments stem from a parliamentary bill presented in May 2024 by the Ministry of Health and Care Services (the Ministry), which in turn was based on an earlier consultative procedure.

Rationing of medicinal products

Prior to 1 July, the legislative basis for such rationing could be found in the Health Preparedness Act. However, use according to this act requires that there is an emergency situation. The provisions of the act were used for limited rationing during the Covid-19 pandemic. However, the desire of the government is to have legal basis for rationing in cases of shortages of medicinal products also outside of a crisis situation.

Consequently, an amendment in the Medicinal Product Act was implemented, which allows the Ministry to impose wholesalers and others performing wholesale activities (e.g. importers) with restrictions on sale and supply of medicinal products. The amendment is implemented as an "anchor provision", allowing the Ministry to elaborate further on the details in a regulation with basis in the rules.

The use of the provision is "in the case of risk for shortages for medicinal products in Norway". Whether there is a risk of a shortage is a discretionary assessment of the Ministry.

The need for rationing must be assessed specifically in each case and must be subject to a proportionality test. This means that measures such as rationing must be both necessary and appropriate.

Factors such as the availability of other strengths, generics, foreign packs, similar medicines and whether the patient group is large must be weighed up against the need for rationing. When proportionality is not met, the rationing must be removed.

Similarly, an implemented amendment in the Pharmacy Act allows the Ministry to impose a duty on pharmacies to restrict sale and dispensing of medicinal products in the event that there is a risk for shortages for medicinal products in Norway.

Ban on parallel export

The same provision in the Medicinal Product Act also includes a possibility to impose on wholesalers' restrictions on parallel exports of medicinal products. Due to low prices on several medicinal products, Norway has become an attractive market for parallel export during the recent years, and in accordance with EEA law, pharmaceutical wholesalers are entitled to parallel export pharmaceuticals to other EEA countries.

Naturally, any restrictions on parallel export raises potential issues concerning compliance with EEA law. This is addressed in the parliamentary bill. The Ministry assumes that a ban on parallel exports of certain pharmaceuticals will be covered by Article 12 of the EEA Agreement, which prohibits quantitative export restrictions or other measures having equivalent effect.

However, Article 13 of the EEA Agreement contains measures that are nevertheless lawful. The purpose of the authority to prohibit parallel exports of certain pharmaceuticals is to ensure access to pharmaceuticals in Norway so that the shortage situation has the least possible consequences for the patient. In the Ministry's opinion, a ban on parallel exports justified on the grounds of protecting human and animal life and health will be covered by the exemption in Article 13 of the EEA Agreement.

The application of the exception rule requires an assessment of whether there is proportionality between the restriction and the interest to be safeguarded. In order to derogate from the prohibition on export restrictions in Article 12 of the EEA Agreement, the measure must be proportionate. The European Court of Justice and the EFTA Court have emphasized that it is up to the states to determine the level of protection of public health and how this protection is to be achieved. According to the Ministry, this means that the countries have a certain margin of discretion, but that the margin of discretion must be safeguarded within the framework of the principle of proportionality. This means that the measure must be suitable for achieving the objective, and that the same objective cannot be achieved as effectively by measures that hinder trade in the EEA to a lesser extent. The proportionality test consists of two main elements: Suitability and necessity.

The Ministry is of the opinion that the measure is suitable for ensuring access to medicines in Norway so that the consequences for the population in a shortage situation are limited as far as possible.

The purpose of a legal basis for banning parallel exports of pharmaceuticals is to implement measures that can limit or avoid shortages. It is assumed that such a measure could have an effect on access to medicines in the event of a shortage. The Ministry is of the opinion that there is reason to believe that being able to impose a ban on parallel exports is suitable for achieving the objective. On this basis, the Ministry assumes that the measure meets the suitability requirement under Article 13 EEA.

The Ministry also highlights that Norway is a small market, and pharmaceutical shortages are a global problem. In a shortage situation, it is therefore conceivable that medicines in stock at Norwegian wholesalers intended for the Norwegian market will be exported to a market that is willing to pay a higher price for them. In order to safeguard the population's access to medicines, the Ministry is proposing to authorize the imposition of export restrictions if there is a risk that access cannot be safeguarded.

It may also be the case that shortages elsewhere in the world lead to a decrease in supply in the Norwegian market as a result of exports. In such cases, it is necessary that the authorities have done what they can to ensure that the number of products intended for the Norwegian market actually reaches the Norwegian market and remains there until a normal supply situation has been restored. The Ministry therefore believes that it is necessary to have a legal basis to be able to prohibit wholesalers from exporting certain medicines when there is a risk that access cannot be maintained.

Reporting requirements

A slightly more controversial amendment was the introduction of an obligation for pharmacies and wholesalers to provide electronic access to their current inventory, in order for the authorities to effectively monitor the situation in case of shortages. During the

pandemic, the Norwegian Medicines Agency (now Norwegian Medical Product Agency) gained access to the wholesalers' inventory via a temporary login function. This access saved both the wholesalers and the Norwegian Medicines Agency time and ensured that the assessments were based on the most accurate information possible. However, this was provided on a voluntarily basis.

According to the parliamentary bill, access to inventory is a prerequisite for being able to make a good assessment of shortage situations and implement appropriate measures. Without access to stock status, the authorities will not be able to assess whether measures are proportionate in a good way, which is a prerequisite for satisfactory use of the measures that can be implemented in the event of a shortage. The Ministry therefore proposed that a legal basis was provided for wholesalers and pharmacies to provide the Norwegian Directorate for Medical Products with electronic access to their inventory so that the authorities on their own initiative can obtain a snapshot of the stock status of medicines covered by a shortage situation, or medicines that are equivalent to or can replace the medicine in question. This will help to ensure a quick and appropriate handling of shortage situations. The use of the provision is intended to cover only situations where the authorities need to obtain information related to inventory in order to handle cases where there is a risk to the availability of medicines in Norway.

Sanctions in case of non-compliance

Violation of imposed rationing restrictions by pharmacies or wholesalers, or a violation of an imposed ban on parallel export, can be subject to violation fines. According to the Ministry, failure to comply with a rationing decision could lead to a worsening shortage situation, pose a risk to public health and may have major consequences for patients. This also applies to a ban on parallel exports. It is therefore important that the sanction system contributes to the parties seeing themselves as benefiting from complying with the regulations. In the Ministry's view, the authority to impose infringement fees would send a signal to the parties about the importance of complying with the regulations and could have a preventive effect.

Violation fines are however not possible in the event of breach of the reporting requirements. This was assessed by the Ministry, but it concluded that there is a difference between breaches of rationing decisions and bans on parallel exports compared with lack of electronic access to stock status. In the event of a breach of a decision on rationing and a ban on parallel exports, the breach has taken place and cannot be remedied. If there is no electronic access to stock status, it will still be possible to access stock status, but not in time. Such a breach can therefore be remedied by a coercive fine, e.g. in the form of a daily penalty until access is granted.

Comments

The new rules entered into force with effect from 1 July 2024 and was put to use immediately from that date by the Norwegian Medical Product Agency (to which the Ministry had delegated the task). Rationing for the diabetic drug Ozempic was introduced with effect from 1 July 2024, with the consequence that Ozempic could only be dispensed by pharmacies if the patient had a prescription for pre-approved reimbursement (so-called "blue prescription"). The cause for this could partially be attributed to the fact that many physicians likely had prescribed Ozempic for the treatment of obesity via non-reimbursable prescription ("white prescription").

The rules on rationing can be expected to be used frequently by the Norwegian Medical Product Agency in the future, as shortages have plagued and continue to plague the Norwegian medicinal market. Whether the Norwegian Medical Product Agency is equally eager to use the possibility for a ban on parallel export is more uncertain, given the potential implications with EEA law. A decision on such restrictions is also more likely to be challenged by a wholesaler in the courts, as it has a larger impact on the economy of the wholesalers.

Locked or unlocked? That is the question.

Supply of medicinal products in a mail-box can be a surprisingly complicated affair, as evidenced by a recent case before the Norwegian courts.

Overview of the case

In 2021, the Norwegian Medicines Agency (NOMA), which later changed to the Norwegian Medical Product Agency, issued a decision towards an online pharmacy due to finding that the pharmacy chain's practice on delivery of medicinal products to mailboxes violated the Norwegian regulation on prescription and dispensing of medicinal products (the Regulation).

The alleged violation was that the pharmacy chain had failed to document that the right recipient had received the medicinal products when sending their products as shipment to customers. This constituted a violation of a provision in the Regulation. This alleged violation was due to the fact that the pharmacy for OTC products allowed a delivery method directly to the mailbox of the customer, meaning that the customer could opt for delivery in their mailbox, so long as the mailbox was properly marked, and the customer was registered to be living at the address in question. This was insufficient according to NOMA, which required that the customer showed identification upon delivery.

Relevant for the case was the interpretation of two provisions in the Regulation. Paragraph 11-1 stated that *"Shipment of medicines must occur in such a way that it is ensured that they reach the right recipient, and that they are undamaged and without quality deterioration.", while paragraph 11-3 stated that "When dispensing medicines by shipment, documentation must be required to ensure that the right person receives the medicines."*

In January 2022, the pharmacy lodged a complaint against the decision towards the Pharmacy Complaint Committee (PCC), which is an independent board serving as an appeal instance for complaints concerning certain provisions in the Pharmacy Act and appurtenant regulations. At the same time, NOMA amended its decision,

insofar that NOMA no longer required identification upon delivery of all medicinal products, save for certain classes of medicinal products. A delivery to a locked mailbox which was labelled with the name of the recipient would be considered sufficient to ensure that the right recipient had received the medicines if the pharmacy used tracking of the delivery.

But the key aspect for NOMA was that the mailbox would have to be locked in order for there to be compliance with the rules - a position that was not acceptable to the pharmacy. After reviewing the position, the PCC concluded with a violation, and upheld the decision in February 2023.

As the pharmacy had not fulfilled the implementation of new routines, NOMA in 2023 issued a decision on day penalties to ensure compliance, which the pharmacy eventually paid. However, the battle was far from over, as the pharmacy decided to challenge NOMA's decision to the court.

Rather late in the case preparation, it was discovered that the PCC actually had no competence to rule on the decision, and that the complaint should have been processed by the Ministry of Health and Care, i.e. the supervisory authority to NOMA. This was solved somewhat pragmatically by the Ministry which decided to uphold NOMA's original decision in a subsequent decision in November 2023. However, this was problematized by the pharmacy for several reasons, including that the Ministry was in fact the defending party in the ongoing dispute, and that for these reasons, a temporarily vicarious ministry should have been established and managed the complaint. Even worse, according to the pharmacy, was that the case manager who rendered the decision for the Ministry had previously been involved in the preparations for the court on behalf of the Ministry. There were also several alleged infractions on the procedural rules of the complaints, and claims that the decision was

invalid due to these. The pharmacy also requested damages suffered as a consequence of NOMA's decision.

The court's reasoning

In February 2024, Hordaland District Court ruled in favor of the Ministry, i.e. that the decision by NOMA was indeed correct. The pharmacy decided to appeal the decision, but in October 2024, Gulating Court of Appeal came to the same result, although with a dissenting opinion.

The majority of the court found that the relevant provisions required a strict interpretation as it applies both for prescription medicines and OTC-medicines that the wording leaves little doubt, and that the patient safety consideration weighs significantly higher than the right of the pharmacy to perform business activities, particularly because other shipment methods than packages delivered in mailboxes may be used. The majority also focused on that one of the aims of the Pharmacy Act was to ensure proper use of medicinal products, and that it is only when a medicinal product is in the hand of the recipient that it is possible to hinder that other people can obtain access to it. The provision was thus an expression of this view.

The majority found support for this view when looking at other rules governing sales of OTC-medicines, finding that OTC-medicines cannot be considered to be any other goods that the pharmacy sells. The Pharmacy Regulation requires that when a pharmacy places OTC-medicines in the "pick-your-own" section of the pharmacy, the pharmacy must be able to keep supervision with the OTC-medicines that can be misused. Furthermore, when groceries etc. sell OTC-medicines under the LUA-arrangement, it is a requirement that the medicines are placed under supervision by the store (i.e. they are not allowed to be in the pick-your-own section).

The majority also found support for its view by referring to the preparatory works of the regulation, which described that a shipment to a customer was not considered to be properly handled if the mailbox was not locked or located outdoors. The majority also leaned on NOMA's own routines of September 2022, where this was stated.

The majority of the court thus found that the practice of the pharmacy was not in compliance with the provisions of the Regulation.

The minority, on the other hand, found that the fact that the provisions in the Regulation did not distinguish between prescription medicinal products and OTC-products, in itself could not justify a strict interpretation of the wording. On the contrary, a strict interpretation should be used cautiously as the decision should be considered a significant impediment on the core activities of the pharmacy. The minority also considered that there are different requirements of caution for various categories of medicinal products, and that it was relevant to look at the risk profiles of the various types of drugs. In this case, the medicines in question had a low risk profile.

The minority also pointed out that even if the medicines are delivered to a locked mailbox, it cannot be controlled when the recipient

picks up the medicines. Nor could it in a household with several members be controlled which person picks up the medicines. The minority thus found that an absolute requirement of a mailbox having to be locked would be contrary to one of the other goals of the Pharmacy Act, namely availability of medicinal product in the entire country. The minority also pointed out that previous routines by NOMA had not stated anything about locked mailboxes, and that the insertion from 2022 was prompted by this exact case. In routines from 2015, NOMA had stated that supply to customer's mailbox was "normally" to be considered as improper if the mailbox was unlocked and/or located outdoors, urging pharmacies to ensure proper dispensing upon shipments.

The use of "normally" was in the view of the minority a consideration that shipment to an unlocked mailbox could be accepted, if the shipment and the dispensing of the medicines were otherwise proper. In other words, an absolute requirement of a locked mailbox was not something that followed from the provision in the Regulation. When NOMA had considered that tracing was acceptable as documentation of the correct recipient, an additional requirement of locked mailbox based on the wording was unfounded. The minority thus found that interpretation by NOMA and the Ministry was wrongful, and thus that the decision was invalid.

The pharmacy had also argued that the decision had to be invalidated based on the errors done in the complaint procedure by NOMA and the Ministry. However, the court did not accept this, as the subject of the case was the interpretation of whether the application of the law had been proper, and if this was the case, there was no room for invalidation of a decision which the court could fully review. Consequently, in line with the majority's position that this was the case, this position was not accepted.

The Court of Appeal thus ruled in favor of NOMA and the Ministry and upheld the decision.

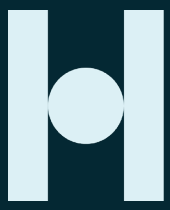
Comments

This decision is interesting, since it is one of the few examples of court cases in Norway concerning the Regulation governing requisitions and dispensing of medicinal products in Norway, a Regulation that is applied by thousands of pharmacies every single day. It should thus come as no surprise that the decision has received quite a lot of media attention in the pharmaceutical market in Norway.

When looking at the details of the assessments of the majority and the minority, both raise valid questions. The key decisive factor is whether you in the decision should open for a relativization of the medicines in question based on a risk assessment, or whether medicines should be treated as a single category and thus that a single set of rules should apply. If one accepts that the courts should adapt the former position, this could have wider ramifications on other provisions in the pharmaceutical legislation, as it can be argued that rules that by the wording govern all medicinal products must be subject to the same relativization based on a risk assessment. That opens up for quite an interesting position for future cases. On the other hand, it is hard not to see the slightly unreasonable result following the interpretation of the majority which in particular affects the supply situation for consumers in rural areas.

Irrespective of whether the interpretation of the provisions in the Regulation should be seen as restrictive or flexible, there is a question of whether they are fit for purpose. While the Regulation was significantly revised in 2022, these particular rules where not, and remain with the same wording as in 1998, in a time where shipments of medicinal products was highly regulated and certainly not common.

Finding solutions



Haavind