SØR-ROGALAND DISTRICT COURT

COURT ORDER

Rendered:	30 November 2022 by the Sør-Rogaland District Court,
Case No.:	22-150569TVI-TSRO/TSTA
Judge:	District Court Judge Richard Saue
Subject-matter of the case:	Petition for a preliminary injunction

---

MSD (Norge) AS	Attorney Beret Luise Sundet and co-counsel Attorney Anja Elverum
v.	
Helse Vest Rhf	Attorney Alf Amund Gulsvik and co-counsel Attorney Isabell Fjetland and Attorney Guro Bøhm
Helse Sør-Øst Rhf	Attorney Alf Amund Gulsvik and co-counsel Attorney Isabell Fjetland and Attorney Guro Bøhm
Helse Midt-Norge Rhf	Attorney Alf Amund Gulsvik and co-counsel Attorney Isabell Fjetland and Attorney Guro Bøhm
Helse Nord Rhf	Attorney Alf Amund Gulsvik and co-counsel Attorney Isabell Fjetland and Attorney Guro Bøhm
Sykehusinnkjøp Hf	Attorney Alf Amund Gulsvik and co-counsel Attorney Isabell Fjetland and Attorney Guro Bøhm

---

Disclosure to the general public is not subject to any restrictions

---

True translation certified.
5 December 2022

Knut Hogne Engedal
Government-authorised translator
English – Norwegian • Norwegian – English

STATSAUTORISERT TRANSLATØR · KNUT HOGNE ENGEDAL · OSLO · ENGELSK NORSK - NORSK ENGELSK

The case concerns the adjudication of a petition for a preliminary injunction filed in order to stop the signing of a contract for the public procurement of pharmaceuticals for the specialist health service.

MSD (Norge) AS is the Norwegian distributor of pharmaceuticals developed and marketed through companies in the international Merck Sharp & Dohme, Inc. group.

The company's Norwegian portfolio includes several pharmaceuticals, of which the present case is exclusively concerned with the pharmaceutical Keytruda. The key active substance of Keytruda is pembrolizumab, and this pharmaceutical is used in the treatment of various types of cancer.

Keytruda was some years ago approved by the Norwegian Medicines Agency for use in the Norwegian market, with a stipulated maximum sales price for the various package sizes [for sales] from pharmacies, which price is based on a basket of known prices in the European market. These prices are in the public domain.

The largest potential customer for Keytruda in the Norwegian market is nonetheless the public specialist health service, which has since 2004 been organised into four regional health authorities pursuant to the Health Authorities Act (Helse Vest RHF, Helse Sør-Øst RHF, Helse Midt-Norge RHF and Helse Nord RHF). The regional health authorities have been established, and are owned, by the Norwegian State only, and are under Section 2a responsible for the implementation of national health policy in the relevant region. It is under the Specialist Health Service Act the responsibility of the regional health authorities to ensure that the population is provided with specialist health services, including hospital services. Each regional health authority may, as part of this, establish separate health trusts, on its own or together with other regional health authorities. Both the regional health authorities and the underlying health trusts may be named as claimants or defendants in legal proceedings, while the owner(s) has/have unlimited liability for the authorities/trusts.

Section 2-1a, Sub-section 2, of the Specialist Health Service Act stipulates that the regional health authorities shall organise the services provided in accordance with the following priority criteria:

a. the patient treatment benefits of measures;
b. the resources required to implement measures; and
c. the severity of the conditions to be treated.

In order for a pharmaceutical which is approved by the Norwegian Medicines Agency to be entered into general use in the government-funded specialist health service, it needs to be considered sufficiently cost effective under the said priority criteria. This is organised through a structured approval arrangement, called New Methods, which is a joint arrangement for the regional health authorities and their underlying health trusts.

If a pharmaceuticals manufacturer would like a pharmaceutical to be entered into use in the public specialist health service for one or more treatment indications, such manufacturer will need to submit the product for assessment under New Methods. The process from there involves, briefly summarised, a technical assessment of the effect and overall benefit provided by the relevant pharmaceutical for the relevant treatment indication in respect of which approval is being sought, relative to the price at which the supplier is willing to sell it. This price will never be higher than the price approved by the Norwegian Medicines Agency, but may, depending on the circumstances, be lower. The final decision as to whether a pharmaceutical shall be entered into use in the public specialist health service for the relevant treatment indication is made by the Decision Forum for New Methods ("Beslutningsforum"), which is comprised of the CEOs of the four regional health authorities. The price at which the pharmaceutical is approved by Beslutningsforum is normally not made public.

The procurement of pharmaceuticals for use in the specialist health service is subject to the limitations laid down in the Act relating to Public Procurement and the associated Public Procurement Regulations.

Sykehusinnkjøp HF is a health trust established by the regional health authorities, for the purpose of, *inter alia*, conducting the procurement of equipment and pharmaceuticals for use in the health trusts that are subordinated to the regional health authorities.

For pharmaceuticals, Sykehusinnkjøp will on a regular basis conduct competitive tendering processes in which suppliers may tender pharmaceuticals to be supplied under a framework agreement within the categories for which these are approved under New Methods. A supplier that has submitted a pharmaceutical for assessment under New Methods may participate in competitive tendering with regard to the said pharmaceutical in the category for which such pharmaceutical is under assessment, subject to subsequent approval by Beslutningsforum. The pharmaceutical will in such case be assessed on the basis of the tendered price under New Methods.

If multiple pharmaceuticals are considered equivalent within a treatment category – termed a "reference group" for purposes of the procurement process – all tenderers will be offered a framework agreement, although physicians will normally be obligated to prescribe the first-ranked pharmaceutical to the patient, and the choice of a lower-ranked pharmaceutical in the same category must be based on treatment-related considerations. There is a more cumbersome procedure for prescribing to a patient a pharmaceutical that is not included in a framework agreement.

The ranking has under the existing agreement and in the new competitive tendering round for the pharmaceuticals with which the present case is concerned, exclusively been based on the treatment cost of the pharmaceutical to the specialist health service, based on the price tendered for the pharmaceutical itself, with the addition of administration costs according to a predefined calculation method. The price of the pharmaceutical under the framework agreement with the specialist health service is normally not made public. Where a pharmaceutical has approval under New Methods for multiple treatment indications, the competitive tendering terms will generally require the same price to be tendered for the said pharmaceutical in all categories for which such pharmaceutical is tendered.

Under existing framework agreements with the regional health authorities under procurement LIS 2131, concluded in the autumn of 2021, MSD has been included with Keytruda for the treatment of skin cancer, in reference group 2.4, leukaemia and lymphoma, in reference group 3.8, breast cancer, in reference groups 4.3 and 4.4, lung cancer, in reference groups 5.7 and 5.8, and urologic cancer, in reference groups 6.1 and 6.5.

The company's competing suppliers under the existing framework agreement are BMS and Roche, and Sanofi-Aventis has, in the new competitive tendering round with which the present case is concerned, joined as a new competitor in reference group 5.7, where MSD has thus far been the sole supplier. Sanofi has here tendered the pharmaceutical Libtayo, which at the time of the competitive tendering round has still not been approved under New Methods for this treatment indication. Sanofi has pursuant to the public procurement provisions participated in the competitive tendering round subject to subsequent approval under New Methods. It was stated during the oral hearing that Sanofi's pharmaceutical would be considered by Beslutningsforum for this indication on 21 November 2022. A subsequent check of the minutes of that meeting has confirmed to the Court that approval for use was granted in the said meeting. Besides, MSD and BMS have both submitted their pharmaceuticals for assessment under New Methods with a view to obtaining approval for treatment in what are in this competitive tendering round established as new reference groups 8.2 and 8.3. They have both participated in the competitive tendering for this category as well, subject to subsequent approval under New Methods. It was stated during the oral hearing that BMS' pharmaceutical would be considered by Beslutningsforum for this indication on 21 November 2022. A subsequent check of the minutes of that meeting has confirmed to the Court that approval for use was granted in the said meeting.

After the new competitive tendering round, MSD with Keytruda is ranked in the same way as under the existing agreement for reference groups 2.4, 3.8, 4.3, 4.4, 5.8 and 6.5. For reference group 5.7; first-line lung cancer, where the company had previously been alone, Sanofi with Libtayo is now ranked as the first choice, ahead of MSD with Keytruda. For reference group 6.1, a combination of two pharmaceuticals is used in the treatment. Keytruda has there been included under the existing agreement in a combination with Inlyta, with the current competitive tendering round including, in addition thereto, a combination of Keytruda and Kisplyx in two variants based on administration intervals. MSD's pharmaceuticals are in group 6.1, as before, ranked behind three combinations based on Opdivo from the supplier BMS. The difference from before is that the new variants with Keytruda and Kisplyx are ranked immediately ahead of the pharmaceuticals based on Keytruda that MSD had included in the framework agreement from before. These suppliers are included in categories 8.2 and 8.3 for the first time, in both cases subject to approval of the introduction of the new indications under New Methods. In category 8.2, the competitor BMS is ranked as the first choice, while MSD is ranked as the first choice in category 8.3.

MSD has in a timely manner filed [a petition for] a preliminary injunction against Sykehusinnkjøp HF pursuant to Section 9, cf. Section 8, of the Public Procurement Act in order to prevent the conclusion of contracts with the competing

tenderers in all reference groups in which Keytruda is included, until the validity of the contract award has been subjected to judicial review.

The principal basis for the petition from MSD is that the company's discounted unit prices for Keytruda under existing framework agreements have on two occasions been exposed to its competitors in such a way that it is argued that it would be contrary to the basic principles in Section 4 of the Public Procurement Act to complete a new competitive tendering round now, instead of extending the existing framework agreement by exercising the option on such an extension under the agreement. The arguments are based on the premise that the unit prices are a trade secret on the part of MSD, which the health authorities are also obligated to safeguard and keep confidential pursuant to Section 13, Sub-section 1, No. 2, of the Public Administration Act.

One of the incidents happened in October 2021, by way of the pharmacy wholesaler sharing unit prices with suppliers in a document pertaining to reversed clawback between the wholesaler and each supplier in respect of the sale of medicines under the framework agreement with the health authorities to other customers than the specialist health service. The incident and potential measures are described as follows in a letter of 16 November 2021 from Sykehusinnkjøp to affected suppliers:

> *«Sykehusinnkjøp HF was on 2 November made aware that Alliance Healthcare Norge AS (hereinafter referred to as «AHN») has in connection with the issuance of reversed clawback to suppliers shared information on prices across suppliers. Sykehusinnkjøp HF is taking this incident very seriously, and we will in the following explain what measures we have adopted. Before doing so, it is, however, necessary to provide a brief account of the structural relations between Sykehusinnkjøp HF, the regional health authorities, Sykehusapotekene and AHN.*
>
> *It is the regional health authorities that have concluded an agreement for the supply of pharmaceuticals, pharmacy products, as well as wholesaler and logistics services, to the to the customer services and production departments of the hospital pharmacies (the Wholesaler Agreement 2021). This agreement is managed by the Wholesaler Administration, which is a national service provider for the four pharmaceutical trusts, but which is organised under Sykehusapotekene HF.*
>
> *The following is agreed in the Wholesaler Agreement 2021:*
>
> > *«Information that comes to the knowledge of the Parties in connection with the Wholesaler Agreement and the implementation of the agreement shall be kept confidential, and such information shall not be made available to unauthorised persons without the consent of the Customers. A corresponding duty of confidentiality shall be imposed on the Parties' employees, subcontractors and third parties acting on behalf of the Parties in connection with the implementation of the agreement. The Parties may only transmit confidential information to such subcontractors and third parties to the extent necessary for the implementation of the agreement.»*
>
> *Tendered prices received by Division Pharmaceuticals in connection with tendering or negotiations, which become the subject of supply agreements for products that are to be distributed within the scope of the Wholesaler Agreement 2021, must necessarily be shared with AHN. It is the latter*

which places the orders under the regional health authorities' supply agreements after having received orders from Norway's hospital pharmacies (or upon the accumulation of emergency stockpiles), and which also pays the suppliers for the products ordered from them.

Sykehusinnkjøp HF has for quite some time been focusing on how unit prices of pharmaceuticals should be dealt with in view of the duty of confidentiality under Section 13, Sub-section 1, of the Public Administration Act. As one will be aware, the unit prices of pharmaceuticals are in all key respects considered confidential information, and the sharing of such price information is considered by Sykehusinnkjøp HF to be in breach of the Wholesaler Agreement 2021. We have for this reason notified the Wholesaler Administration and explained what consequences this incident may conceivably have for the competition situation between the pharmaceuticals suppliers in ongoing or future competitive tendering rounds. We are aware that the Wholesaler Administration has not finalised its follow-up of AHN in the wake of the incident, and we are ourselves considering, on an ongoing basis, what action points to pursue in relation to AHN. Finally, we have requested that the incident be included in the assessment as to whether the Wholesaler Agreement 2021 shall be extended after the expiry of the minimum term, which last until 31 January 2025.

Sykehusinnkjøp HF is now assessing whether this incident may have damaged the competition situation for the affected pharmaceuticals, as well as what damage-limitation measures, if any, may be implemented on our part.

In a letter of 7 December 2021 from MSD to Sykehusinnkjøp, the supplier emphasised how seriously it was taking the situation.

«At the outset, we would like to emphasize that MSD's data were shared by Alliance Healthcare without knowledge or permission from MSD.
MSD considers this a severe breach of confidentiality that could potentially lead to economic loss for MSD, not only in Norway, but also in other countries. As Sykehusinnkjøp is aware of, MSD operates globally and prices offered in one country may impact both list prices and negotiated prices in other counties.

It is correct that MSD did obtain price files from Alliance Healthcare. Alliance Healthcare sent these files on its own initiative without prior knowledge, consent, or request from MSD. We can confirm that all MSD recipients deleted the files in question promptly after realising the nature of the files and the files have not been distributed within MSD or to other MSD group companies or to any third parties. MSD alerted Alliance Healthcare to its error and confirmed deletion of the files, on the day following receipt."

A letter to affected suppliers of 27 December 2021 outlines, on the basis of an attached e-mail from the pharmacy wholesaler, the measures the wholesaler had adopted to avert similar incidents in future, as well as the additional measures one would be adopting in the time to come. It was also stated therein that the wholesaler had confirmed and documented to Sykehusapotekene HF (which

manages the wholesaler agreement) and to Sykehusinnkjøp that all suppliers that had received the e-mail which exposed the competitors' unit prices had deleted it.

The other incident giving rise to the claim for an injunction occurred in February 2022, when the Norwegian Pharmacy Association published a list of the ten most sold pharmaceuticals in Norway in 2021, with sales revenue figures, which list included sales revenue figures for Keytruda. This information was reported in industry media. This list does not in itself reveal the discounted unit price at which MSD sold Keytruda to the health authorities. It has been argued by MSD that combining the sales revenue figures with statistics, including public-domain statistics from the pharmacies on the number of package units of Keytruda sold in 2021, will reveal the discounted unit price, since Keytruda is sold in one single package size and is exclusively sold to the public specialist health service under a framework agreement.

MSD reacted shortly after the publication of the sales statistics, in relation to Sykehusinnkjøp and in relation to the Norwegian Pharmacy Association. A letter from MSD to the Norwegian Pharmacy Association of 14 February 2022 included, *inter alia*, the following statements:

> *«MSD has recently become aware that the Norwegian Pharmacy Association has published information on the top ten pharmaceuticals with the highest sales revenues in Norway in 2021 on the Norwegian Pharmacy Association's website, and that the published information is making the confidential unit price of Keytruda in Norway public.*
>
> *The seriousness of such publication cannot, of course, be overstated. The purpose of this letter is to request immediate action from the Norwegian Pharmacy Association in response to this information sharing.*
>
> *The sharing of price and sales information must be done in a manner that respects the trade secrets of suppliers, and we assume that the Norwegian Pharmacy Association agrees with this. MSD is sharing its unit prices with Sykehusinnkjøp HF in competitive tendering processes under a strict statutory confidentiality obligation, cf. Section 13, No. 2, of the Public Administration Act. The issue of unit price confidentiality was thoroughly examined by Sykehusinnkjøp HF some years ago, and the conclusion was that the trade secret status of unit prices has been established in consistent and long-standing public administrative practice.[1] There cannot, in the opinion of MSD, be any doubt that the unit price of Keytruda is a trade secret on the part of MSD, cf. Section 2 of the Trade Secrets Act, and that the said unit price was shared with Sykehusinnkjøp HF under a confidentiality obligation.*
>
> *MSD is of the understanding that the Norwegian Pharmacy Association has received the relevant information from Sykehusinnkjøp HF. MSD is aware that Sykehusinnkjøp HF is sharing unit prices with the pharmacies, and that the pharmacies need this information to execute sales, but the said information cannot be made public. MSD is therefore deeply*

disappointed that the Norwegian Pharmacy Association has published information that enables anyone to calculate the unit price of Keytruda, and considers this to be an infringement of the protections afforded to MSD under Section 3 of the Trade Secrets Act.

MSD would like to emphasise that MSD appreciates that the Norwegian Pharmacy Association is routinely publishing statistics on the use of pharmaceuticals in Norway and supports this transparency effort. Such publication must nonetheless, and in every instance, respect trade secrets, and it is our understanding that the publications of the Norwegian Pharmacy Association are by and large doing exactly that. In the case of Keytruda, on the other hand, the fact that Keytruda is a product that is distributed through a competitive tendering process with Sykehusinnkjøp HF, and is only marketed in one package size, makes it possible to calculate the confidential unit price of Keytruda based on the information published by the Norwegian Pharmacy Association.»

In a letter from the Norwegian Pharmacy Association to MSD of 16 February 2022, the Norwegian Pharmacy Association confirmed that it had removed the price information from its own website and stated that one would in future ensure that one did not publish sales revenue figures that might reveal unit prices of pharmaceuticals that were not already in the public domain. The following was also stated in the said letter in relation to this matter:

Until 2016, the Norwegian Pharmacy Association published annual statistics on sales revenues by active substance. On the basis of a decision from the regional health authorities to the effect that pharmaceuticals prices tendered in public procurement processes should no longer be made public, such statistics were not published for the years 2017 and 2018 for pharmaceuticals that are funded by the health authorities. In the winter of 2019, the Norwegian Pharmacy Association had a dialogue with Sykehusinnkjøp HF and the Norwegian Institute of Public Health. It was then clarified that the Norwegian Institute of Public Health will continue its practice of the Norwegian Prescription Database publishing actual sales and volume (DDD) figures at the active substance level. The Norwegian Pharmacy Association informed Sykehusinnkjøp HF, against this background, that we would resume our practice of publishing sales revenue figures for pharmaceuticals, incl. pharmaceuticals that are funded by the regional health authorities. We have for each of the years 2019 to 2021 published sales revenues for the ten most sold active substances in Norwegian pharmacies. The reasoning we provided to Sykehusinnkjøp HF in support of this practice was that:

- *The Norwegian Prescription Database has a corresponding practice (incl. DDD)*
- *The Norwegian Pharmacy Association does not at the same time publish DDD or the number of packages*
- *There are normally several article numbers per active substance*
- *Prices may change over the course of a calendar year*

[...]

We have not received any negative reactions to this practice until last week. On 9 February 2022, we were contacted by Sykehusinnkjøp HF regarding the publication and disclosure of sales revenue figures. A meeting was held between Sykehusinnkjøp HF and the Norwegian Pharmacy Association on 11 February 2022, in which we provided an account of the background and existing practice.

We acknowledge, against the background of the letter from MSD and our dialogue with Sykehusinnkjøp HF, that our publication of sales revenue figures for the pharmaceutical Keytruda differs from other active substance in two ways. The active substance has only one article number, and it is not dispensed by prescription, thus implying that the Norwegian Prescription Database has not published sales revenues and volume for this pharmaceutical.»

These two incidents, as well as a third one in February 2022, in which Sykehusinnkjøp itself accidentally exposed price information on other suppliers in preparing for the competitive tendering process that resulted in the current competitive tendering round, also occasioned a communication from the suppliers' trade association; the Association of the Pharmaceutical Industry in Norway (LMI), and the Confederation of Norwegian Enterprise (NHO) to Sykehusinnkjøp and the Ministry of Health and Care Services, in which they expressed concern about the competition situation in this market as the result of confidentiality breaches in relation to unit prices. It is not considered necessary to address this in further detail for purposes of the present ruling.

The third instance of confidentiality breach did not concern the prices in any of the reference categories encompassed by MSD's petition for a preliminary injunction. That matter is duly addressed in the Court's order of today in another case – Case 22-152332TVI-TSRO/TSTA – to which the Court makes general reference.

Since MSD, and other suppliers whose price information under the existing framework agreement had been exposed to others, argued that the announced competitive tendering round would have to be terminated, and that the health authorities would instead have to exercise the option on an extension of the existing agreement for these categories, Sykehusinnkjøp considered the said argument and reached a conclusion.

It was noted, as part of the account provided by Sykehusinnkjøp on 28 February 2022, that it had carried out an assessment as to whether one should, as the result of the three instances of price information exposure, exercise the option on an extension of existing framework agreements instead of conducting a new competitive tendering round for some of the existing suppliers:

«Sykehusinnkjøp HF, Division Pharmaceuticals has continuously since October 2021 been assessing what measures must be taken to neutralise any competitive advantage that some suppliers might have as the result of the situation discussed in Section 2.1 above. For oncology tendering round 2207, the assessment prior to February 2022 was that the procurement process could be completed as planned.

The project group has, against the background of the overall situation resulting from the incidents outlined in Sections 2.1 to 2.3 above, inclusive, maintained a dialogue with the specialist group, and has also informed the regional health authorities of the incidents. We have also carried out a renewed assessment of how we consider the incidents to have influenced the competition situation. Attached as Appendix 01 to this memorandum is the project group's assessment as to how Sykehusinnkjøp HF considers the situation to be for all subsets planned for 2207. This assessment is based on technical procurement considerations and legal considerations, as well as adopted Guidelines for the introduction of new indications and new pharmaceuticals.

In summary, 34 of a total of 41 reference groups will be subjected to competitive tendering in oncology tendering round 2207. The other 7 reference groups will be prolonged in accordance with existing agreement 2107, i.e. for up to 12 months.»

The attachment to this account included a summary from the project group of the assessments made in respect of each reference group, which started out as follows:

«Sykehusinnkjøp HF, Division Pharmaceuticals («Sykehusinnkjøp»), has embarked on the conduct of a new procurement process for pharmaceuticals for the treatment of cancer (LIS 2207 Oncology). In a total of 3 instances, confidential information on pharmaceuticals encompassed by the oncology tendering round have entered the public domain. The undersigned have, against this background, reviewed all therapeutic areas and reference groups to examine whether the competition situation has been, or may have been, decisively impeded as a result of the mishaps.

Where changes are taking place in the market, these are assumed to change the competition situation. Two events, in particular, will influence the competition situation. Firstly, patent expiry for pharmaceuticals that are already on the market will be of major importance, because it is known from experience that this will cause a significant price reduction and increased availability for patients. Secondly, the introduction of new indications for existing pharmaceuticals or new pharmaceuticals will be of importance.

Where there are changes in indications for pharmaceuticals included in a procurement process, these are held to potentially influence the competition situation, since experience suggests that there will be a need for a new reduced price. It is also in situations in which new pharmaceuticals are included in a procurement process expected that this will influence suppliers' assessment of how changes in the competition situation will affect price setting. The various scenarios for the introduction of new pharmaceuticals and new indications in the context of a procurement process are described in the Guidelines for the introduction of new indications and new pharmaceuticals. Reference is made to the handbook for a complete description of various scenarios, but the following scenarios are, briefly summarised, of relevance in this context:

*-**Scenario 2:** The indications of a pharmaceutical are expanded and it is not anticipated that the expanded indication will face competition from therapeutically equivalent pharmaceuticals. Experience shows that there will nonetheless often be a need for a reduced price in order to obtain approval for a new indication and this will affect existing prices, thereby making knowledge less significant.*

*-**Scenario 3:** A pharmaceutical is introduced for an indication for which there are already therapeutically equivalent pharmaceuticals. Experience suggests that this will change market dynamics in such a way as to make knowledge of existing prices less significant. It may be of importance to patients to have access to different treatment alternatives and this may in itself constitute sufficient grounds for announcing a competitive tendering round for situations involving scenario 3.*

*- **Scenario 4:** The indications of a pharmaceutical are expanded to include an indication for which there are already therapeutically equivalent pharmaceuticals. Experience suggests that this will change market dynamics in such a way as to make knowledge of existing prices less significant. It may be of importance to patients to have access to different*

treatment alternatives and this may in itself constitute sufficient grounds for announcing a competitive tendering round for situations involving scenario 4.

Each reference group will in the following be reviewed per therapeutic area. The model is based on the reference group specification in the draft procurement documents for LIS 2207 Oncology. Each reference group will be considered with regard to the scenario expected to arise as the result of changes in the market situation.»

For the reference groups in the procurement process that include MSD's pharmaceutical Keytruda, the assessment was that both MSD and a competing supplier had applied for the introduction of the new indications for their pharmaceuticals and that this would be expected to affect the pricing in the new competitive tendering round. The assessment is virtually identical for all of the relevant reference groups, and only the assessment for reference group 5.7, where MSD and Sanofi would be competitors in the competitive tendering round, is quoted here:

«5.7. Cemiplimab (Sanofi) and pembrolizumab (MSD) will be compared to each other for the treatment of NSCLC with PD-L1 expression of no less than 50% without EGFR- or ALK-positive mutations in tumour

Both Sanofi and MSD have applied for the introduction of new indications for their pharmaceuticals. The introduction of these new indications is held to fit both scenario 2 and scenario 4. It is anticipated that this will influence the competition situation for all suppliers. It is, against this background, the assessment of Sykehusinnkjøp that the competitive tendering may be conducted since existing prices will not guide the upcoming procurement process.

It is our recommendation that the said reference group be subjected to competitive tendering.»

A follow-up letter from Sykehusinnkjøp to MSD on 25 March 2021 goes on to state the following:

«It is the assessment of Sykehusinnkjøp that subsets for which it is expected that the introduction of new indications, new competitors and/or patent expiry will give rise to uncertainty as to whether the existing price level will be maintained or changed in connection with the upcoming procurement process. Sykehusinnkjøp is of the view that the said uncertainty is of material importance in connection with the assessment as to whether competitive tendering should be conducted for, inter alia, the 10 reference groups that include Keytruda. This is not an assessment based on the premise that MSD will be tendering a lower price in LIS 2207, but on the premise that the supplier market must expect uncertainty with regard to price level in these reference groups. It is the experience of Sykehusinnkjøp that prices change in reference groups as the result of competitive tendering in general, and not least upon the introduction of new indications, although it would appear that MSD is not sharing the same practice.

Sykehusinnkjøp will in the following comment on the competition situation of MSD in relation to the various competitors in the upcoming procurement process.

The competition situation between MSD's Keytruda and Sanofi's Libtayo is based on Sanofi having been granted the introduction of new indications for its pharmaceutical. MSD is arguing that Sanofi may have a competitive advantage as the result of having knowledge of MSD's confidential unit price.

Sykehusinnkjøp disagrees with this, since a supplier will, prior to the introduction of a pharmaceutical, be offered routine guidance on what price level is likely to be necessary in order to meet the priority criteria. This forms part of the process of making pharmaceuticals available via a positive decision in the Decision Forum for New Methods ("Beslutningsforum"). Such price guidance was provided to Sanofi by Sykehusinnkjøp on 21 February this year.

As far as the competition situation between MSD's Keytruda and BMS' Opdivo is concerned, the facts of the matter are that none of the pharmaceuticals were included in LIS 2107, BMS did not obtain information through AHN's incident, but both were included in the Norwegian Pharmacy Association's publication of sales figures. It is therefore the assessment of Sykehusinnkjøp that BMS has not gained more of a competitive advantage than what may have been gained by MSD as the result of the incident involving the Norwegian Pharmacy Association.

As far as the competition situation between MSD's Keytruda and Roche's Tecentriq is concerned, the assessment is the same as for Libtayo above, although with MSD being the supplier that will be provided with routine price guidance.

All in all, it is the view of Sykehusinnkjøp that it is important to subject areas with the introduction of new indications, new competitors and/or patent expiry to competitive tendering. This is important to ensure that patients get access to the broadest possible range of new pharmaceuticals and indications. The solution outlined by MSD will result in fewer treatment alternatives for patients in the coming year. Sykehusinnkjøp will, against this background, conduct procurement processes for the reference groups as described in the memorandum to affected suppliers with attachments.»

A call for tenders in accordance with Sykehusinnkjøp's decision was thereafter announced on 10 April 2022, with a deadline of 30 May 2022 for submitting tenders.

MSD submitted, along with others, tenders prior to expiry of the deadline.

MSD filed a complaint against Sykehusinnkjøp with the Complaints Board for Public Procurement («KOFA») on 24 June 2022. Sykehusinnkjøp stated during the proceedings that it would not finalise the competitive tendering process and announce the choice of suppliers until after it had examined the decision from KOFA.

KOFA has in an advisory pronouncement (Case 2022/902) of 22 September 2022 in MSD's complaint proceedings concluded that Sykehusinnkjøp was liable for the pharmacy wholesaler and the Norwegian Pharmacy Association having exposed confidential price information on Keytruda to MSD's competitors and that this resulted in a duty to terminate the procurement process. It was acknowledged in the pronouncement that the likely consequence of this would be a duty to exercise the option on an extension of the existing framework agreement. The conclusion in this decision was the same as that reached by KOFA on 24 August 2022 in Case 2022/802, when ruling on a complaint filed by another supplier in the same procurement process.

Sykehusinnkjøp disagreed with this decision and completed the competitive tendering process, the outcome of which was announced on 11 October 2022, with the result reported above.

MSD has in a timely manner filed a petition for a preliminary injunction in order to stop the signing of contracts with its competitors in accordance with the outcome of the competitive tendering process. Since the petition is not only brought against Sykehusinnkjøp HF, whose court of domicile is in Finnmark, but also against the four regional health authorities, of which Helse Vest HRF [sic] has the Sør-Rogaland District Court as its court of domicile, the petition against all defendants could be lawfully filed with the Sør-Rogaland District Court due to the right of cumulation. The defendants have in a timely manner contested that there are grounds for granting a preliminary injunction. Shortly thereafter, another tenderer in the competitive tendering process – Janssen-Cilag AS – filed a similar petition for a preliminary injunction against Sykehusinnkjøp HF before the Indre & Østre Finnmark District Court. That case has at the request of the defendants and with the consent of both parties been transferred to the Sør-Rogaland District Court pursuant to Section 38 of the Courts of Justice Act and has here been allocated case number 22-152332TVI-TSRO/TSTA. A joinder of the said case with the present case for joint preparation and oral hearing has been effected by decision of the Court. The joint oral hearing of these cases was conducted on the permanent premises of the Sør-Rogaland [District Court] at Handelens Hus in Stavanger on 14-17 November 2022. Counsel to the parties were in attendance, and testimony was rendered by three representatives of the parties and by six witnesses. As some information on prices and pricing was held to potentially constitute trade secrets also between the two claimants, brief parts of the presentation of evidence and the oral submissions took place without the other claimant in attendance. There was made such documentation as is recorded in the court record.

Separate rulings are today handed down in respect of the two petitions.

The main arguments invoked by the **claimant; MSD (Norge) AS**, are as follows:

It is argued that there are grounds for granting a preliminary injunction to the effect that the regional health authorities, acting through Sykehusinnkjøp, are prohibited from concluding contracts for reference groups 2.4, 3.8, 4.3, 4.4, 5.7, 5.8, 6.1, 6.5, 8,2 and 8.3 in open procedure procurement LIS 2207 Oncology for the supply of pharmaceuticals for the treatment of cancers, until the issue of whether the public procurement provisions have been violated in the implementation of the procurement process has been resolved with final and binding effect.

The underlying claim in the case is that the regional health authorities, acting through Sykehusinnkjøp, have a duty to terminate the procurement process. There is, under applicable law, a duty to terminate the procurement process if the contracting authority has committed an error that cannot be remedied in a less intrusive manner than by termination of the procurement process, and there is a distinct possibility that the error may have affected the outcome of the procurement.

The health authorities currently have a framework agreement LIS 2131 with MSD for the supply of the pharmaceutical Keytruda. The term of the said agreement expires on 30 September 2022, but includes an option for the customer for a further extension of up to 12 months. Sykehusinnkjøp has already extended this agreement by two months.

Sykehusinnkjøp was planning to conduct a new oncology procurement process to replace the existing agreement upon ordinary expiry of the agreement. There are two instances of participants in the sales chain, which have been handling information on MSD's discounted unit prices for Keytruda under the framework agreements for the health authorities, having exposed such information to the competitors that are included in, or wishing to become included in, the agreement in competition with MSD now that the said agreement is subject to rotation. The first incident happened already in October 2021, when the pharmacy wholesaler which MSD is obligated to use under the agreements with the health authorities by mistake shared the price of Keytruda with other suppliers under the same framework agreement. The other incident happened in February 2022, when the Norwegian Pharmacy Association published sales revenue figures for the ten most sold pharmaceuticals in Norway in 2021. These included the sales revenue figures for Keytruda. Since this pharmaceutical comes in one package size and the sole customer is the specialist health service, competitors with access to the pharmacies' statistical information would be able to ascertain the unit price under the agreement by comparing the sales revenues with the number of packages sold in 2021.

The unit prices are trade secrets of the supplier in relation to competing tenderers, and it has until now indisputably been the rule that the sharing of such information represents a violation of the statutory duty of confidentiality under Section 13, Sub-section 1, No. 2, of the Public Administration Act, and thereby also a violation of the public procurement rules, cf. Section 7-4 of the Public Procurement Regulations. It is not contested that the need for protection may become less the older the price information becomes, thus implying that such information will at some point in time no longer be subject to any statutory duty of confidentiality. The price information that was shared through the health authorities' subcontractors was not of such a nature, since these prices applied under a contract with an option for the customer to extend it to the autumn of 2023. Consequently, the suppliers whose information was shared did at the time of the new competitive tendering round have a clear interest in such information not being shared with competing tenderers, which interest is worthy of protection.

MSD has not shared its discounted unit price for Keytruda with anyone other than the health authorities. It is the health authorities that are responsible under the Public Administration Act for ensuring that the pharmacies and their associations do not expose trade secrets to unauthorised parties, as was done in these two instances.

It is argued that the unlawful sharing of MSD's unit prices, for which the health authorities are liable, does to such a material extent undermine the prospects of fair competition in the competitive tendering round announced by Sykehusinnkjøp for a new Oncology framework agreement, that this procurement process must be terminated and postponed to a significantly later date in order to minimise the damage caused by the breaches of the duty of confidentiality. By sharing confidential price information a short time before announcing a new call for tenders, the health authorities are liable for violation of, and material failure to apply, the basic requirements of competition and equal treatment as laid down in Section 4 of the Public Procurement Act. This also applies in the event of the Court concluding that the health authorities are not formally liable for their own subcontractors' exposure of confidential information. It is not of decisive importance whether any of the competitors that

were exposed to confidential information did in fact take note of such information or use it in determining its own tendered price. The knowledge in the market that prices have been shared is in itself of significance to the suppliers' pricing in the procurement process. This will presumably have different consequences for different tenderers. Reference is made to the fact that only some of the suppliers' prices have been shared, and that only some suppliers have downloaded documents and thereby been afforded an opportunity to take notice of the competitors' prices. This may for example result in suppliers that have taken note of prices having tendered a lower price than they had originally planned. Others may choose to leave the existing price unchanged because they fear new breaches of the duty of confidentiality, and allow this consideration to override concern for this specific framework agreement. As far as MSD's own handling of these challenges is concerned, reference is made to the submitted internal correspondence and to the General Manager's testimony before the Court regarding to the implications of the leaks for MSD's pricing strategy in the new procurement process.

Reference is made, in particular, to the assessment of these issues on the part of KOFA in ruling on MSD's complaint in its complaint decision of 22 September 2022. The assessment in the said decision is largely the same as KOFA's assessment of the same issue in its decision of 24 August 2022 on Janssen-Cilag AS' complaint regarding breach of the duty of confidentiality in relation to its unit prices on two other occasions. KOFA's decisions in these two cases are well aligned with established practice where there is confidential price information.

The subsequent prices that are based on an unlawful procurement process carry, for the same reason, little or no evidential value, and cannot be invoked as evidence of what would have been the outcome of a procurement process that had been conducted in accordance with the public procurement provisions. Besides, MSD has not had access to the competitors' prices in the new procurement process, and only has knowledge of the ranking disclosed in the announcement made by Sykehusinnkjøp in October this year.

Sykehusinnkjøp's invocation of changed circumstances in relation to the competition situation as a justification for including these reference groups in a new procurement process, despite the breaches of the duty of confidentiality, is non-tenable. As noted in the decision delivered by KOFA, this is a general account with little specific discussion of the reference groups in which MSD's pharmaceutical is included. Nor would this account withstand a detailed analysis in relation to the introduction of new indications. Sykehusinnkjøp's attempts in the court hearing at explaining that the competitors did in fact have, on the basis of known market information, a good idea of the discounted unit price of MSD's products were also largely unsuccessful.

The remedial measures referred to by Sykehusinnkjøp are not sufficient. What may have been seen cannot be made unseen, and the references made by the health authorities to provisions regarding prohibition against the misuse of the trade secrets of others that are laid down in the Competition Act and the Act relating to Trade Secrets are in themselves nothing other than an attempt at disavowing liability for the consequences of circumstances on their own part.

The interests of Sykehusinnkjøp, patients and the market in general are well attended to by an extension of the existing Oncology Agreement by way of the health authorities exercising the option on an extension until the autumn of 2023. This will result in the health authorities at no point in time being without an agreement that has been subjected to competitive tendering. This is also the assumption made in the decision handed down by KOFA, and is in line with established practice where the error cannot be remedied in a less intrusive manner.

Consequently, the underlying claim has been demonstrated, on the balance of probabilities.

Grounds for securing the claim have been demonstrated, on the balance of probabilities, pursuant to Section 34-1, Sub-section 1 a), cf. Section 34-2, Sub-section 1, of the Civil Procedure Act. MSD has an interest in the conclusion of oncology-related agreements that comply with the basic requirements under the public procurement rules, and has a financial and reputational interest in such agreements being concluded on appropriate terms. The signing of a new framework agreement will, as the result of the ranking therein, impose a significant economic loss on MSD, which loss it will be difficult to document in the absence of a preliminary injunction. The company will in such case lose a position in the market as the result of a procurement process that should not have been conducted. A preliminary injunction will in such a situation also safeguard the system with regard to the duty of confidentiality, as well as efficient pricing of, and access to, pharmaceuticals both in Norway and globally.

It is therefore also contested that there is no legal interest in obtaining a preliminary injunction for the reference groups for which there have been changes in the ranking between MSD's and its competitors' pharmaceuticals under the new procurement process. It is also noted that if MSD were to have to conclude new framework agreements with the health authorities for these categories in order to maintain sales, the health authorities would at the same time have a unilateral right to extend the agreement at the same price for one additional year.

As far as concerns, in particular, the invoked proportionality test under Section 34-1, Sub-section 2, of the Civil Procedure Act, reference is also in this regard made to the alternative available in the form of the health authorities exercising, upon termination of the procurement process, the option to extend the existing framework agreement for the reference groups that are encompassed by the claim for a preliminary injunction.

If it is deemed necessary, in the specific treatment of individual patients or groups of individual patients, to use other approved pharmaceuticals for the relevant treatment indication, the health authorities already have procedures for this. This is also accommodated under the existing framework agreements. With regard to reference group 5.7, in particular, it was established in the presentation of evidence that Keytruda and Libtayo are deemed to be equivalent and to have virtually identical side effect profiles. It is therefore unlikely that patients who experience side effects from Keytruda will be transferred to Libtayo, or vice versa. It must be expected that patients who do not tolerate one of these two pharmaceuticals will be reassigned to a different form of treatment. With regard to reference groups 8.2 and 8.3, in particular, where both tenderers are now included for the first time subject to subsequent approval under New Methods, there will in any event be a number of other adequate treatment alternatives available to this patient group at present.

The claimant entered the following **statement of claim**:

1. *Helse Vest RHF, Helse Sør-Øst RHF, Helse Midt-Norge RHF and Helse Nord RHF, as well as Sykehusinnkjøp HF, to be prohibited from concluding contracts in open procedure LIS 2207 for the reference groups in which Keytruda is included (2.4, 3.8, 4.3, 4.4, 5.7, 5.8, 6.1, 6.5, 8.2 and 8.3), until MSD (Norge) AS' claim for the termination of LIS 2207 has been resolved with final and binding effect.*

2. *Helse Vest RHF, Helse Sør-Øst RHF, Helse Midt-Norge RHF and Helse Nord RHF, as well as Sykehusinnkjøp HF, to be ordered to pay, jointly and severally, the legal costs of MSD (Norge) AS.*

The main arguments invoked by the **defendants; Helse Vest RHF, Helse Sør-Øst RHF, Helse Midt-Norge RHF, Helse Nord RHF and Sykehusinnkjøp HF**, are as follows:

There are no grounds for granting a preliminary injunction in this case, as it is contested that there is any duty to terminate the procurement process for the reference groups to which the claim for an injunction pertains. If it is concluded that the underlying claim has been demonstrated, on the balance of probabilities, it will not be contested that MSD has grounds for securing the claim. It will in such event nonetheless be argued that the claim for an injunction would be disproportionate and that a preliminary injunction therefore can nevertheless not be granted. As the result of MSD having in the new procurement process achieved that same ranking for several reference groups as under the existing agreement, it will however be argued that MSD has no legal interest, within the meaning of Section 1-3 of the Civil Procedure Act, in obtaining a preliminary injunction as far as those reference groups are concerned.

Upon legal action in respect of the underlying claim, the Court will under Section 8 of the Public Procurement Act have a discretionary right to set aside decisions made by the contracting authority in violation of the public procurement rules. When the claimant is in the petition for a preliminary injunction required to demonstrate the underlying claim, on the balance of probabilities, this entails both a requirement to demonstrate, on the balance of probabilities, that there is an error that results in a duty to terminate the procurement process and, furthermore, a requirement to demonstrate, on the balance of probabilities, that the courts will in a legal action pursuant to Section 8 exercise their discretionary power to order Sykehusinnkjøp to terminate the procurement process that has now been finalised.

Several conditions will have to be met in order for there to be a duty to terminate the procurement process pursuant to the public procurement rules. The contracting authority must have committed an error in its application of the public procurement provisions that cannot remedied otherwise than through termination of the procurement process. Moreover, the error must have impacted the outcome of the procurement process for the claimant. Sykehusinnkjøp and the regional health authorities contest that any of these conditions are met in the present case.

It is not contested that price information on MSD's Keytruda under the existing framework agreement was exposed to other suppliers under the framework agreement, upon the pharmacy wholesaler's distribution of reversed clawback documentation to the suppliers in October 2021. Nor is it contested that it was possible, on the basis of the Norwegian Pharmacy Association's published list of the 10 bestselling

pharmaceuticals in Norway in 2021, to deduce the discounted unit price of Keytruda under the framework agreement. This would, however, only be possible if the competitor actively used available statistical data from a third party on the number of units of Keytruda sold.

However, Sykehusinnkjøp and the regional health authorities are not liable for these entities' exposure of the suppliers' price information. It is admittedly the case that the suppliers are under the framework agreements with the health authorities obligated to supply all medicines of the type included under the framework agreements to a pharmacy wholesaler with which the health authorities have an agreement, at the discounted price, while allowing for the sale of such medicines to other purchasers than the health authorities to be made at a higher price, with subsequent reversed clawback between the pharmacy wholesaler and each supplier. How this is going to be implemented is regulated in an agreement between the wholesaler and each supplier. These are agreements which have not been submitted in these proceedings and to which the health authorities do not have access. The exposure of discounted price information that occurred upon the wholesaler's distribution of documentation as a basis for reversed clawback upon the sale of pharmaceuticals to third parties is therefore something that should be for the account and risk of each supplier, rather than the health authorities. The same applies, in the view of the health authorities, to the Norwegian Pharmacy Association's publication of sales revenue statistics from hospitals.

That the health authorities are in a competitive tendering context in any case carrying the risk associated with disclosure of this information, even if it this does not fall within the responsibilities of the health authorities under the confidentiality provisions, as appears to be the alternative argument invoked by MSD, has no basis in the public procurement rules, including the objectives and principles on which these are premised.

It will in any event be argued that the price information that was exposed through these incidents is of historical interest in the new competitive tendering round, and therefore no longer constitutes confidential trade secrets within the meaning of Section 13, Sub-section 1, No. 2, of the Public Administration Act. The price of Keytruda had been tendered by a tender deadline of 4 November 2020 for existing framework agreement LIS 2131, and was at the time of the announcement of a new framework agreement an old price. MSD has itself in correspondence with Sykehusinnkjøp referred to practice suggesting that one will in a competition context assume, as a main rule, that price information is historical after 12 months. The same is indicated by guidance from the European Commission. Norwegian practice also provides examples from the Parliamentary Ombud for Scrutiny of the Public Administration under which price information for pharmaceuticals is considered to be historical after 6 months.

The use of trade secrets received in error is in any event regulated by a number of regulatory provisions that prohibit the recipient from making use thereof. Reference is in this regard made to, *inter alia*, the Act relating to the Protection of Trade Secrets and analogous provisions in the Competition Act. Tenderers that have been exposed to competition-sensitive information are thus under an obligation to distance themselves from such information, and may in the opposite case be faced with the imposition of cease-and-desist orders, administrative penalties, liability for damages and criminal sanctions due to violation of Section 10 of the Competition Act. It cannot be assumed, against this background, that competing

tenderers that have been exposed to the price information will commit unlawful acts be exploiting such information.

The public procurement provisions make a clear distinction between the objectives of these provisions and the principles laid down to bring about the attainment of such objectives. In case of conflict, the statutory objective shall take precedence over the said principles. The objective of the public procurement provisions is, according to Section 1, to promote the efficient use of society's resources and to inspire confidence in public sector integrity. Practice demonstrates that KOFA and the courts are actively drawing on the statutory objective in interpreting and supplementing these provisions. Considerations relating to the statutory objective are of particular importance in cases relating to the mitigation of errors. Efficient resource use considerations suggest that the contracting authority should not be subjected to more extensive sanctions than are necessary, and that a procurement process may only be terminated if it can be demonstrated that the error has impacted the outcome of the procurement process. This latter consideration has been discussed, at the level of principles, by KOFA in decision 2020-116, paragraphs 22-26, and decision 2021-1998, paragraphs 23-24. To the extent that KOFA's decision in the present case and the analogous decision in the complaint proceedings initiated by Janssen-Cilag AS are invoked in support of a lower impact probability threshold, this will not be in conformity with established practice before KOFA and the courts. If such a lower probability threshold is applied in the present case, it will mean that a market prohibition is imposed on the contracting authority, inasmuch as it will have to continue a cancer treatment agreement that is no longer wanted, and that new providers that offer new treatment methods on more favourable terms will be excluded from the market for the benefit of an existing supplier, without any specific relationship having in any way been demonstrated, on the balance of probabilities, between the error and the outcome of the procurement process. Such a one-sided approach to the basic principles under Section 4 of the Public Procurement Act is not in accordance with applicable law, whether nationally or under EU law, where these have their origin.

If the Court concludes that there is an error that has not been adequately rectified, it will be argued that such error has not impacted the outcome of the procurement process. In order for an error to have impacted the outcome of a procurement process, it is both a requirement that it does by its nature have the ability to cause such an impact and a requirement that the said ability has manifested itself inasmuch as it has in fact impacted the outcome of the procurement process.

It will be noted from the outcome of the procurement process that the ranking between existing suppliers under the framework agreement is largely the same as before. There has been a minor rearrangement in the lower ranks of reference group 6.1 as the result of MSD having tendered two additional combination products. In reference groups 8.2 and 8.3, which are new, there is a mix of Opdivo from BMS and Keytruda from MSD. And Sanofi with Libtayo has been made the first choice in reference group 5.7, where MSD has until now been alone with Keytruda.

Sanofi's product Libtayo had not been approved under New Methods when the competitive tendering round was conducted, but participated in the tendering subject to subsequent approval thereunder. It will thus be the tendered price that will be Sanofi's price for purposes of the approval arrangement under

New Methods. Since Sanofi has applied for approval of the pharmaceutical for an indication for which there is an existing equivalent treatment, it is a requirement for approval under New Methods that the new product entails, all in all, a treatment cost that is lower than, or at about the same level as, Keytruda, which was at that time the sole pharmaceutical in this reference group.

Price guidance is offered as part of this approval process, within the limits imposed by the duty of confidentiality, in order for the manufacturer seeking approval of a product for a new treatment indication with existing competition to be provided with some direction as to what price level it would have to offer for the product in order to be competitive as far as approval of the product under New Methods is concerned. The manufacturers are well aware of this approach, and it has been documented before the Court that Sanofi was provided with price guidance as part of the approval process.

As will be noted from the ranking after this competitive tendering round, the treatment cost when using Libtayo at the tendered prices is less than when using Keytruda. The health authorities are subject to a duty of confidentiality with regard to the exact price tendered by Sanofi for Libtayo. It is nonetheless evident from the witness testimony from Sykehusinnkjøp's personnel that the difference in treatment cost when using Sanofi's product, compared to MSD's product, is not compatible with a notional deliberate attempt at closely undercutting what one assumed to be the former price of MSD's product.

Besides, the presentation of evidence substantiates the correctness of Sykehusinnkjøp's initial assessment that historical price information was of minor significance when MSD's and the other suppliers' pharmaceuticals are exposed to competition from new competitors, as happened with MSD in reference group 5.7, and by way of approval for new indications having been applied for under New Methods in respect of its own pharmaceutical or other existing competitors' pharmaceuticals. This implies that all companies needed to adapt the pricing of their own products to the new market situation if they wanted to remain competitive in the procurement process.

If the Court concludes that the underlying claim has been demonstrated, on the balance of probabilities, it will not be contested that there are grounds for securing such claim, although it is, as noted, argued that there is no legal interest in granting of the petition in respect of the reference groups for which the new competitive tendering round has not entailed any changed ranking.

It is, however, argued that the granting of an injunction for the benefit of MSD would be clearly disproportionate to the interests of the public specialist health service and its patients in the conclusion of contracts, cf. Section 34-1, Sub-section 2, of the Civil Procedure Act.

The defendants entered the following **statement of claim**:

1. *The petition for a preliminary injunction not to be granted.*

2. *Helse Vest RHF, Helse Sør-Øst RHF, Helse Midt-Norge RHF, Helse Nord RHF and Sykehusinnkjøp HF to be awarded legal costs.*

The observations of the Court

1. Introduction

A tenderer that believes it has been passed over in a public procurement process may, pursuant to Section 8 of the Public Procurement Act, bring legal action concerning violation of the Act and associated regulations. If the Court finds that there is violation of the public procurement rules, it has the discretionary power to set aside decisions made by the contracting authority in violation of the Act or regulations laid down pursuant to the Act. Sub-section 2 of the said provision indirectly implies that once a contract with a competing tenderer has been concluded, the claim from the tenderer that believes that it has been passed over will be a claim for damages only.

In order to attend to its interest in concluding a contract with the public sector, Section 9 of the Public Procurement Act stipulates that a tenderer that believes that it has been passed over may until a contract has been concluded file a claim for a preliminary injunction against the contracting authority in order to prevent the latter from concluding a contract with its preferred tenderer. In contrast to other instances in which a party moves for preliminary securing of a claim, there is under the public procurement legislation a waiting period before a contract may be concluded, and a further waiting period that runs from service of a petition for a preliminary injunction until the District Court has ruled on the petition. A potential appeal from the tenderer will not extend the waiting period.

The petition from MSD has been filed by the end of the waiting period under Section 25-2 of the Public Procurement Regulations, and has been lawfully served on Sykehusinnkjøp, thus implying that the latter is prevented, under Section 25-3 of the Public Procurement Regulations, from signing a contract with competing tenderers until the District Court has ruled on the petition.

If the Court, upon application of the preliminary injunction provisions of the Civil Procedure Act, finds in favour of the claimant, it will result in a conclusion, within the scope of the entered statement of claim, to the effect that Sykehusinnkjøp is, until an ordinary judgment is handed down pursuant to Section 8 of the Public Procurement Act regarding the lawfulness of the competitive tendering round, prohibited from concluding an agreement with regard to the reference groups stipulated by the Court. Since the contract concerns the procurement of pharmaceuticals for a limited period of time, while the regional health authorities have an option to extend the existing agreement for a year, it must be assumed that the real consequence of a final and binding court order granting a preliminary injunction is that the existing agreement is extended, and that a potential legal dispute subsequent thereto will concern claims and counterclaims in relation to the amount of damages.

A preliminary injunction pursuant to Chapter 34 of the Civil Procedure Act may normally only be granted if the party petitioning for such an injunction pursuant to Section 34-2 demonstrates, on the balance of probabilities, both the underlying claim and grounds for securing such claim

pursuant to Section 34-1. Sykehusinnkjøp and the regional health authorities have contested the underlying claim, but have acknowledged that there are grounds for securing the claim if the underlying claim is demonstrated on the balance of probabilities. However, Sykehusinnkjøp and the regional health authorities have argued that patient safety considerations will in any event imply that an injunction would be disproportionate within the meaning of Section 34- 1, Sub-section 2.

For the reference groups in which the ranking of MSD's Keytruda is the same after the current competitive tendering round as under the existing framework agreement, Sykehusinnkjøp and the regional health authorities have argued that the petition must in any event be dismissed, as they argue that MSD lacks legal interest in the claim for an injunction.

The Court will first address the claim for dismissal in respect of reference groups 2.4, 3.8, 4.3, 4.4, 5.8, 6.1 and 6.5.

2. *Specifics on MSD's interest in an injunction in respect of reference groups 2.4, 3.8, 4.3, 4.4, 5.8, 6.1 and 6.5*

Sykehusinnkjøp and the regional health authorities have argued that the petition for a preliminary injunction must be dismissed as far as reference groups 2.4, 3.8, 4.3, 4.4, 5.8, 6.1 and 6.5 are concerned, since MSD has in respect of these ended up with the same ranking as under the existing framework agreement.

Although the claim for an injunction, as set out in the petition, is a motion for the defendants to be prohibited from concluding contracts for the relevant reference groups until a final and binding judgment on the validity of the contract award has been handed down, it is an acknowledged fact between the parties that the only real alternative if an injunction is granted in accordance with the statement of claim is for the health authorities to exercise the option under the existing agreement on an extension thereof. Under the argument invoked on the part of MSD, such an extension must cover the full option period until the end of September 2023 in order for the price information on Keytruda to which competing suppliers are claimed to have been exposed to be considered historical.

It is in view of this that the Court must assess what legal interest MSD has in an injunction in the case, irrespective of the viability of an underlying claim. The Court notes that the invoked grounds for securing the claim pursuant to Section 34-1, No. 1 a), of the Civil Procedure Act are premised on the defendants' conduct making it «*necessary to preliminarily secure the claim because enforcement or execution of the claim would otherwise be considerably impeded*» (emphasis added by the Court). This is a parallel to the rule that a legal action regarding an underlying claim may, pursuant to Section 1-3 of the Civil Procedure Act, only pertain to legal claims in respect of which the claimant has a current need for obtaining a judgment. Since it is the assertion of MSD that it has an underlying claim and grounds for securing such claim, the Court presumes that it must in ruling on the petition for a preliminary injunction also do so on the merits of the case, based on the viability of the claim for an injunction, which will be based on the requirements that the underlying claim must be demonstrated on the balance of probabilities and that the grounds for securing such claim must also be demonstrated on the balance of probabilities, cf.

Section 34-2, Sub-section 1, of the Civil Procedure Act. Although this may entail the Court finding that the legal basis for the defendants' perspective falls within the scope of the ruling on the claim for an injunction on its merits, in terms of whether the requirement for grounds for securing the claim is met, rather than the general statutory requirement for legal interest, the Court assumes that it is nonetheless keeping within the scope of the grounds invoked by the parties in support of their claims, cf. Section 11-2, Sub-section 1, cf. Section 11-3, of the Civil Procedure Act.

It is an undisputed fact that the ranking between MSD's Keytruda and competing pharmaceuticals upon the award of the new framework agreement is the same as under the existing framework agreement for reference groups 2.4, 3.8. 4.3, 4.4, 5.8 and 6.5. It is, furthermore, an undisputed fact that the only new aspect with regard to the new award for reference group 6.1 is that MSD has been included with a combination product of Keytruda and Kisplyx in two different dosage intervals, which in relation to the existing framework agreement have been ranked as the fourth and fifth choice, respectively, thereby superseding two combinations of Keytruda and Inlyta, which are now ranked as the sixth and eighth choice. Between these are, as before, a combination of Opdivo from BMS and Inlyta, now ranked as the seventh choice.

The existing framework agreement and new framework agreement are based on the premise that the pharmaceuticals offered shall have the same price in all reference groups.

The Court does not know the discounted price of Keytruda under the existing framework agreement or the exact discounted price tendered by MSD for this pharmaceutical in relation to the new framework agreement, the conclusion of which it is now seeking to stop. There has on the part of MSD been disclosed information in open court regarding the relationship between the level of the discounted unit price under the new tender and the level of the discounted unit price under the existing agreement. The information disclosed to the Court implies that the Court is unable to see that MSD will, with regard to any of the reference groups for which the ranking is the same as before, be financially worse off by concluding a new agreement rather than obtaining an injunction that results in the health authorities having to renew the existing agreement. This also applies to reference group 6.1, for which MSD will under a new agreement be included with a combination product based on Keytruda, which will rank ahead of an existing combination product that is also based on Keytruda.

It is an undisputed fact that MSD will, if the injunction is not granted, conclude a new framework agreement with the health authorities in accordance with the outcome of the procurement process that the company is now seeking to stop. MSD has, with regard to its interest in an injunction, argued that it will upon the conclusion of a new framework agreement also be bound by an option provision that gives the health authorities the right to extend the new agreement by up to one year. The Court notes that the general trend is for the price of pharmaceuticals to decline over time, as the result of these being subjected to competitive tendering. The Court is unable to see, in view of this, that it has been demonstrated, on the balance of probabilities, that it would be financially disadvantageous for MSD if the new agreement were to be extended at the same unit prices. Besides, the presentation of evidence has demonstrated that it is a priority for the health authorities, precisely in order to include new pharmaceuticals or treatment indications in the framework agreements, to subject

the pharmaceuticals agreements to competitive tendering on an annual basis, and that any extensions have largely been of short duration and based on practical implementation considerations.

MSD's alleged interest in the granting of an injunction in order to ensure compliance with public procurement provisions cannot in itself justify, in the assessment of the Court, a claim for an injunction.

The Court notes, for the sake of good order, that the information that the Court is relying on in ruling on this part of the petition was not known to KOFA when it deliberated and ruled on MSD's complaint. Nor was it the role of KOFA to rule on any petition for a preliminary injunction.

The Court has concluded, based on the above, that MSD has not demonstrated, on the balance of probabilities, any interest in an injunction pursuant to Section 34-1, Sub-section 1, cf. Section 34-2, of the Civil Procedure with regard to reference groups 2.4, 3.8, 4.3, 4.4, 5.8, 6.1 and 6.5. It will therefore in respect of these reference groups be handed down a ruling to the effect that the petition for a preliminary injunction is not granted.

3. Specifics on reference groups 8.2 and 8.3

The Court is of the understanding that Sykehusinnkjøp and the regional health authorities are not arguing that there are, as far as the remaining reference groups are concerned, any purely procedural obstacles to MSD being granted an injunction in conformity with its claim for an injunction, and that they are instead contesting the underlying claim and, alternatively, arguing that the proportionality test under Section 34-1, Sub-section 2, of the Civil Procedure Act is not met.

Although the claim for an injunction is formally a motion for the health authorities to be prohibited, until a final and binding judgment is handed down, from concluding agreements based on the new procurement process for the reference groups listed in the petition, the underlying reality is not that the competitive tendering round will be announced anew, but that the health authorities will, as their only real alternative, have to exercise the option on an extension of the existing framework agreement until the autumn of 2023.

There is an internal logic to this as long as the outcome of the procurement process entails a change in ranking between MSD's Keytruda and its competitors when comparing the existing agreement and the outcome of the competitive tendering round.

Such is not, however, the case with reference groups 8.2 and 8.3.

Here none of the tenderers are included under the existing framework agreement. MSD with Keytruda and BMS with Opdivo have both applied for approval under New Methods for their pharmaceuticals for these indications and are participating in the competitive tendering round for the said reference groups with their pharmaceuticals subject to subsequent approval under New Methods. In reference group 8.2, both suppliers are participating with two dosage intervals, with BMS with Opdivo being ranked as the first and third choice, while MSD with Keytruda is

ranked as the second and fourth choice. In reference group 8.3, MSD with Keytruda is ranked as the first and third choice, while BMS with Opdivo is ranked as the second and fourth choice.

If one or both of these pharmaceuticals are approved by Beslutningsforum, the practical consequences of the claim for an injunction would mean that those administering treatment would not necessarily be able to offer any of these pharmaceuticals for these treatment indications as a matter of routine without having to take the direct procurement route.

The Court is unable to see that this implication has been acknowledged or discussed in KOFA's ruling. In any event, KOFA was not ruling on a petition for a preliminary injunction under the provisions of the Civil Procedure Act.

In view of the acknowledged real consequence of an injunction in this case, which entails an extension of the existing framework agreement that does not include any supplies from MSD or its competitors in reference groups 8.2 and 8.3, the Court is unable to see that it has been demonstrated, on the balance of probabilities, that there are any real grounds for an injunction under any of the alternatives under Section 34-1, Sub-section 1, of the Civil Procedure Act as far as groups 8.2 and 8.3 are concerned.

For the eventuality that the Court is bound, with regard to the actual grounds for an injunction, by the acknowledgments of the defendants, the Court notes that it is in any event unable to see that MSD's interests – if any – that were to be secured through a preliminary injunction in respect of the said groups, are for purposes of an assessment under Section 34-1, Sub-section 2, of the Civil Procedure Act in any way reasonably proportionate to any lifesaving or life-sustaining needs of the affected patient groups, based on medical assessments, for this type of drug treatment rather than existing treatments, provided that the pharmaceuticals are approved under New Methods.

It is for these reasons not necessary for the Court to address MSD's underlying claim as far as these two reference groups are concerned, including the significance of the competitor BMS not having been exposed to MSD's price information through the distribution of documentation from the pharmacy wholesaler or any other prospect that BMS might have for calculating a level of MSD's discounted price under the existing agreement as the result of both of them having multiple rankings in category 6.1.

There will thus be handed down a ruling to the effect that the petition from MSD is also not granted as far as reference groups 8.2 and 8.3 are concerned.

4. The remaining parts of MSD's claim for an injunction – reference group 5.7

The Court now moves on to assessing whether a preliminary injunction should be granted in accordance with the petition as far as it pertains to reference group 5.7, which concerns pharmaceuticals for first-line lung cancer treatment.

For this reference group, MSD with Keytruda is currently included as the sole supplier of this type of pharmaceuticals, with the outcome of the procurement process being that Sanofi with the pharmaceutical Libtayo is ranked as the first choice, provided that approval is given under New Methods for the introduction of the new indications in respect of this pharmaceutical, while the two dosage variants of Keytruda are relegated to second and third choice rankings.

It must be assumed that Sanofi, like all other suppliers in the market, were exposed to the Norwegian Pharmacy Association's disclosure of total sales revenues for the pharmaceutical Keytruda in the Norwegian market in 2021, either by accessing the Norwegian Pharmacy Association's website as long as the information was posted thereon, or through the reporting of the same information in industry media. It is assumed that Sanofi, like other suppliers, had access to statistics on unit sales, also from its competitors, from the statistics bureau of the pharmacies, and thus would – if it has taken note of the said information – have been able to calculate an approximate level of MSD's discounted unit prices under the existing framework agreement with the health authorities. This possibility is also acknowledged by the health authorities, without anyone having before the Court raised any issue in relation to the fact that the term of the existing agreement commenced on 1 February 2021, while the statistics as presented to the Court concerned the year 2021 as a whole, or in relation to the fact that the sales revenue figures also include the markup charged by the pharmacy wholesaler, which is not information in the public domain. The Court nonetheless assumes that a qualified third party embarking on such a calculation would in any event be able to determine an approximate level for MSD's discounted price for Keytruda under the existing framework agreement. There has been no presentation of evidence in the case as to whether Sanofi has in this way sought to calculate MSD's price.

Sanofi was as a supplier in other reference categories also exposed to MSD's discounted price for Keytruda through the distribution of the spreadsheet in connection with the pharmacy wholesaler's reversed clawback of the purchase price difference between discounted prices charged to the specialist health service and other prices charged to other purchaser groups. Documentation has been presented to the effect that both the pharmacy wholesaler and Sykehusapotekene HF, which manages the health authorities' agreements with the wholesaler, had been in contact with the recipients and obtained confirmation that the information had been deleted on their part. It has neither been argued, nor been presented any evidence purporting to demonstrate, that Sanofi or others that have received the said information have in fact made use of such information in the competitive tendering process.

The arguments invoked by MSD are based on the premise that the discounted unit prices under the existing framework agreement are trade secrets on the part of MSD, which Sykehusinnkjøp was obligated to keep confidential under the provisions in Section 13, Sub-section 1, No. 2, of the Public Administration Act, cf. Section 7-4, Sub-section 1, of the Public Procurement Regulations. As this information was managed on behalf of the health authorities, it is argued that the health authorities are liable for both the error on the part of the pharmacy wholesaler and the Norwegian Pharmacy Association's publication of sales revenue figures for Keytruda. Moreover, it is argued that the fact that confidential information has been subjected to unauthorised disclosure does in any event constitute, in itself, such a disruption of the marketplace that the procurement process cannot be completed for that reason.

Section 13, Sub-section 1, of the Public Administration Act has the following wording:

> *Section 13 (Duty of confidentiality)*
> *It is the duty of any person rendering services to, or working for, a public administrative body, to prevent others from gaining access to, or obtaining knowledge of, any matter disclosed to her or him in the course of her or his duties concerning:*
>
> *1. the personal affairs of any individual; or*
> *2. technical devices and procedures, as well as operational or business matters, which it is for competition reasons important to keep secret in the interests of the person to whom the information pertains.*

The Court is of the understanding, based on MSD's presentation of the facts of the case, that pharmaceuticals manufacturers generally find it in their interest for existing unit prices under agreements with the public health service to be kept secret, partly as the result of the manufacturer having a market-diversified pricing mechanism for the pharmaceuticals it supplies in different markets, and partly because it does not want its competitors to tailor their pricing in response to its price upon renewal of the contract. The Court finds it obvious that these may be legitimate interests on its part.

The Court has noted that Sykehusinnkjøp some years ago concluded, in assessments that have been communicated to the industry, that the unit prices that are submitted in a procurement process and that are included in an ongoing agreement shall be considered trade secrets that are subject to a statutory duty of confidentiality pursuant to Section 13, Sub-section 1, No. 2, of the Public Administration Act. Sykehusinnkjøp has also, in the wake of the mishap that resulted in prices under the existing agreement being available in documentation distributed to the tenderers in the spring of 2022, concluded that this involves information that is subject to a statutory duty of confidentiality. KOFA has in a number of pronouncements stated that specific unit prices, hourly rates and similar may be competition-sensitive. Nor was it in the complaint proceedings before KOFA argued on the part of Sykehusinnkjøp that the information was not confidential as such. Testimony was also rendered by witnesses in the oral hearing to the effect that one would in providing price guidance to new tenderers in relation to approval proceedings under New Methods be vigilant about not entering into any detail on the prices of the pharmaceuticals that have already been approved by Beslutningsforum for the relevant treatment indication.

Consequently, the Court will base its ruling on the premise that information on the supplier's discounted unit prices will as a general rule constitute a trade secret that enjoys protection under the confidentiality provisions in Section 13, Sub-section 1, No. 2, of the Public Administration Act.

It is nonetheless not obvious that the information on the price at which the public health service agrees to procure a pharmaceutical shall be considered a business matter that it is for competition reasons important to keep secret in the interests of the supplier *over time*, as this criterion is stipulated in Section 13 of the Public Administration Act. Keeping such information secret is fundamentally at odds with the right of the general public to access to information on the use of society's resources as reflected in, *inter alia*, the Freedom of Information Act, subject to the limitations laid down in, *inter alia*, Section 13. Although the scope of the duty of confidentiality under

Section 13, Sub-section 1, No. 2, of the Public Administration Act must now be considered in the context of the trade secret protections currently conferred on businesses under the Act relating to Trade Secrets, which implements the obligations of the Norwegian State under EU Directive EU 2016/943, there is nonetheless an analogous tension between secrecy and transparency under EU law as well.

It is therefore appropriate to pose the question of how long such price information shall be considered so competition-sensitive that the supplier continues to be entitled to secrecy. The Court has noted that MSD has stated before the Court that the relevant type of price information may be considered outdated when it is older than one year, but that this one-year period can only be calculated from the expiry of the framework agreement, including the agreed option period, and not from the date of the tendered price under the existing framework agreement, which was tendered on 4 November 2021. The Court assumes that this comes down to an overall assessment, as indicated by the Parliamentary Ombud for Scrutiny of the Public Administration in respect of a complaint against denial of access in Case SOMB-2009-1960, which assessment involves, *inter alia*, considering the supplier's own views in the context of the presumed changes in the market situation for the product at the time of any new competitive tendering round. As noted above, Sykehusinnkjøp was also at the time of the leak of the view that this amounted to a leak of confidential trade secrets.

Based on the assessments that the Court will in the following make in relation to Section 4 of the Public Procurement Act, it will not be necessary for the Court to take any definite view on this, or on whether the duty of the health authorities to secure confidential information in its contract with a third party does not encompass the incident at the pharmacy wholesaler or the Norwegian Pharmacy Association's publication of sales revenue figures. The Court will for purposes of the discussion below *assume* that the price information that was shared by the said parties still constituted trade secrets on the part of MSD, which Sykehusinnkjøp, under its contractual relationships with the pharmacies, was obligated to ensure that the latter kept confidential from third parties.

The Court now moves on to assessing whether the competitive tendering round for a new framework agreement for the procurement of cancer medicines represents a violation of Section 4 of the Public Procurement Act, as the result of unlawful sharing of unit prices under the existing agreement, thus implying that Sykehusinnkjøp has a duty to terminate the procurement process for the indication groups listed in the injunction [petition].

Section 1 and Section 4 of the Public Procurement Act have the following wording:

> *Section 1. Objective*
> *The Act shall promote the efficient use of society's resources. It shall also contribute to public sector integrity, in order to give the general public confidence that public procurement is effected in a manner that benefits society*
>
> *[...]*
>
> *Section 4. Basic principles*
> *The contracting authority shall act in accordance with the basic principles of competition, equal treatment, predictability, verifiability and proportionality.*

After having concluded that Sykehusinnkjøp was liable for the confidential price information having been shared, KOFA based its ruling on MSD's complaint on the following premise:

> *«(51) In this procurement process, «treatment cost» was the sole award criterion for therapeutically equivalent pharmaceuticals. Knowledge of competitors' price level enables suppliers to tailor their tenders. This also applies in a situation in which the recipients have confirmed deletion of the information. Since the tendered price was of decisive importance, the general rule is that there is a low threshold for concluding that the disclosure of unit prices may have impacted the outcome of the procurement process.»*

The parties have during the oral hearing started out, to the same extent, from the general approach adopted by KOFA to this issue when ruling on Janssen-Cilag AS' complaint one month earlier, when it also ruled in favour of the complainant, and in respect of which it stated the following:

> *(33) There is a duty to terminate the procurement process where an error has been committed, provided that such error cannot be remedied otherwise than through termination of the procurement process. There must, in addition, be a distinct possibility that the error may in fact have impacted the outcome of, or participation in, the procurement process; see,* inter alia*, the judgment of the General Court in Case T-345/03, paragraph 147, and the decision of the Complaints Board in Case 2021/683.*
>
> *(34) The Complaints Board will proceed on the understanding that the disclosure of unit prices of pharmaceuticals in Mercell represented a breach of the defendant's duty of confidentiality, cf. Section 7-4, Sub-section 1, of the Regulations, cf. Section 13, Sub-section 1, No. 2, of the Public Administration Act.*
>
> *(35) The defendant argues, however, that changes in the market situation mean that the disclosure of the information has had no impact on the procurement process in the reference groups that include the complainants' pharmaceuticals.*
>
> *(36) The Complaints Board notes that there is in procurement processes in which much weight is attached to the price criterion a low threshold for concluding that the disclosure of unit prices may have impacted the outcome of the procurement process. Knowledge of competitors' price level enables suppliers to tailor their tenders. In the present case, «treatment cost» is the sole award criterion for therapeutically equivalent pharmaceuticals.*

The Court has noted that Sykehusinnkjøp has during the hearing before the Court argued that established practice under the Norwegian statute and under EU law, which the Norwegian public procurement rules are based on, applies an impact requirement that is stricter, from the perspective of the supplier, than that applied by KOFA in paragraphs 33 and 36, as outlined above. The Court finds, based on the facts of the present case, that it is not necessary for the Court to rule on this legal disagreement, since the conclusion of the Court will be the same irrespective of whether one applies one or the other of the two alternative interpretations invoked.

The Court does not, as mentioned, know the discounted prices of the pharmaceuticals addressed in the court order.

All of the tenderers that participated in the procurement process for the reference groups listed in the petition form part of multinational pharmaceuticals groups which operate as competitors in a

large number of markets, and which on a regular basis encounter each other, and are ranked on price, in procurement processes corresponding to the one which the petition is seeking to stop. The Court takes it for granted that one does through coordination internally within these company groups across borders have a well-founded view as to the approximate level at which relevant competitors are pricing their products in the markets that they are operating in or would like to enter. The national distributors, such as MSD (Norge) AS in the present case, do in no way operate on their own in this regard, and this was also clearly reflected in the testimony rendered before the Court by the General Manager of the company.

Since Sanofi was not included under the framework agreement in competition with MSD's Keytruda from before, the Court cannot assume that Sanofi was in a position to calculate a competitor's approximate [price] level on the basis of the existing ranking of the products within a reference category, as has been argued on the part of the health authorities with regard to other tenderers. The Court assumes that such calculations are primarily viable where several suppliers are included with different rankings based on dosage frequency, as is the case under the existing framework agreement with, *inter alia*, the relationship between BMS' and MSD's products in reference group 2.4.

Sanofi's product Libtayo was at the time of the competitive tendering round not finally approved under New Methods as a first-line lung cancer treatment, which is the indication for reference group 5.7, and it was in the procurement documents stipulated that the tendered prices would in such cases form the basis for the assessment under New Methods.

All pharmaceuticals manufacturers that have applied for approval of a pharmaceutical for a treatment indication under New Methods are offered guidance on what price level they must opt for in order to have a prospect of being approved by Beslutningsforum. When approval is sought for a pharmaceutical in respect of a treatment indication for which there is already an approved pharmaceutical, it is under the written guidelines for New Methods a condition that the total treatment cost of the pharmaceutical that a supplier is submitting for assessment under New Methods must reflect a price that entails a lower, or about the same, treatment cost as the pharmaceutical or pharmaceuticals previously approved for the same treatment indication. This is, in the present case, Keytruda from MSD.

Witness testimony rendered before the Court leaves the impression that one will in providing such guidance indicate to the relevant supplier whether it is within what is presumed to be an acceptable level or whether it will have to «somewhat» or «considerably» reduce the price tendered for purposes of the assessment under New Methods in order to have a prospect of obtaining approval from Beslutningsforum. The Court assumes that the form of guidance thus outlined is consistent with Sykehusinnkjøp's duty of confidentiality in relation to competitors that are already included in framework agreements with competing products.

Sanofi's has in relation to the assessment of Libtayo under New Methods for the indication first-line lung cancer, where MSD's Keytruda has until now been the sole pharmaceutical, received price guidance from Sykehusinnkjøp. Sykehusinnkjøp has recorded the following in the minutes of the price guidance meeting on 21 February 2022:

> «*Sanofi must tender a potentially cost-effective price in LIS 2207 prior to the decision of Beslutningsforum and needs guidance.*

Sykehusinnkjøp outlined that there would, in view of pharmaceutical cost and administration costs, be a need for a minor price adjustment in order to be cost effective, although they would in addition have to pay due heed to the travel costs outlined in the procurement documents and would therefore have to correspondingly reduce the pharmaceutical cost in order for the priority criteria to be met.» (emphasis added by the Court)

The Court must on this basis assume that Sanofi had through the price guidance been given a clear direction as to what level its own price would have to be at in order for the treatment cost of Libtayo to be cheaper than or about the same as the treatment cost associated with Keytruda. MSD was on 25 March 2022 informed that Sanofi had received price guidance, and the minutes of the said meeting have been submitted in these proceedings and reviewed during the presentation of evidence, without MSD having argued that Sykehusinnkjøp has violated any statutory duty of confidentiality in providing the price guidance.

The reality of the approval arrangement under New Methods for treatment with pharmaceuticals for indications for which there are already competing pharmaceuticals implies, in the assessment of the Court, a system in which suppliers will, through guidance on the cost level necessary for their own pharmaceuticals to attain a treatment cost that can be approved by Beslutningsforum, also systematically get a good insight into the treatment cost, and thereby also the discounted unit prices of their competitors' pharmaceuticals under the existing framework agreement. The level of precision of such insight into their competitors' prices will depend on whether it is one or more competitors' pharmaceuticals that have already been approved for the relevant treatment indication. For reference group 5.7, MSD with Keytruda was, as mentioned, the sole pharmaceutical under the existing framework agreement.

Existing suppliers must at the same time be expected to know that competing providers that are seeking approval of a pharmaceutical for the relevant indication will receive price guidance that enable such competitors to have a fairly good impression of the treatment cost (and thereby also of the discounted unit price) of the existing suppliers' pharmaceuticals as far as such indication is concerned. If a competing supplier has in addition thereto obtained approval of its pharmaceutical from Beslutningsforum under New Methods, existing suppliers will know for certain that the new competitor has for this indication tendered a price in connection with the approval process that implies that its pharmaceutical will entail a treatment cost that is either lower than, or equivalent to, their own pharmaceuticals.

This creates a dynamic with regard to the annual rotation of the pharmaceutical tenders in which pharmaceuticals in the same reference group are only competing against a ranking based on what pharmaceutical provides the lowest treatment cost.

A certain uncertainty is introduced into the competition situation by way of the scope for a supplier to participate in the procurement process in relation to a reference group before it has obtained approval of its pharmaceuticals under New Methods, provided that the discounted price under the tender is the highest price at which the pharmaceutical is to be assessed under New Methods. Since a pharmaceutical cannot, irrespective of its ranking after the competitive tendering round, be entered into ordinary use until it has obtained approval under New Methods, it may for existing suppliers also be an

element for consideration, in putting together their own tender for submission in the procurement process, whether and, if applicable, when the competitor will obtain approval under New Methods. The Court has noted that MSD takes a different view on the market dynamics of this aspect, especially in relation to Sykehusinnkjøp's assessment of the market situation between MSD, BMS, Roche and Sanofi prior to the call for tenders, as the result of all of the suppliers having applied for approval of their pharmaceuticals for new indications. The objection is partly to do with approval proceedings under New Methods taking time, and partly to do with the outcome for the major suppliers often being a negative decision in Beslutningsforum because the supplier is not willing, or not to a sufficient extent willing, to tender an even more discounted price in order to comply with the cost effectiveness requirements applicable under this arrangement. A key component of the supplier's price deliberations in this regard will be that a reduced price for one indication will result in a reduced price for all indications for which the supplier has included the relevant pharmaceutical. If one has a large patient population for other indications, and the annual growth in patients for such other indications is not high, there may in the suppliers' joint market dynamics be some reluctance when it comes to tendering a lower price than that already included under an agreement. For MSD with Keytruda it is, as mentioned, a known fact that this pharmaceutical is in the top 10 in terms of sales revenues in the Norwegian market. For providers that do not already have large sales revenues for their pharmaceutical, the capturing of market shares from other providers may be a significant motivation factor in the pricing of their tender.

MSD was made aware by Sykehusinnkjøp's letter of 25 March 2022, at the latest, that Sanofi had been given price guidance for its pharmaceutical under New Methods for an indication that generates considerable sales revenues, and for which MSD's pharmaceutical had thus far been the sole pharmaceutical. As a market player, MSD then also knew that Sanofi was in the final stages of approval proceedings under New Methods, with the discounted unit price at which the supplier was willing to tender the pharmaceutical being the main remaining component prior to a final decision by Beslutningsforum.

The Court must also assume that Sanofi, as part of a group that markets and sells pharmaceuticals in many markets, knew that MSD as a competitor also knew this.

The Court thus finds, unlike KOFA, that Sykehusinnkjøp, with regard to the relationship between MSD's Keytruda and Sanofi's Libtayo for reference group 5.7, was correct in its assessment that it made little difference to competing tenderers to be exposed to a more precise specification of the discounted price of MSD's Keytruda under the existing framework agreement than what they already had from open and legitimate sources.

The Court finds, for the same reasons, no basis for MSD's argument that the leak of prices, as well as the situation that the supplier Janssen has found itself in (which is addressed in the Court's other order of today), has resulted in confidence in the marketplace being so low that one must upon application of Section 4 of the Public Procurement Act call a timeout on new competitive tender-based procurements for oncology indications, and instead extend the existing agreement.

For this issue of inclusion under a new framework agreement, the Court is unable to see that there is any difference between the competitors, whether in access to knowledge or in exposed risk. All participants in the procurement process are offshoots of international companies that have interests to attend to for the same products in a number of different markets. If confidence in the Norwegian marketplace is as undermined by these episodes as has been argued by MSD in the present case and by Janssen in the other case that the Court is ruling on today, the Court assumes that one would expect relatively similar conduct from all of them, and the presentation of evidence lends no support to such an expectation. It is noted, for the sake of good order, that it would appear that this argument was not invoked before KOFA, which in any event cannot be said to have based its decision on anything even remotely similar to this invoked perspective.

MSD's reported market conduct as the result of a reported lack of confidence in the marketplace, as presented to the Court in an internal e-mail, and in the testimony rendered before the Court by the General Manager of the company, thus represents choices and prioritisations that must be for the account and risk of the company itself, as a commercial market player.

The Court is on the basis of the above unable to see that there is any real prospect of MSD obtaining, in an ordinary legal action pursuant to Section 8 of the Public Procurement Act, a final and binding judgment resulting in the procurement process having to be terminated on the basis of the exposure to price information that was experienced by some competitors through the exposure of price information under the existing framework agreement.

Nor has MSD thereby been able to demonstrate, on the balance of probabilities, an underlying claim in relation to reference group 5.7, which under Section 34-2, Sub-section 1, of the Civil Procedure Act is a condition for being granted a preliminary injunction. Hence, the petition for a preliminary injunction is **not** granted for reference group 5.7.

5. Summary

The overall conclusion of the Court after the above review is that MSD's petition for a preliminary injunction cannot be granted in relation to any of the health authorities or the health trust named as defendants in the claim for an injunction.

For major parts of the petition, the Court has, without ruling on the underlying claim, concluded that the requirement under the Civil Procedure Act with regard to the necessity of a preliminary arrangement is not met, when considering the difference between the outcome of the new competitive tendering round and the existing agreement that one is in reality seeking to extend. For reference groups 8.2 and 8.3, where all tenderers are included for the first time, a preliminary injunction in accordance with the petition would have resulted in there being no framework agreement for ordinary prescription of these pharmaceuticals to the relevant patient groups. For this part of the petition, the Court has also found that it would be a disproportionate intervention in relation to the patient groups to make such an arrangement, cf. Section 24-1, Sub-section 2, of the Civil Procedure Act.

With regard to the competition situation between MSD and Sanofi in reference group 5.7, the Court has ruled on the petition on the basis that it is unable to see that MSD has demonstrated the underlying claim, on the balance of probabilities. In this regard, the Court's assessment of the facts of the case differs from that of KOFA when it ruled on the complaint from MSD. The Court also notes that the same decisive considerations that led to the Court's conclusion with regard to the said reference group are, in all material respects, also applicable to the competition situation between MSD and the other tenderers.

6. Legal costs

Both parties have moved for their opponent to be ordered to pay the legal costs incurred by the party.

The conclusion reached by the Court means that the health authorities and the health trust named as defendants have prevailed in the case, cf. Section 20-2, Sub-section 2, cf. Sub-section 1, of the Civil Procedure Act, and application of the main rule under the Act means that MSD (Norge) AS shall normally be ordered to pay their full legal costs. The exemption provision under Sub-section 3 has been considered, but has been found to be inapplicable. The Court specifically notes, in relation to this assessment, that the adjudication of the case has not given rise to such doubt as would occasion application of the exemption provision.

There has with regard to part of the preparations for the oral hearing, as well as the oral hearing itself, been effected a joinder of this case with the analogous petition filed by Janssen-Cilag AS against Sykehusinnkjøp HF, for joint proceedings.

Attorney Gulsvik, who has represented all of the defendants in both cases, has filed a joint legal cost specification in the amount of NOK 1,192,575, of which legal fees, excl. Value Added Tax, account for NOK 1,122,575 and expenses account for NOK 70,000. It has been stated that the defendants have the right to deduct input Value Added Tax. At the end of the hearing, none of the claimants had any objections against the amount of the legal cost specification. Since the joinder of the cases has been effected by the Court and the claimants cannot be considered jointly and severally liable co-claimants under the provisions of the Civil Procedure Act, the costs of the defendants must be apportioned between the two cases. The Court is unable to see that there is any basis for a different apportionment than one half for each case. The Court finds that these costs have been necessary costs to adequately attend to the interests of Sykehusinnkjøp and the regional health authorities in the case. This implies that MSD (Norge) AS is ordered to pay, within two weeks of service of the judgment [sic], the total legal costs of the health authorities and the health trust in the amount of NOK 596,287. This ruling is based the assumption that the legal cost amount will be paid to the client account of Attorney Gulsvik, who will thereafter apportion the cost amount between the four health authorities and the health trust.

CONCLUSION

1. The petition from MSD (Norge) AS for a preliminary injunction against Helse Vest RHF, Helse Sør-Øst RHF, Helse Midt-Norge RHF, Helse Nord RHF and Sykehusinnkjøp HF is **not** granted.

2. MSD (Norge) AS, represented by the Chairperson of its Board of Directors, is ordered to pay, within two weeks of service of this court order, the legal costs of Helse Vest RHF, Helse Sør- Øst RHF, Helse Midt-Norge RHF, Helse Nord RHF and Sykehusinnkjøp HF in the total amount of 596,287 – five hundred and ninety six thousand two hundred and eighty seven – Norwegian kroner.

Court adjourned

Richard Saue

Guidance notes on the right of appeal in civil actions are appended.

True transcript certified.
30 November 2022 Richard Saue