Norwegian Medicines Agency

Guidelines for the duty of confidentiality – single technology assessments (STAs)

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Guidelines

There are two cases in particular where it is relevant for the Norwegian Medicines Agency to consider whether information in STAs can be considered confidential:

1) Upon publication of STA reports / decisions on www.noma.no

2) Upon requests for access to information

The Norwegian Medicines Agency is obligated to follow "forvaltningsloven" (the Public Administration Act) and "offentleglova" (the Freedom of Information Act). Some of the information in the case documents may not be public, pursuant to these laws. Before information is made exempt from the right of access, in an STA, the Norwegian Medicines Agency must consider whether there is information in the documents that is confidential. In these guidelines, the Norwegian Medicines Agency clarifies what is generally considered confidential pursuant to the aforementioned laws.

Information that can be confidential

- Applicant's presumptions about future market share
- Offered reimbursement prices that will not be implemented
- Confidential prices, agreed to by other authorities and used in the STA

Information that is not confidential

- Information that is already publicly available

The Norwegian Medicines Agency does not have the authority to exempt whole document packages from the right of access (e.g. a reimbursement application or model) solely based on a private party making a claim of such.

COMPLEMENTARY JUSTIFICATION FOR THE GUIDELINES

Assessment of confidential documentation

There are several legal bases to exempt information from the right of access. In this text, we consider which information is confidential, and which information the Norwegian Medicines Agency therefore is obligated to exempt from the right of access.

Forvaltningsloven (the Public Administration Act) Section 13 ("Duty of secrecy"), subsection 1, number 2 regulates confidentiality for information about "technical devices and procedures, as well as operational or business matters which for competition reasons it is important to keep secret in the interests of the person whom the information concerns". The central limitation of confidentiality is the condition that it must be for reasons of competition that the information is kept confidential. In order for the information to be considered confidential, there must be a possibility of financial loss or reduced profit for the company if the information is known, either directly or through the exploitation of the information by the competition. This must be based on a specific assessment.

Before the information is made exempt from the right of access, the Norwegian Medicines Agency assesses whether there is information in the documentation that is to be considered as technical devices and procedures, as well as operational or business matters and that therefore is subject to a duty of confidentiality. The Norwegian Medicines Agency also gives the pharmaceutical company the opportunity to address whether there is information in the documentation that is to be considered a trade secret.

The Norwegian Medicines Agency makes the decision for what is to be considered subject to a duty of confidentiality under forvaltningsloven (the Public Administration Act) Section 13 ("Duty of secrecy"), subsection 1, number 2.

Publicly available information

Information that is already publicly available, is not confidential.

General requirements of confidentiality

Some pharmaceutical companies operate with the general presumption of confidentiality. The Norwegian Medicines Agency does not have the authority to exempt information from the right of access based solely on a private party making a claim of such. Upon receiving an application for access, we must consider whether the laws provide a legal basis to exempt the concrete information from confidentiality.

If the company claims that information in the application is confidential, the Norwegian Medicines Agency will ask the concerned party to specify which information this concerns and to justify why the

information it is to be considered confidential. The justification should be presented along with the application.

Upon applications for access, the Norwegian Medicines Agency will ask the company to reconsider its position or justify it further, if we consider it necessary.

Redaction of data that pharmaceutical companies or scientists are planning to publish

In regards to unpublished data, where the plan is to publish the data in a scientific journal, the Norwegian Medicines Agency, with the preconditions below, exempt these data from the right of access until the article has been published. When the information has been published in the journal, the Norwegian Medicines Agency removes the redaction.

The Norwegian Medicines Agency will demand that the pharmaceutical company has a plan for the publication of the information. This plan must be delivered in writing to the Norwegian Medicines Agency. If the plan is not received, these unpublished data will not be redacted from the report.

If the Norwegian Medicines Agency receives an application for access to a report/documentation of this kind, the Norwegian Medicines Agency will consider whether the information shall be exempt from the right of access pursuant to offentleglova (the Freedom of Information Act) and forvaltningsloven (the Public Administration Act). A plan for future publication in a journal does not grant the legal basis to exempt the information from the right of access.