

Peer Evaluation of the Danish Health and Medicines Authority

by the Peer Evaluation Team of the
European Partnership for Supervisory
Organisations in health services and
social care (EPISO)

10th of June 2014 Presentation of the:
**Report of a peer evaluation of the Danish
Health and Medicines Authority,
Sundhedsstyrelsen**

EPISO PEER EVALUATION DENMARK

by the EPISO Peer Evaluation Team members:

Jan Vesseur, (chair)

Geir Sverre Braut,

Glenn Houston,

Jooske Vos.

A Peer evaluation Motivation (1)

Ministry of Health: Letter to EPISO, June 24, 2013:

Request for a peer evaluation of the supervisory function of the Danish Health and Medicine Authority (DHMA):

- **Reason: number of cases brought forward by the press;**
- **Evaluation along the standards used in the evaluation of the Norwegian Board of Health Supervision (2011/2012).**

Aim:

- **Determine whether DHMA works in a way that could be acknowledged as good supervisory practice;**
- **Point out areas of improvement.**

A Peer evaluation Motivation (2)

Ministry of Health: Letter to EPISO, June 24, 2013:

Focus on:

- **Handling of concerns of licensed health personnel;**
- **Handling of incident cases;**
- **Evaluation of changes made by DHMA since 2011;**
- **Supervision of risk organisations with proactive supervision;**
- **Incident handling of risk organisations (case Glostrup and Herlev);**
- **Handling of risk areas (use of misoprostol, radiology case, mammography case);**
- **International standards.**

A Peer evaluation what to expect and what not (1)

A peer evaluation is not:

- **an exhaustive and comprehensive overview of all activities of the regulator;**
- **an investigation of all available information.**

It gives not :

- **a judgement on all political questions;**
- **a vision about causes and consequences;**
- **a historic analyses of how and why, especially not in mentioned cases.**

A Peer evaluation what to expect and what not (2)

A peer evaluation is:

- **ad hoc observation;**
- **by qualified peers -outsiders ;**
- **based on interviews and documentation;**
- **Drawn up in a relatively short period;**
- **mirrored against a set of 'ideal' norms and standards for supervisory organisations.**

It should give :

- **areas for improvement for the organisation and the Ministry;**
- **A constructive judgement against the ideal of best practises of supervisory organisations in Europe.**

A Peer evaluation what to expect and what not (3)

We hope that:

- the Ministry of Health and
- the Danish Health and Medicines Authority,

will find the report;

- useful in helping to take its supervisory functions forward;
- working towards a 'best practice organisation' delivering the supervisory function in health care in Denmark.

A horizontal collage of images at the top of the slide, including a modern building facade, a hospital interior with medical equipment, and a close-up of a person's face.

DHMA Peer evaluation Scope and Approach (1)

EPISO identified 13 key areas as standards of good practice for supervisory organisations in Europe,

based on Standards for supervisory bodies by International Society for Quality in Healthcare (ISQua) and ISO/IEC standard 17020:1998.

A collage of images in the top left corner, including a modern office interior with a table and chairs, a close-up of a person's hands working on a laptop, and a circular graphic element.

DHMA Peer evaluation Scope and Approach (2)

The PE-team evaluated the arrangements of DHMA against 13 standards :

- 1. statutory basis clear and functions clearly defined;**
- 2. independence, impartiality and integrity;**
- 3. confidentiality and safeguarding of information;**
- 4. organisation and management;**
- 5. quality systems;**
- 6. personnel;**

A collage of images in shades of blue and white, including a grid pattern, a meeting room with people around a table, and abstract geometric shapes.

DHMA Peer evaluation Scope and Approach (3)

The PE-team evaluated the arrangements of DHMA against 13 standards:

- 7. facilities and equipment;**
- 8. inspection methods and procedures;**
- 9. engagement and communication with the organisation or individual subject to review;**
- 10. openness and transparency;**
- 11. disciplinary sanctions;**
- 12. impact assessments; and**
- 13. co-operation and engagement with other stakeholders including other supervisory bodies.**

A horizontal banner at the top of the slide features a collage of images: a modern office interior with a desk and chairs, a close-up of a person's hands working on a laptop, and abstract blue and white geometric patterns.

DHMA Peer evaluation Scope and Approach (4)

Methods used by the Peer Evaluation Team:

**(free to choose working methods and discussion partners;
privacy fully respected):**

- **reviewed key strategy and operational documents;**
- **interviewed key members of management, staff and stakeholders; (group discussions with members of staff (> 50);**
- **reviewed samples of work taken forward by the supervisory part of DHMA.**

DHMA Peer evaluation Scope and Approach (5)

Result of this working method:

- **13 chapters with Conclusions;**
- **57 Recommendations (overview in appendix 6);**
- **6 Main focus points for improvement (see executive summary);**
- **Report does not include reference to individuals or organisations who informed the Peer Evaluation team.**

Overall findings

The Peer Evaluation Team found :

DHMA :

- **Is a well led, professional organisation;**
- **Is an ambitious, open and learning organisation striving for best practice and good outcomes for patients and the general public;**
- **DHMA is achieving efficiencies within financial constraints;**
- **DHMA has faced significant challenges in respect of maintaining a focus on supervision whilst undergoing transition.**

Main focus for improvement (1)

- 1. Clear Communication lines (internal and external)**
- 2. Prioritisation and risk assessment based on division of tasks between 'obligation to act' and 'opportunity to act'**
- 3. Feedback mechanisms**
- 4. Management of expectations**
- 5. Co-ordination and quality management**
- 6. Independent Organisational Context of the Supervisory arm of DHMA**

Main focus for improvement (2)

1. Clear Communication lines (internal and external)

Internal communication:

Relationship central and the regional offices require significant improvement. (unresolved tensions with impact on the way the organisation delivers its supervisory functions)

External communication:

Sharing information is actively developed. Nevertheless more could be done to involve the public, the press and other stakeholders in sharing their experiences and views to improve supervisory practice, and in seeking their views and experiences by using other networks including social media.

Main focus for improvement (3)

2. Prioritisation and risk assessment is main challenge

Report provides indications for improvement based on

- division of tasks between ‘obligation to act’ and ‘opportunity to act’,**
- sound interpretation of the legislation agreed between Ministry and DHMA**
- communicated with the wider public.**
 - need strong and guided support from the Ministry and**
 - over time, change in the legislative and /or budgetary context.**

Main focus for improvement (4)

3. Feedback mechanisms

- **questions as to how DHMA is informed on matters of non-compliance and risk;**
- **feedback procedures are not functioning in an active and timely manner;**
- **important opportunities to improve performance in this area.**

Main focus for improvement (5)

4. Management of expectations

- **DHMA is through its supervisory functions held responsible for matters which ought to be placed primarily or at least shared with others, including service providers.**
- **DHMA needs to be clear as to the limitations of its role and responsibilities so that the organisation can concentrate on its primary duties and tasks.**

Main focus for improvement (6)

5. Co-ordination and quality management

- **Co-ordination of tasks and quality management are not yet functioning appropriately and therefore important focus points (critical issue for improvement);**
- **The peer evaluation identified a number of possibilities to improve on these topics.**

Main focus for improvement (7)

6. Independent Organisational Context of the Supervisory arm of DHMA

The independence of the supervisory aspects of the role of DHMA is not in all circumstances clearly defined and transparent;

The supervisory arm of DHMA should develop - in consultation with its key stakeholders- a strategic vision stating its mission, values and how to adhere to core principle of remaining independent and autonomous.

The EPISO Peer Evaluation Team thanks


We are very grateful for the support and co-operation of:

- **management and staff of the Danish Ministry of Health (especially those directly involved in this project);**
- **The support from all departments of DHMA;**
- **All representatives of stakeholders, partner organisations, health institutions and others who all -without exception- accepted our invitation to speak with us.**

The EPISO Peer Evaluation Team follow up

Some remarks about the follow up of this report ?

- 1. The Peer Evaluation Team has no role as to the follow up of this report;**
- 2. It is easy to predict that things will not easily change by itself;**
- 3. It might be necessary to find out what is keeping things as they are;**
- 4. The Team could - if being asked - provide some background and outside views to find ways for improvement based on the recommendations of the report.**



Report of a peer evaluation of the Danish Health and Medicines Authority (Sundhedsstyrelsen)

EPSON peer evaluation report

EPSON contact

c/o EURINSPECT, Ms. Joeske Vos
Benoordenhoutseweg 21-23

2596 BA Den Haag

The Netherlands

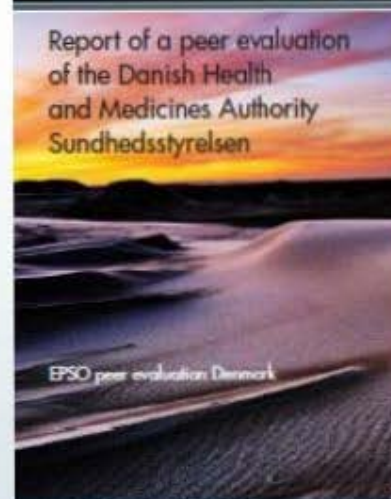
T +31703142458

M +31613163557

info@epsonet.eu

info@eurinspect.eu

www.epsonet.eu



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EPSON peer evaluation Denmark



Performed by a delegation of the European
Partnership of Supervisory Organisations in
Health Services and Social Care
(August 2013 – June 2014).

10th of June 2014



EPSON: European Partnership for Supervisory Organisations in Health Services and Social Care
to improve the quality of health care and social care in Europe;
to connect between supervisory organisations and their individual members;
to improve exchanges of ideas, outcome of research, information and good practice;
to promote co-operation on topics such as education and dissemination of knowledge