



Holbergsgade 6
DK-1057 Copenhagen K

P +45 7226 9000
F +45 7226 9001
M sum@sum.dk
W sum.dk

European Partnership of Supervisory Organisations in Health
Services and Social Care (EPSO)
c/o EURinSPECT
Benoordenhoutseweg 21-23
2596 BA Den Haag

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Section: Sundhedsjura og
lægemiddelpolitik
Case Officer: SUMMSB
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Doc No.: 1242955

Request for a peer evaluation of the supervision function of the Danish Health and Medicines Authority (DHMA)

The Danish Ministry of Health hereby kindly request EPSO to organise and preform a peer evaluation of the DHMA's supervisory function of the health care sector and licenced health care personnel that is preformed according to the Danish legislation named in the Health Act § 212-222 and the Health Personnel Act.

According to the Health Act the main purpose of the DHMA's supervision is surveillance, counseling and supervision.

The Ministry is familiar with the peer evaluation that EPSO performed of the Norwegian Board of Health Supervision (Helsetilsynet) in 2011/12.

The immediate reason for the request is a number of cases brought forward by the press, that have introduced doubt whether the health care supervision of the DHMA lives up to the common expectation and predictability of a national supervisory organisation.

The Ministry therefore kindly request EPSO to coordinate and preform a peer evaluation of DHMA according to the same standards, as the evaluation of the Norwegian Board of Health Supervision.

The peer evaluation should be done respecting the formal conditions such as legislation and budgets, under which the DHMA works.

The aim of the evaluation

The aim of the evaluation is to determine whether the DHMA works in a way that could be acknowledged as good supervisory practice and point out areas of improvement. Focus should be on the methods, documentation and ability to react to and address issues of patient safety in the Danish health care sector.

The DHMA supervision of the health care sector is preformed by one central department (Supervision and Patient Safety) and 3 regional departments (The Regional Medical Health Officers). The peer evaluation shall include all the mentioned departments working with supervision and the collaboration between these in the relevant areas.

The DHMA supervision works with the following three major groups of focus:

- Risk health personnel
- Risk organisations
- Risk areas

The peer evaluation should give focus to the way concerns about licenced health personnel is handled by the DHMA and the reactions to these concerns and the handling of incident cases. The peer evaluation should evaluate if the changes already made by the DHMA in 2011 are sufficient to manage a relevant quick reaction to licenced health personnel that put patient safety at risk.

Also the evaluation should look at the risk organisations where supervision is preformed proactively, such as Nursery Homes, Cosmetic Clinics and Private Medical Care and also the incident handling of risk organisations (case Glosstrup and Herlev).

The handling of risk areas will often result in letters to the whole health care sector or binding guidelines. This task is only performed by the central department of Supervision and Patient Safety. Concrete cases with issues of patient safety in risk areas should include the handling of the use of misoprostol in birth inducement; the radiology case and the mammography case.

The peer evaluation should also include an assessment of how the three risk areas interact and compliment each other considered in an international standard.

It should be up to EPSO to choose subjects to explore outside the areas stated in this request and to elect members of the Peer Evaluation Team. The Ministry assumes that EPSO will handle any conflicts of interest in the connection with the appointment of members of the Peer Evaluation Team.

The Ministry will hope that EPSO will appoint a Swedish or Norwegian member of the Peer Evaluation Team due to translation issues. DHMA will provide necessary translation of documents after further agreement with the Peer Evaluation Team.

The process and results of the peer evaluation should be documented by a written report and we would be grateful if it could be presented for the Ministry at a meeting.

Practical issues

The Ministry hopes that the members of the Peer Evaluation Team can participate as part of their daily work, with permission from their organisations. The Ministry greatly appreciate this possibility.

The Ministry is prepared to cover all direct expenses as costs related to travel and accommodation on field visits in Denmark. As a preliminary budget the Ministry will suggest an upper limit of DKK 300.000,-. Claims for reimbursement of expenses shall be sent to The Danish Ministry of Health, Holbergsgade 6, 1057 Copenhagen K and will be dealt with according to Danish procedures.

The Ministry is looking forward to further corporation on this issue and to receiving a proposed time schedule for the evaluation, which the Ministry will request to commend on as soon as possible.

Yours sincerely,

Mie Saabye