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

EPSO PEER EVALUATION DENMARK[1]

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Foreword

The EPSO[2] Peer Evaluation Team[3] is pleased to present this report to the Danish Ministry of Health (Ministeriet for Sundhed og Forebyggelse). This peer evaluation is the second of its kind and has, provided an important opportunity for the participants to learn from one another, to compare knowledge of working methods, styles and circumstances in various European countries with the working methods in Denmark, and to identify opportunities to make improvements.

We hope that the Ministry of Health and the Danish Health and Medicines Authority, Sundhedsstyrelsen, (DHMA), will find this 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. The report will demonstrate to stakeholders that the Danish supervisory authority is performing well in a considerable number of areas. Nevertheless, the report also identifies areas for improvement.

Those reading this report will find that at some points it is critical of current practice, and this is indeed the case. However, as this is a peer evaluation any criticism has to be seen as constructive between peer organisations, and is made with the intention of facilitating improvement, based on experiences elsewhere.

The findings and recommendations are addressed not only to the supervisory organisation DHMA, but also towards the Ministry of Health. The evaluation acknowledges the political context which may have influenced, over time, a supervisory system in which some elements are not conducive of best practice. This is especially the case when we look at opportunities to improve risk assessment and prioritisation within regulation of the Danish healthcare system.

We found that DHMA is a well led, professional organisation. DHMA has faced significant challenges in respect of maintaining a focus on supervision whilst undergoing transition, and achieving efficiencies within financial constraints. The Peer Evaluation Team found an ambitious, open and learning organisation striving for best practice and good outcomes for patients and the general public.

We are very grateful for the support and co-operation of the management and staff of the Danish Ministry of Health, especially those directly involved in this project, as well as to the direct and indirect support from all departments of DHMA.

This report and its findings could not have been realised without the full co-operation of all those who met with the Peer Evaluation Team. We are greatly indebted to all representatives of stakeholders, partner organisations, health institutions and others

[2] EPSO see Appendix 1
[3] EPSO Peer Evaluation Team Danish peer evaluation see Appendix 2

who actively engaged with us throughout this evaluation. All those who were asked to meet with the evaluation team agreed to do so, without exception. They provided insight into the working of DHMA and its supervisory departments, as well as insight into the functioning of the Danish healthcare system. We owe them many thanks.

The Peer Evaluation Team

Executive Summary

In June 2013 the Danish Ministry of Health asked The European Partnership of Supervisory Organisations in Health Services and Social Care (EPSO) to perform a peer evaluation of the supervisory function of the Danish Health and Medicines Authority (DHMA).

The request from the Danish Ministry of Health was to assess how effectively DHMA fulfils the common expectations and requirements of a national supervisory organisation.

The Peer Evaluation commenced in August 2013. In November 2013 the Peer Evaluation Team reviewed documents and interviewed more than 50 individuals including representatives of management, staff and external stakeholders.

This peer evaluation made use of the 13 EPSO standards of good practice for supervisory organisations, based on the ISO/IEC standard 17020:1998.

From the conclusions and the 57 recommendations the Peer Evaluation Team identified the following key areas for improvement:

1. **Clear Communication lines (internal and external)**

Internal communication: The relationships between the central and the regional offices require significant improvement. There are unresolved tensions which are impacting on the way the organisation delivers its supervisory functions. Clear communication lines and lines of responsibility between the central office and the regional departments, and between the departments and the Board of Directors, is a major point of attention.

External communication: Sharing information is an important and actively developed task of DHMA, but this does not always happen in a planned and structured way. 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.

2. **Prioritisation and risk assessment based on clear division of tasks between 'obligation to act' and 'opportunity to act' in relation to a sound interpretation of the legislation agreed between the Ministry and DHMA and communicated with the wider public.**

Risk assessment and prioritisation in the work of the supervisory functions of DHMA is a main challenge for the organisation. The Report provides indications for improvement. An approach including successful prioritisation and risk assessment will however need strong and guided support from the Ministry and, over time, a change in the legislative and / or budgetary context.

3. Feedback mechanisms

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

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.

5. Co-ordination and quality management

Co-ordination of tasks and quality management are not yet functioning appropriately and therefore is an important focus points for the organisation. These topics should be a critical issue for improvement. The peer evaluation identified a number of possibilities to improve on these topics.

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 it will adhere to the core principle of remaining independent and autonomous.

Introduction to the report

The Request from the Ministry to EPSO

A request for a peer evaluation [4]of the supervision function of the Danish Health and Medicines Authority (DHMA), including the supervisory functions of the health care sector and the licensed health care personnel performed according to the Danish legislation, was issued on 25-06-2013 by the Ministeriet for Sundhed og Forebyggelse (The Danish Ministry of Health), to the European Partnership for Supervisory Organisations in Health Services and Social Care (EPSO).

In 2011/2012 EPSO had completed a peer evaluation of the Norwegian Board of Health Supervision, (Statens Helsetilsyn). This peer evaluation used, as a framework, standards agreed by partners from other inspectorates in Europe, and focused on a range of quality objectives.

The context for the request by the Danish Ministry of Health was a number of high profile cases, that had introduced a concern as to how well health care supervision in Denmark lives up to the common expectations and predictability of other national supervisory organisations.

The Ministry invited EPSO to co-ordinate and perform a peer evaluation against the set of standards used in the evaluation of the Norwegian Board of Health Supervision.

The peer evaluation was undertaken in the context of respecting the legislative framework and budgets under which DHMA works.

The Ministry proposed that the aim of the evaluation was to determine whether DHMA works in a way that could be acknowledged as good supervisory practice, and to identify areas for improvement.

The Ministry referenced in a letter of June 24th 2013, under the heading: 'The aim of the evaluation' a number of areas and topics which should be considered in the peer evaluation, these included:

- methods to address issues of patient safety;
- documentation used to address issues of patient safety;
- ability to react to issues of patient safety;
- including attention for all departments of DMHA (supervision and patient safety and the three regional departments) and the collaboration between these departments;

[4] See Request letter Appendix 3

- including the way concerns and the reaction to these concerns about licensed health personnel is handled, including the changes made by DHMA in 2011 regarding management of a quick reaction to licensed health personnel that put patient safety at risk;
- the way incident cases are handled;
- the way risk personnel, risk organisations and risk areas are handled;
- the way binding guidelines are used;
- special attention for some concrete cases with issues of patient safety in risk areas such as the case regarding the use of misoprostol, the radiology case and the mammography case;
- the way the proactive supervision of risk organisations (nursing homes, cosmetic clinics, private medical care) is performed;
- the way incidents of risk organisations are handled;
- an assessment of how the risk areas (risk health personnel, risk organisation and risk areas) interact and complement each other considered in an international standard.

In the letter to EPSO the Ministry mentioned that it would be up to EPSO to identify any other subjects to be explored, outside the above stated areas.

Furthermore, it was up to EPSO to identify and select members of the Peer Evaluation Team and to handle any conflicts of interest of members of the team. The Ministry expressed a wish to have a Swedish and Norwegian member of the team, due to translation issues.

The process and results of the peer evaluation were to be documented in a published report to be presented to the Ministry at a date to be agreed with the Peer Evaluation Team.

The Response from EPSO

In response to this letter EPSO discussed e.g. in a meeting with members of the Peer Evaluation Team and members of the Ministry on the 28th of August 2013 specific points before the request to organise and perform the peer evaluation was accepted and the peer evaluation commenced.

For reasons of good and independent fact-finding by the Peer Evaluation Team, the first point discussed with the Ministry was the Freedom of Information, including the freedom for the team to speak in private with respondents, and the right of the team to refuse to disclose information from the interviews or discussions with the Peer Evaluation Team. The team wanted to be in a position to speak with all respondents in private, which meant that information shared with the team by individual respondents would be treated in strict confidence. This was agreed as an appropriate pre-condition.

The second point was the request of the Ministry regarding the specific cases mentioned in their letter. The Peer Evaluation Team clearly stated that they did not feel it would be appropriate for a peer evaluation to investigate the circumstances and to make a determination on specific cases. Although the Peer Evaluation Team agreed that information received from third parties regarding these cases would be taken into account, the team indicated that the aim of the peer evaluation is not to determine the appropriateness of decisions in specific cases, but to evaluate the effectiveness of the supervisory functions of DHMA, and to provide an opinion in relation to the quality standards used in the peer evaluation. This approach was agreed before the request was accepted by EPSO.

A third point was the overall approach by EPSO to this peer evaluation. As requested by the Danish Ministry, EPSO agreed to apply the same principles and methodology applied in Norway as the guiding principles for this evaluation. The points mentioned in the letter from the Ministry were to be taken into consideration within that framework, as background material and, where possible, afforded particular attention.

Furthermore the Ministry sought and received advice on the question of confidentiality and the integrity of the peer evaluation. In recognition of the outcome of its advices, the Peer Evaluation Team signed a declaration of confidentiality[5] and a statement of integrity[6].

A final point of discussion was the presentation of the report and the working procedures of EPSO.

EPSO agreed to send the draft report without conclusions and recommendations for a factual accuracy check to the Ministry, and to send afterwards the final report, including the conclusions and recommendations, together with a Danish translation, to the Ministry. The Ministry was of the view that the final report had to be sent actively to Parliament and to the Danish press. The EPSO Peer Evaluation Team agreed with this approach and proposed to present the final report on the 10th of June 2014 to the Ministry.

The Scope and Approach of the EPSO peer evaluation

In developing the scope and approach for this Danish EPSO peer evaluation careful consideration was given to the standards that other organisations have developed for supervisory and audit bodies, including those set by the International Society for Quality in Healthcare (ISQua) and ISO/IEC standard 17020:1998[7].

EPSO identified 13 key areas that were to be considered as standards of good practice for supervisory organisations in Europe. These EPSO standards are based on the above mentioned ISO standards, on good practice from EPSO member states

[5] See Appendix 5
[6] See Appendix 5
[7] General criteria for the operation of various types of bodies performing inspection

and the principles discussed within the EPSO context by the EPSO members. The Standards are not fixed, in the sense that they will not change over time. They may be adapted to take account of research developments, new developments in supervisory practice and new doctrines and theoretic developments regarding supervisory practice. Each new peer evaluation will add to the knowledge base on best practice.

The team examined and evaluated the arrangements that DHMA has in place to ensure that its statutory basis and functions are clearly defined, and that it has satisfactory arrangements in place in relation to:

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;
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.

Methods used in the peer evaluation

The Peer Evaluation Team :

- reviewed key strategy and operational documents[8];
- interviewed key members of management, staff and stakeholders;
- held group discussions with members of staff;
- reviewed samples of work taken forward by the supervisory part of DHMA in relation to:
  - incident investigation;
  - planned inspections;
  - risk assessment.

The Peer Evaluation Team was free to choose its own discussion partners and interviewees and to apply particular working methods. The team was assisted by the Ministry in identifying people and organisations. All of the people who were asked to participate in the peer evaluation did so in one way or another. Not everyone was

[8] See documents reviewed Appendix 4

able to come to Copenhagen, therefore the team travelled to other parts of Denmark, and used teleconference facilities to speak with some respondents.

Respondents were given the opportunity to provide a factual accuracy check of the notes of their interviews. The draft report (without conclusions and recommendations) was checked for factual accuracy by the Ministry and, on request of the Ministry, by the supervisory division of DHMA. The comments to the draft version of the report have been reviewed by the Peer Evaluation Team and used where appropriate to inform the final version of this report. The information from the respondents is aggregated in this final report.

A summary of the documents reviewed is provided at Appendix 4.

As the interviews were confidential and the Peer Evaluation Team had guaranteed to the interviewees that their identity was not being revealed in the final report, this report does not have a list of interviewed persons or organisations.

The Team has conducted more than 25 interviews and spoken to more than 50 people from all parts of Denmark (regions) and from various backgrounds, and various types of healthcare organisations (i.e. management, staff and external stakeholders).

The team did speak with people working at various levels in the healthcare organisations, in government, in the supervisory department of DHMA, and within the wider DHMA organisation.

Chapter 1

Is the statutory basis of DHMA clear and has its functions been clearly defined?

The supervisory body or the organisation of which it forms part should:

- be legally identifiable;
- have a documented function defined by legislation and its area of competence shall be clearly defined; and
- have documentation describing the goals and responsibility of the inspection body.

1.1 Legally identifiable

The statutory basis, including the general powers of the Danish Health and Medicines Authority (DHMA), is defined in Title XVII, Part 66 of the Health Care Act, sections 212 – 221. This part of the Health Care Act includes the general powers for DHMA, along with DHMA's supervisory functions. In addition, the wider functions, such as Evaluation, and promoting quality improvement of healthcare, are referenced in these sections.

The legal framework does not make a strict distinction between the general and supervisory powers of DHMA. Fundamental supervisory powers, including the registration of health care providers, are specifically mentioned in sections 215, 215a, 215b, 219 and 220. Other sections, such as 213 on surveillance and monitoring of health conditions, updating professional knowledge and providing information to the public and to competent authorities in the health area, and 214 on guidance of the health care services and advice to authorities etc. are closely related to supervision, but have a broader scope than supervision (in Danish: Tilsyn), with its more traditional and specific connotation. Sections 213 and 214 are very important to understand the role of supervisory practice in Denmark and the way it uses information (informing, guidance, advice and monitoring) to improve patient safety in the health sector.

Regarding decisions on registration (section 215b), DHMA is the only designated authority with the remit to determine requirements and suspending activities. These responsibilities, including the sanctions available to DHMA, are clearly defined in the legislation.

The roles and responsibilities of DHMA relating to authorisation and sanction of individual healthcare personnel are also defined in the Act (see Chapter 11).

Assistance to judicial and police authorities is explicitly mentioned in section 218, but is limited to an extent determined by an agreement between the Ministers of Justice and Health.

The description of the powers in the various sections is clear but not balanced. Some sections such as 215a, 215b and 219 contain very many detailed obligations for the regulator and allow little scope for professional judgement regarding the best way to handle supervision in this context. For instance ‘risk based supervision’ or a balanced mix between announced and unannounced inspections can only be achieved if the legal framework provides DHMA with the necessary authority to use its powers, and the available resources, to supervise in a balanced way.

The formal relationship between the central organisation and the regional offices (embedslægerne) is clearly defined in section 212, paragraph 2, of the Health Care Act as ‘part of the agency’. Nevertheless, there are different opinions inside the organisation related to the autonomy and governance of the regional offices (see findings under Chapter 4). Apparently the definition of being ‘part of the agency’ is not unanimously understood.

The statutory duties and responsibilities of the Danish Health and Medicines Authority are clear, but the legislation gives rise to ambiguity regarding the regulator’s ability to set priorities within the legal framework. Traditionally the supervisory functions, as defined in the legislation, have been reactive. But the supervisory powers of DHMA have evolved over time to facilitate a more proactive approach to supervision, with significant revisions made in 2002 (nursing homes); 2007 (planned supervision); 2008 (cosmetic clinics); 2010 (extension of powers); 2012 (inspection of private clinics), and in 2013 (further extension of powers (sanctions and proactive powers, ‘requirements’) regarding the evaluation of provisions and inspection of healthcare in the public sector, (section 215b).

The people interviewed by the Peer Evaluation Team (the respondents) claim that it is too soon to say with certainty how and to what extent the additional powers granted in 2013 will impact on the proactive investigation of issues and concerns in public hospitals throughout Denmark.

Whilst statutory powers have increased, this has happened in an era of financial austerity which has resulted in a 20% reduction in the revenue allocation to DHMA, with an associated reduction in capacity.

A number of respondents stated that the legal obligations of DMHA are too restrictive and limit opportunities for independent decision making about which facilities should be inspected routinely, and which should be inspected according to a risk based approach.

1.2 Documented function defined by legislation and its area of competence shall be clearly defined

The supervisory functions and formal competences related to supervision are described in detail in the legislation (see chapter 1.1).

In those areas where DHMA has specific supervisory obligations stated in legislation, standards have been developed against which to measure the performance of service providers under supervision.

Some respondents felt that there is an imbalance between the powers available to DHMA in respect of private health care providers, in comparison with the powers to inspect public hospitals. There would appear to be no proactive supervision of services delivered through public hospitals, with the exception of specific investigations following reported incidents.

There is a sense amongst staff in both the central office, and in the regional offices, that DHMA is being asked to undertake additional responsibilities with relatively fewer resources at its disposal.

Whilst DHMA has the statutory authority to engage in proactive supervision its main focus, to date, has been responding to alleged failings of individual clinicians (reactive supervision).

1.3 Documentation describing the goals and responsibility of the inspection body

Comprehensive documentation describing the overall goal and responsibilities of DHMA was not readily available. The supervisory functions are only partially dealt with in the annual contract between the Ministry of Health and DHMA.

Although the Peer Evaluation Team was advised that an annual work plan is in place (see section 4.5), none of the respondents made any reference to either a corporate strategy or to an annual plan, setting out the strategic mission and operational goals of DHMA.

DHMA has focused its activities on reactive supervision and reactive measures. The Peer Evaluation Team was advised that as a consequence of that focus, the organisation has not got the capacity to drive planned supervision and inspections in the public sector.

There is a sense among respondents that health supervision in Denmark is changing, with a desire to move towards a more proactive approach. However, this is tempered by a concern that public expectation may exceed the capacity of the organisation to respond to new priorities. This was expressed by respondents indicating that the organisation cannot do everything that is expected of it.

There was a sense that inside the organisation, both at central and regional level, some tasks are undertaken in response to external pressures, and that DHMA is not as independent of the political system as it could or should be.

Chapter 1 Conclusions and recommendations

Conclusions chapter 1

1.1 Legally identifiable

The supervisory functions of DHMA are legally identifiable and clearly stated. However the supervisory functions are not clearly separated from the additional responsibilities of DHMA. The close connection in the Health Care Act between the supervisory functions and the additional responsibilities of DHMA raises questions about how far the supervisory functions go, and whether there is sufficient independence from the Department of Health (see chapter 2 on independence). This close connection between DHMA and the Department of Health gives rise to expectations of DHMA from outside the organisation which cannot be fulfilled.

1.2 Documented function defined by legislation

The responsibilities of DHMA are stated within the legislation and its area of competence is clearly defined. However the legal basis for the supervisory powers and obligations of DHMA are clear but not balanced, and therefore also not balanced in its effects. Some sections in the legislation contain very detailed obligations for the regulator, with limited opportunity to exercise discretion or professional judgement regarding the best way to handle supervision. Other sections are open to interpretation but provide no clear indication as to how they should be implemented. The definition and application of DHMA's statutory obligations is to some extent open to interpretation. This can give rise to questions as to how far the statutory obligations should be applied, and whether a wider interpretation is possible. If a narrow interpretation is taken, the system will always be perceived as reactive and unbalanced.

As available resources are limited, DHMA cannot make a balanced and open choice between the legally prescribed tasks and obligations and the more generally described tasks and functions. The effect is that the supervisory tasks of DHMA are mainly focused on its statutory responsibilities. This legal obligation makes it difficult for DHMA to be proactive in pursuit of the public interest and to engage in proactive supervisory activities based on a professional risk based approach.
The legal basis for the supervisory responsibilities of DHMA requires the organisation to focus on its core priorities. Even if the legal framework were permissive, the supervisory system has some unbalanced elements within it. It is important therefore that the legal boundaries are reviewed so that DHMA has the authority to act confidently and proactively within the law, and also in the public interest.

1.3 Comprehensive documentation describing the goals and responsibilities

A comprehensive document describing the goals and responsibilities, while limiting too high expectations of the inspection body as part of DHMA, is not readily available. A corporate strategy and an annual business plan - of any substance - setting out the strategic mission and operational goals of the inspection body as a whole is not available. The annual contract between DHMA and the Ministry of Health, and the annual work plan cannot be substituted for an appropriate strategy and business plan.

Recommendations chapter 1

1.0 DHMA must organise a clear division between the supervisory tasks and its other statutory responsibilities.

2.0 The supervisory task should be clearly identifiable and balanced and defined by statute in such a way that it allows DHMA to make the best use of all available resources. DHMA should determine its supervisory priorities by focusing its activities in areas which will best serve the interests of patients and the wider public.

3.0 DHMA must have a clear and appropriately resourced strategic plan setting out the key objectives of the supervisory arm of the organisation and how its performance will be measured over time. This strategy has to clarify and define the boundaries of the supervisory tasks of DHMA and incorporate a risk based approach to priority setting (see for priorities chapter 8.4).

4.0 DHMA must determine its core priorities and how it will use its limited resources to best effect in providing the Minister, elected representatives and the general public with assurance as to the quality and safety of healthcare provisions across Denmark. It must determine priorities by focusing on activities in areas which will best serve the interests of patients and the wider public (see for priorities chapter 8.4).

5.0 DHMA needs to be clear as to the limitations of its role and responsibilities so that the organisation can concentrate resources on its primary duties and tasks. There ought to be clear procedures related to where DHMA has an "obligation to act" and where DHMA has an "opportunity to act". If no distinction is made between these categories and the obligation to act is specified in legislation, DHMA will have no opportunity to exercise professional discretion as to the broader scope of its tasks. The division between opportunity and obligation to act must rely upon sound interpretation of the legislation, agreed between the Ministry and DHMA and communicated with the wider public.

6.0 Before DHMA extends its role into proactive supervision of public hospitals, it must be confident that it has robust systems and processes in place to discharge all of its core functions.

Chapter 2

Is DHMA independent, objective, impartial and is its role delivered with integrity?

The supervisory body should have processes and systems in place that ensure that:

- its independence is safeguarded to the extent that is required with regard to the conditions under which it performs its services. As a supervisory body, its dependence or independence of the political system should be defined;
- it remains impartial to the influence of key stakeholders (umbrella organisations, press);
- its personnel are clear and understand what is required of them to ensure that they act with integrity at all times; and
- personnel do not have a conflict of interest in relation to the area of work that they are required to perform. Procedures should be implemented to ensure that experts assisting the inspection body in specific cases declare a statement about conflicts of interest, for example political, commercial, financial pressure.

2.1 Its independence is safeguarded to the extent that it is required with regard to the conditions under which it performs its services. As a supervisory body, its dependence or independence of the political system should be defined.

The supervisory functions sit within and are funded directly by the overall budget of DHMA. The Director General of DHMA can exercise significant influence and control over the activities of both the central and the regional offices.

Outside influence is not seen by all respondents as being entirely benign or impartial.

Some decisions were described as influenced by political expediency. Staff explained that on occasions political considerations, and the influence of the media, can bring undue pressure to respond to specific events.

The Head of Division Supervision and Patient Safety (Tilsyn and Patientsikkerhed) of DHMA, has a pivotal role in preserving the independence of the supervisory functions and in protecting DHMA from undue influence. This is considered to be an important leadership responsibility.

Boundaries for the supervisory functions are not clearly understood by all stakeholders, and they have called for clarification of the ability of the supervisory arm of DHMA to remain within but to act independently of the rest of DHMA, (see also chapter 1).

Some respondents raised a concern over the close contact between the Ministry of Health and DMHA which could compromise the independence of the actions of DHMA in supervisory cases.

It was notable that in recent cases, neither the Parliamentary Ombudsman nor the Auditor General had challenged the integrity of the supervisory functions of DHMA.

DHMA has a relatively large number of stakeholders, and must engage with a range of external parties, both public and private, with their own tasks and obligations, some of which are closely related to the functions of DHMA.

The supervisory system is not perceived to be fully transparent, as it is not easy for individuals from outside DHMA to understand who is doing what, and why. An example of this complexity can be found in the way information is shared between the patient ombudsman ('Patientombuddet') and DHMA, and in the way DHMA uses this information to best effect.

2.2 It remains impartial to the influence of key stakeholders (umbrella organisations, press)

In general, respondents felt that the regulator acts impartially and is not constrained by undue influence from third parties. Examples were quoted of how the supervisory authority maintains independence in the face of political or media pressure to act in a partial or irrational manner.

Representatives of umbrella organisations generally spoke positively about relationships with DHMA and felt that the organisation was approachable and had been responsive to requests to meet with them.

There was some uncertainty as to when a matter should be taken up with the regional offices or with the central office, but in general DHMA was described in positive terms by those who interact with it on a regular basis.

The central office fronts almost all media interviews. A concern was expressed about the need to develop a robust communications strategy (see chapters 9 and 10).

2.3 Its personnel understand what is required of them to ensure that they act with integrity

Respondents who met the Peer Evaluation Team stated that they are clear as to their statutory duties, and are able to act with integrity.

There are tensions between the priorities of the central office and the priorities of the regional offices. This has its origins in the structural reorganisations which have taken place since 2006.

There are competing priorities between the public health and supervisory functions of the Regional Medical Officers. Not all doctors in the regional offices take part in supervisory functions. Many of the public health functions have no direct bearing on supervision, which raises a question as to the sustainability of the current structures.

The legal support for all supervisory work (both at regional and central level) is located in the central office. Whilst this makes for ease of co-ordination of complex cases, and adds some economy of scale, which is important for quality reasons, it means that any investigation requiring legal intervention is usually passed to the central office. Responsibility for the co-ordination of the investigation (between Public Health Medical Officer and the Central Office) may also shift to the Central Office, subject to the decision of the task force. This is not making optimum use of the skill sets of the RMOs in the regional offices.

Relations between central and regional offices are also addressed in chapters 4, 5, 6, and chapter 8 for comments regarding the ‘task force’.

2.4 Personnel do not have a conflict of interest in relation to the area of work that they are required to perform. Procedures should be implemented to ensure that experts assisting the inspection body in specific cases declare a statement about conflicts of interest, for example political commercial, financial pressure

Staff did not express conflicts of interest, and in general felt well supported by managers, particularly in circumstance where decisions are challenged by third parties.

Some staff did express concern about perceived threats to the integrity of the organisation as a consequence of external interference in specific matters, and stated that on some occasions political expediency may influence operational decisions.

Chapter 2 Conclusions and recommendations

Conclusions chapter 2

2.1 Independence defined

The independence of the supervisory functions of DHMA is clearly described in the legislation. But, the legal structure includes requirements related to supervision, along with duties and responsibilities related to other tasks of DHMA. The independence of the supervisory aspects of the role of DHMA is not, in all circumstances, clearly defined and transparent.

The independence from other, external parties, public and private, is evident and is maintained at all levels and for all supervisory functions. This independence is accepted and is not challenged. It seems however that DHMA, through its supervisory functions, is held responsible for matters which ought to be placed primarily, or at least shared with others, including service providers.

2.2 Impartial to the influence of key stakeholders

The influence of the media is a significant factor and more could be done to improve relations with the media, and to strengthen the decision making arrangements for responding to requests from the media for statements about specific investigations. The relations with the media seem to be more reactive than proactive. Although the outcomes of investigations are actively published, interaction with the media appears to be focused on the need to protect the healthcare system rather than to be open and transparent about the circumstances of individual or organisational failures.

2.3 Personnel understand to act with integrity

Personnel engaged in supervision understand what is required to ensure that they act with integrity. Personnel do not have conflicts of interest in relation to their work, but perceive some external interference driven by political expediency as a problem for the organisation as a whole. Specific procedures for experts to prevent conflicts of interest were not mentioned, but integrity in relation to experts is not perceived as a problem.

Recommendations chapter 2

7.0 The procedures for reporting and communicating the outcomes of supervisory tasks should be defined and made transparent.

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

9.0 A comprehensive media strategy which describes how DHMA will communicate the outcomes of supervisory tasks should be put in place as soon as possible.

Chapter 3

Does DHMA have the necessary arrangements in place to safeguard the data and information it holds and to ensure its confidentiality?

The supervisory body should:

- ensure the confidentiality of information according to national legislation;
- have policy and procedures in place to safeguard its data and information; and
- ensure that personnel can only access sensitive data that is relevant to their job function.

3.1 Ensure confidentiality of information according to national legislation

Confidential information is shared electronically between the centre and the regions using a secure electronic network. The reliance on electronic communication brings with it increased risk of data loss. However, DHMA has not reported any significant problems with loss of confidential personal information.

Staff are aware of and fulfil their duties and responsibilities in respect of confidentiality and data protection. Senior managers are confident that the necessary arrangements are in place across the whole organisation to hold data securely, in both written and electronic formats.

Some staff expressed a concern that confidentiality may be compromised by the open plan nature of the office environment. However, separate rooms are available where confidential discussions can take place.

Staff are permitted to work from home and have remote access to electronic files They can also remove case records from offices for the purposes of home working. However homeworking is facilitated primarily by accessing files through a secure internet connection, and not by case records. Nevertheless there is no specific policy or procedure, referring to the need to protect the security of confidential case records or personal information which may be removed from the offices for the purposes of home working.

DHMA has not undertaken any testing of its resilience against any unauthorised attempt to breach its network security for the purposes of accessing confidential case records.

3.2 Have policy and procedures in place to safeguard its data and information

Whilst policies and procedures are in place in respect of confidentiality and data protection, these refer mainly to electronic information held at the central and regional offices.

There was no indication that DHMA has a robust training programme for staff on matters relating to records management and data protection.

Appropriate arrangements are in place to record and capture information from whistle-blowers.

DHMA has advised that appropriate arrangements are in place to respond to requests for information under the Freedom of Information legislation.

3.3 Ensure that personnel can only access sensitive data that is relevant to their job function

Staff can access and exchange emails remotely. Case records and journals can be shared appropriately between staff on a need to know basis. Staff cannot make any amendment to a journal, or case record, without the necessary authorisations.

Chapter 3 Conclusions and recommendations

Conclusions chapter 3

3.1 Ensure confidentiality of information according to national legislation

Staff engaged in supervision are aware of and fulfil their duties and responsibilities in respect of confidentiality and data protection.

3.2 Policy and procedures to safeguard data and information

Some policies and procedures are in place to safeguard data and information; common procedures, testing of systems and training for staff is not comprehensive or complete.

3.3 Personnel can only access sensitive data that is relevant to job

Confidential information is shared between the centre and regional offices using a secure network. Staff are permitted to work at home without having a specific policy or procedures to protect confidential case records.
DHMA has not undertaken any testing of the resilience of its IT networks in respect of confidentiality and data protection.

Recommendations chapter 3

10.0 DHMA should review the policies and procedures for confidentiality and data protection for both electronic data and written records to make sure they are comprehensive and complete.

11.0 DHMA should have a policy and procedure for reporting and responding to any incident of loss of sensitive confidential information.

12.0 DHMA should make sure that employees are appropriately trained in the principles of confidentiality, record management and data protection. Refresher training should be available on a regular basis.

13.0 DMHA should test the resilience of its IT security systems to ensure that the necessary safeguards are in place, and are appropriate for the nature and extent of personal confidential data and information stored and accessed. DHMA should evaluate the risk of adverse events or system failures, and take appropriate measures to prevent unlawful access involving data loss. DMHA should assess whether it has taken all appropriate steps to mitigate all identified risks.

Chapter 4

Does DHMA have the necessary organisational and managerial arrangements in place?

The supervisory body should:

- have well defined relationships with the Department of Health, umbrella organisations, patient organisations;
- have well defined relationships with the regional offices of the inspection body;
- have a well described and documented organisational and management structure;
- define and document the responsibilities of its personnel and the reporting structure of the organisation;
- have procedures in place to prioritise its activities and is transparent about that prioritisation;
- ensure its inspection activities are carried out in accordance with legislation and the defined Standards;
- ensure the effective supervision of all personnel; and
- have procedures in place that ensure the co-ordination of the various supervisory activities.

4.1 Have well defined relationships with the Department of Health, umbrella organisations, patients' organisations

DHMA recognises the importance of having well defined relationships with the Danish Health Ministry, and with umbrella organisations including, for example, the Danish Nurses Organisation, the Patients Association and the National Agency for Patients' Rights and Complaints (Patientombuddet).

The relationship with the Ministry of Health is also referenced in chapter 2, on independence.

Some organisations felt that more could be done by DHMA to engage with them on a regular basis on matters of strategic interest.

DHMA acknowledged the need to improve communication with key stakeholders, including the public, so that expectations can be managed appropriately, (see also chapter10).

DHMA does not currently use social media. It is likely that this will be a key challenge in future, as more people rely on social media as an instant means of communicating about significant events and in obtaining information from public bodies about responses to these events.

4.2 Have well defined relationships with the regional offices of the inspection body

Many staff recognised that relationships between the central and regional offices require focused intervention and facilitation.

There are tensions between the centre and the regional offices about workload, capacity and prioritisation of tasks. There is no sense of a coherent organisational culture. The tensions, which are particularly evident at managerial level, relate to a range of issues such as authority, autonomy and resource allocation. These issues would appear to be a significant impediment to effective co-ordination of actions and decision taking. The impact is also felt in respect of co-ordination of actions between front line staff.

Since the summer of 2013, a Task Force has been set up as a starting point to improve co-ordination and collaboration between the central and regional offices in respect of supervisory investigations. This development has been positively received, but it is too early to make an independent assessment of its impact on relationships and decision taking.

4.3 Have a well described and documented organisational and management structure

The organisational structure within DHMA makes it difficult to know who has overall operational responsibility for the supervisory functions, especially when both the central office and the regional offices are involved. There is no shared understanding of the operational and organisational rules within DHMA. Furthermore, there is no current and comprehensive description of the total system for supervision, including the central as well as the regional offices, covering the different roles and describing responsibilities of each team or department, and of those attributed to the managerial team as a whole. Thus, there is no current and comprehensive description for corporate decision making related to supervisory issues.

The Board of Directors of DHMA consists of a Director General and two other directors. The authority of the Head of Division of Supervision and Patient Safety is not clear in relation to the authority of the leaders at the regional offices (the three Public Health Medical Officers).

The directors have various responsibilities for different aspects of the supervisory function. The central office provides a co-ordinating role in respect of key functions such as chairing the Task Force.

There is not one clear and separate line of reporting for all supervisory tasks to the board of directors, including the most senior director in DHMA (Director General).

The three regional offices (Public Health Medical Officers) have separate reporting lines to members of the Board of Directors without a formal connection to the central office, except for the so called ‘Task Force’.

There would appear to be little or no effective team identity regarding supervisory functions between the managers in the regional offices and those in the central office.

4.4 Define and document the responsibilities of its personnel and the reporting structure of the organisation

The organisational structure which was presented to the Peer Evaluation Team by the Director General at the start of the peer evaluation process, in November 2013, is shown below (the second model).

This organisational chart illustrates that supervision is one component of the overall function of DHMA. The supervisory arm does not operate as a fully independent and integrated entity.

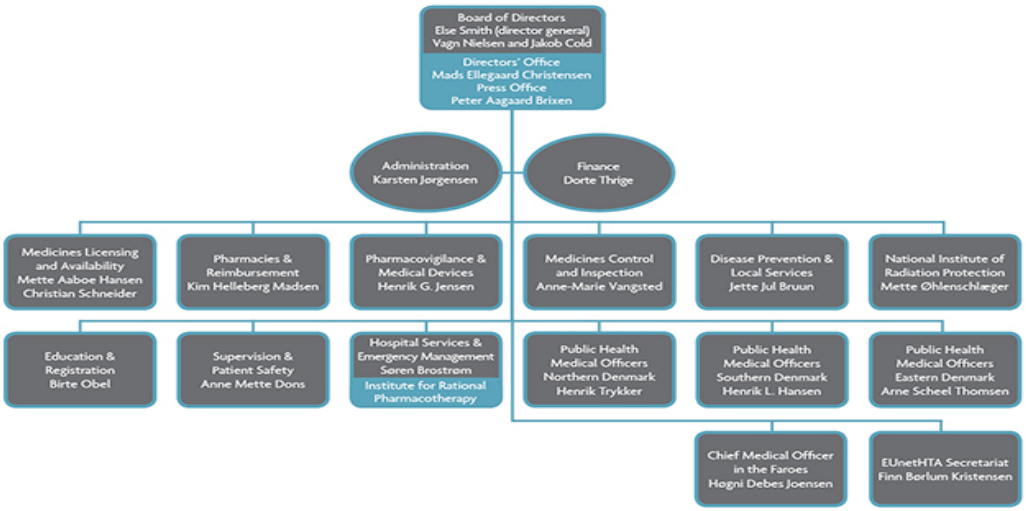
In November 2013 the diagram, as seen by the Peer Evaluation Team, did not have a clear and direct line of report between the supervisory functions at the regional level and the supervisory functions at the central office.

In May 2014 the Peer Evaluation Team was advised of a new organisational chart which came into effect in December 2013 (the first model).

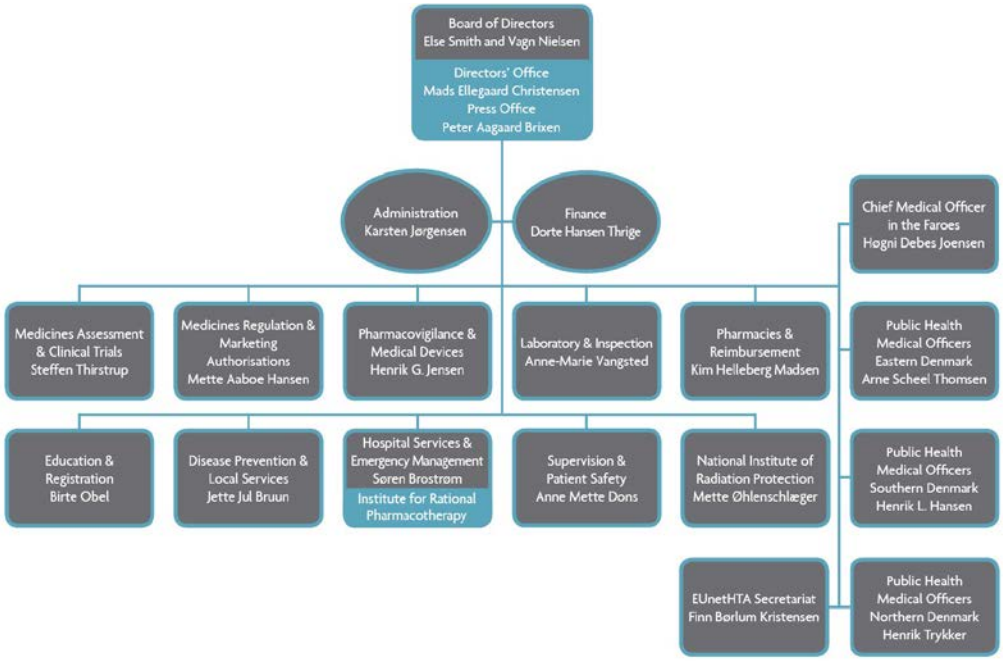
The new chart illustrates the reporting lines between the regional offices and the central offices which indicate there are still separate lines of reporting, and not one single line of reporting for the supervisory function within DHMA.

Updated Organogram of 15 December 2013

The Board of Directors now consists of a Director General and two Directors. The updated organogram is included below



The original organogram which was presented to the Peer Evaluation Team in November 2013 consisted of a Board of Directors of two



Currently there is not a clear and single direct line of report covering both the relationship between the supervisory functions at the regional level and the supervisory functions at the central office.

4.5 Have procedures in place to prioritise its activities, and is transparent about that prioritisation?

The Board of Directors of DHMA sets the strategic direction for the organisation, based on a contract with the Ministry of Health.

The Head of Division of Supervision and Patient Safety meets on a regular basis and 'as necessary ', with the Director General to discuss matters of strategic importance.

The Head of Division of Supervision and Patient Safety does not attend Board meetings on a regular basis. The Board of Directors does not attempt to interfere with operational decisions of the inspectorate. Meetings between the Head of Division of Supervision and Patient Safety (Central Office) and the Public Health Medical Officers (the Heads of the Regional Offices), together with the Directors and the Director General take place at three monthly intervals.

There is an annual work plan and all available resources are identified within the work plan. There is also regular feed back to the Board of Directors through the quarterly budget reporting system where budgets and as a consequence, work plans are reported on and adjusted.

The budget is agreed annually and decisions have to be made with regard to staff retention and prioritisation of the overall workload.

However, there would appear to be no formal or factual system of reporting to the Board of Directors on actual performance against strategic priorities and objectives, and on changes in the day to day work plan.

4.6 Ensure its inspection activities are carried out in accordance with legislation and the defined Standards

In general it is clear that the Inspectorate is operating within the legislation and within its defined standards. However, staff and other stakeholders expressed a concern that specific parts of the legal framework for inspection are too narrow.

Others expressed a concern that issues which had been raised in respect of patient safety, in particular services such as mental health clinics and other patient safety issues were not receiving appropriate consideration, (see also chapter 1).

It is particularly important that allegations of professional malpractice are investigated in accordance with legislation and the correct procedures. These investigations need to be thorough, transparent and completed within the shortest timeframe possible. Urgent and serious cases need to be dealt with as a priority, (see also chapter 8).

Some sanctions are challenged legally, but DHMA has a good track record in defending its decisions, with only 3 out of 30 actions having been challenged legally, with two of these being upheld on appeal.

4.7 Ensure the effective supervision of all personnel

Staff felt well supported in dealing with difficult cases.

There is an annual personnel appraisal system, (MUS), where every employee receives personal feedback, where development plans are discussed, including training needs, etc., but there is no system of providing all staff with regular monthly supervision.

Staff explained that induction for new employees could be improved, as there was little opportunity for structured induction on taking up a new appointment in the central office.

In-service training was described as sporadic and is not provided on a planned or co-ordinated basis.

For staff training and staff supervision in greater detail see chapter 6.

4.8 Have procedures in place to ensure the co-ordination of the various supervisory activities

To ensure the co-ordination of the various supervisory activities there are various fora in place:

-The central contact forum (meetings twice yearly);

-The regional strategic fora (2-4 times/year);

-The Task Force (weekly)

Except for the Task Force these fora were not mentioned by the respondents in the interviews with the Peer Evaluation Team,

The Task Force was described as a relatively recent intervention which has been beneficial in co-ordinating activities related to supervisory investigations and in reducing the time required for completing complex cases. Furthermore, the Task Force is described as a relatively successful instrument for co-ordination between various supervisory activities within DHMA. This is at an early stage of development, but almost all respondents spoke positively about the impact of the Task Force in raising confidence and improving systems for the management of complex cases.

Some staff in the regional offices expressed mixed views about the Task Force. Whilst they appreciate its impact on the management of complex cases, they expressed the view that making a referral can result in a loss of control to the central office (see chapter 2).

Chapter 4 Conclusions and recommendations

Conclusions chapter 4

4.1 Well defined relationships with Ministry of Health, umbrella- and patient organisations.

DHMA has well defined relationships with umbrella and patient organisations. The relationship with the Ministry of Health could be improved by strengthening the independence of the supervisory functions of DHMA. The need to improve communication with key stakeholders, including the use of social media, and engaging effectively with the press and general public, requires further consideration.

4.2 Defined relationship with regional offices

A start has been made to improve information sharing and co-operation between the centre and the regional offices. However, the relationships between the centre and the regional offices could be significantly improved and strengthened. There are tensions between the centre and regions are about workload, capacity and prioritisation; and there is no sense of a coherent organisational culture. The 'Task-Force' has, since 2013, undertaken significant responsibilities for the co-ordination of investigations, but, it is too early to make an independent assessment of its impact.

4.3 Well described and documented organisational and management structure

A clear organisational and management structure could help to improve the independence and authority of DHMA, resulting in better outcomes.

4.4 Define and document responsibilities of personnel and reporting structure

Shared prioritisation and transparency of the decisions, including clear targets and lines of reporting, is not yet fully in place, although the aims and initial activities of the Task Force point in this direction.

4.5 Have procedures in place to prioritise and be transparent on prioritisation

No formal or factual system of reporting to the Board of Directors on actual performance against strategic priorities and objectives, and on changes in the day to day work plan, appears to be in place.

4.6 Ensure Inspection activities in accordance with legislation and defined standards

The inspection activities are operating within the legislation and defined standards, although specific parts of the legislation are too narrow to allow DHMA to exercise discretion regarding decisions and choices, and to give appropriate consideration to professionally selected patient safety issues- including allegations of professional malpractice - when needed.

4.7 Ensure effective supervision of all personnel

Effective supervision of all personnel is assured, although improvement is possible on specific themes such as training and induction of newly appointed staff at the central office.

4.8 Have procedures to ensure co-ordination of the various supervisory activities

DHMA has procedures in place to ensure the co-ordination of the various supervisory activities:

-Central contact forum (meetings twice yearly);

-The regional strategic fora (2-4 times/year);

- The Task Force (weekly).

The Task Force is a relatively recent intervention which has been beneficial in co-ordinating activities related to supervisory investigations and in reducing the time required for completing complex investigations. Furthermore, the Task Force is a relatively successful instrument for co-ordination between various supervisory activities within DHMA. However this is at too early a stage of development for final conclusions regarding the impact of the Task Force on the longer term, and its effect on the co-ordination of investigations within DHMA.

Recommendations chapter 4

14.0 Relationships between the central and the regional offices require significant improvement. The Peer Evaluation Team considers this to be one of the most important areas for improvement.

15.0 *Consideration should be given to supporting the role of the Public Health Medical Officers in the regional offices to retain responsibility as lead investigators in supervisory matters, co-ordinating investigations from initial referral through to final determination.*

16.0 The lines of authority and accountability of the senior managers in each of the regional offices and in the central office requires urgent clarification. Establishing formalised structures for corporate decision making should be considered.

17.0 The internal structure should be revised to ensure clear division of tasks and power between the central and regional offices, and between the supervisory tasks and other tasks of DHMA.

18.0 DHMA should implement a coherent system to assess all new cases and to prioritise work.

19.0 The use of information from adverse events for supervisory purposes should be further developed.

20.0 There should be a clearly defined threshold for referral of cases to the Taskforce. DHMA should make this clear in any planned evaluation of the role and functions of the Task Force.

21.0 Consideration should be given to a system of providing effective leadership of the supervisory function across Denmark. This could be achieved by establishing a forum of senior officers with responsibility for supervisory functions.

22.0 DHMA can improve arrangements for sharing information with other health organisations and should concentrate on improving systems for sharing knowledge and information between the central and the three regional offices.

Chapter 5

Does DHMA have an appropriate and well defined quality system in place?

The supervisory body should:

- define and document its policy and objectives for, and commitment to quality, and shall ensure that this policy is understood, implemented and maintained at all levels of the organisation;
- operate a defined quality system which is fully documented. The system should consist of feedback procedures;
- have a quality system in place that is up to date and accessible to the relevant personnel;
- maintain a system for the control of all documentation relating to its activities. It should ensure that the appropriate documentation is available at all relevant locations and to relevant staff;
- ensure that all actions (documentation and legal actions) are conducted according to national law;
- have documented procedures in place for dealing with feedback and corrective action when discrepancies are detected in the quality system and/or in the performance of inspections; and
- review the quality system at appropriate intervals to ensure its continuing suitability and effectiveness. The results of such reviews should be recorded.

The Peer Evaluation Team was told that there is a quality system available, but the system is not working effectively across the whole organisation. The central and regional offices have quality systems in place and have access to the same systems, but they are not working in an integrated and coherent manner. There is a gap when it comes to the quality system, as it has not been kept up to date in respect of all relevant procedures. The lack of effective IT systems (see chapter 7) hampers the process of establishing an up to date quality system on all procedures.

The regional offices had been successfully operating the same quality system for over 10 years and it has worked well. The regional offices felt that the system which had been operating successfully for some years should be retained. Formalised

procedures for dealing with supervisory cases were an integral component of the quality system.

The Peer Evaluation Team was told that five years ago DHMA had a well-defined and well operated quality system. However, the Board of Directors decided that a new system was needed but the new system was never properly implemented.

Some respondents commented that the centre has not seen the quality system as a priority. However, a working group has been set up to develop the new quality system, representatives from all departments and the regional offices are on the working group.

The Peer Evaluation Team was told that the new quality system is available in DHMA, and could be put into operation with little revision. Not all respondents showed the same feeling of appreciation for the new quality system.

Regional offices are very focused on the quality system, but the supervisory centre has developed its own ways of working, without reference to a quality system, partly due to the fact that no one knows how to add new documents to the existing system.

To ensure the quality of work several processes are in place:

- procedures have been written internally but these have not been systematised.
- all new staff are allocated a supervisor who will oversee their work and review it.
- new staff are given an introduction pack and a handbook which details rights and duties.
- there is a formalised induction programme for secretaries, doctors but not for lawyers.
- training days are held, but there is no formal education programme.
- training days have been held for the new supervisory activities, one day per annum of training per area – nursing homes, cosmetic treatments and private doctors.
- audits are held to check the consistency of supervision across nursing homes, cosmetic treatments and private doctors, but also within the supervision of risk personnel.
- standards for planned supervision of private doctors, for cosmetic treatment and for nursing homes have been developed. For the various areas the standards are developed with expert input, and specific consultation.
- all supervisory cases have at least one doctor working on them.
- all supervisory cases are discussed in a forum.
- all decisions are signed off by two people; previously when only one person had signed, the decision was seen to be that of an individual and not of the organisation.

Chapter 5 Conclusions and recommendations

Conclusions chapter 5

5.1 Define and document policy and objectives for and commitment to quality, ensure that this policy is understood, implemented and maintained at all levels of the organisation;

There are policies and procedures at both regional and central level, but there is no actively operating overall quality system across DHMA. There is a system in place where policies and procedures can be found, but it is not actively in use overall.

5.2 Operate a fully documented defined quality system. The system should consist of feedback procedures;

There is an absence of an internal audit system to ensure that procedures are being followed correctly. The system is not fully documented and there are no internal audits and feedback procedures, therefore it is not possible to assess whether the work of DHMA is being carried out in accordance with the relevant procedures. That gives rise to a risk of not having a robust accountability framework based on the principles of good governance.

5.3 Have a quality system in place that is up to date and accessible to the relevant personnel;

The system in place is accessible but not appropriately functioning for all staff and at all locations.

5.4 Maintain a system for the control of all documentation relating to its activities. It should ensure that the appropriate documentation is available at all relevant locations and to relevant staff;

The system in place is accessible but not appropriately functioning for all staff and at all locations.

5.5 Ensure that all actions (documentation and legal actions) are conducted according to national law;

The actions (documentation and legal action) of DHMA are in accordance with the national health law and other relevant legislation.

5.6 Have documented procedures in place for dealing with feedback and corrective action when discrepancies are detected in the quality system and/or in the performance of inspections;

Feedback procedures and alert systems are not in place, or not actively functioning. The links between the complaints system and the adverse events system are not developed in such a way that effective use of anonymised signals can lead to an active and timely operational supervision, (see chapter 8).

5.7 Review the quality system at appropriate intervals to ensure its continuing suitability and effectiveness. The results of such reviews should be recorded.

As the quality system is not fully active no review at appropriate intervals was available.

Recommendations chapter 5

23.0 DHMA should have one overall quality system in place, where policies and procedures can be accessed on the intranet.

24.0 Regular audits should continue to be performed to confirm that supervision is being carried out in accordance with the approved policies and procedures.

Chapter 6

Does DHMA have the right personnel in place and are they appropriately trained and supported?

The supervisory body should:

- have procedures in place that define an appropriate skill mix of personnel to be able to conduct supervisory activities;
- ensure that all staff have the appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of the functions to be carried out. They should have the ability to make professional judgements as to the conformity with general requirements using inspection results and to report thereon; and
- have in place a documented training system to ensure the relevant training of its personnel, especially the personnel involved in inspection or disciplinary cases. The programme should include introduction, initial training, supervision and continuous education.

The Peer Evaluation Team was provided with a profile of the staff employed by the supervisory arm of DHMA.

At the central office there are:

- 15 doctors
- 9 lawyers
- 1 dentist
- 5 secretaries
- 2 other academics
- 8 students.

The central office has no role in deciding the makeup of staff resources which are deployed at the regional offices.

The quality of the delivery at regional level is the responsibility of the senior medical doctor, Public Health Medical Officer of that area.

There is one common human resources department at the central office of DHMA. This office provides human resource support to the regional offices.

In the regions, for example, the North regional office employs:

- 10 doctors (5 public health doctors)
- 3 academic nurses
- 6 secretaries
- 1 external worker.

There are no lawyers working at the regional offices. The legal support for all supervisory work (both at regional and central level) is located in the central office. However, once a lawyer from the central office becomes involved in an investigation the case is usually transferred from the regional office to the central office (see also chapter 2.3). Since the Task Force was established the shift to the central office is subject to the decision of the Task Force.

The growing pressure of work in the regional offices has been highlighted by an independent assessment made by the Labour Inspection Authority.

As a result of the reorganisation of the regional offices, some employees have to travel further, with one manager estimating that additional travel time can be as much as 500 hours per annum.

Training for supervision

There is no dedicated training programme for inspectors, but a training programme for supervision is delivered once a year. Line managers determine who attends the training.

Staff don`t have to go through induction training before they get involved in supervision, albeit they will shadow others before taking forward work on their own.

Some incidental training activities are arranged, for example, when legislation for the supervision of private clinics was introduced additional funding was provided for staff to receive 2-3 days training. Staff rated this training highly and felt that it should be made routine, but acknowledged that due to financial pressures it was unlikely to be sustained.

DHMA has a forum for infectious diseases, supervision and mental health, which meets twice a year to discuss training needs, and to facilitate training events. However, this training is not routinely available to supervisory personnel.

There was a sense that the pressures on staff are increasing. There are limited numbers of staff available to undertake the inspections of private clinics. Posts were advertised, individuals applied and were called to interview, but appointments were not made, due to budgetary constraints.

It was noted that DHMA had chosen to cut back on educating specialists, therefore the regional offices are finding it difficult to recruit doctors, given that younger doctors were not receiving specific opportunities to complete specialist medical training, and training as an inspector. This was reported to be a particular problem in the north (Jutland). But problems were also reported with vacancies in the southern region remaining unfilled. Only one or two applications are received for each new post.

It was felt that DHMA needed to be clear as to the future role of the regional offices, as some staff expressed concern that the regions are being systematically downgraded, as resources are reduced. Staff at regional level fulfil a number of statutory functions, and advised that some of those working on supervision had stated a preference to work directly to the central office.

As most of the tasks undertaken by DHMA are based on statute, there is little room for prioritisation, or for discontinuing core statutory obligations (see also chapter 1, on a balanced legal basis).

The Ministry of Health is aware of the specific challenge of delivering the core functions and working within the overall budget. Many staff stated that a fundamental evaluation of where resources are being deployed is necessary, for example, whether DHMA should continue inspecting every nursing home on an annual basis.

The workforce is competent to carry out the supervisory roles and responsibilities, but consistency in terms of approach and quality varies, and concerns were expressed that some staff are making decisions without reference to relevant policies and procedures.

Leadership and administrative skills are key competencies required by regional medical officers, and these skills are considered as important in supervisory investigations as being a competent medical practitioner.

Staff Induction

The regional offices have good induction procedures but induction in the central office was described as poor. Some staff expressed a view that structured induction and coaching was needed, to provide new appointees with a comprehensive overview of DHMA’s policies and procedures.

Others referred to existing arrangements in DHMA which ensured that all new staff received two days formal induction that introduced them to the whole organisation.

There was a need for formal induction in respect of legal matters relating to working in a public office, e.g. freedom of information act, public administration act, and personal data protection act.

Staff training

It was stated that training tends to be on the job, sitting next to the person who held the post previously, or who carries out work similar to your own. For those who take on a unique role the first few months can be difficult. More recently, peer partnering is being encouraged, which is mostly ‘learning by doing’.

Although the Peer Evaluation Team was advised that a compendium, a document which includes a comprehensive training programme, is available, this was not explicitly referred to by staff members.

Staff mentioned however that training is mostly ‘on the job’ and ‘learning by doing’ which can be difficult. It was mentioned that this poses an obstacle for new employees and requires a relatively large commitment. A more structured training programme for updating skills in general and legal knowledge, as well as communication skills, and training on media engagement is required.

Doctors employed as part of their specialist training, generally receive structured training, primarily arranged by the organisation in charge of specialist training, and not by DHMA.

Some staff, but not all, receive a training day each year, and some other departments within DHMA are better at providing induction and in-service training.

There is a general desire for more training and coaching among almost all of the employees interviewed as part of this peer evaluation.

Staff supervision

Supervision was felt to be appropriate for doctors in specialist training. They are allocated a contact person (a senior doctor), and meetings are held regularly, to consider whether or not core competencies have been achieved. A work plan is prepared to enable the trainee doctors to achieve the necessary skills across the full range of competencies.

Chapter 6 Conclusions and recommendations

Conclusions chapter 6

6.1 Have procedures in place that define an appropriate skill mix of personnel to be able to conduct supervisory activities;

DHMA has a mix of highly skilled and appropriately qualified staff who undertake a range of statutory duties on behalf of DHMA. These functions are necessary to protect the public interest and to ensure the safety and well-being of citizens using public and private healthcare.

6.2 Ensure that all staff have the appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of the functions to be carried out. They should have the ability to make professional judgements as to the conformity with general requirements using inspection results and to report thereon;

DHMA has to ensure appropriate training, including structured organised in-service training and staff development. This is essential to improving the skills of the workforce and in making sure that all staff maintain the necessary competencies to fulfill their stated roles and functions. There is no dedicated training programme for inspectors, although some training for supervision is delivered on an annual basis. A structured training programme, including training in legal knowledge, supervisory processes and communication skills, is missing. Opportunities for in-service training are limited.

6.3 Have in place a documented training system to ensure the relevant training of its personnel, especially the personnel involved in inspection or disciplinary cases. The programme should include introduction, initial training, supervision and continuous education.

More could be done to improve induction training for new staff, and to extend the range of in-service training opportunities for experienced staff.

Recommendations chapter 6

25.0 DHMA should prepare a workforce development strategy identifying how training needs of all staff will be met in future.

26.0 DHMA should develop formal induction training for newly appointed staff engaged in the supervisory functions at both the central and regional offices.

27.0 Each employee should have regular professional supervision and appraisal with their line manager, and should have a personal development plan identifying key training needs and how these will be met by their employer.

28.0 In-service training linked to the supervisory functions of DHMA should be available at regular intervals to all staff engaged in these duties.

Chapter 7

Does DHMA have access to the facilities and equipment that is required to deliver its function?

The supervisory body should:

- have access to suitable and adequate facilities and equipment that support the delivery of its function. This includes IT systems, databases and relevant documentation.

DHMA has access to suitable and adequate facilities and equipment to support the delivery of its functions. This includes IT systems and databases, and relevant documentation.

At the central office DHMA has a well-appointed modern office building with open working spaces and, in general, reasonably good facilities. However, specific reference was made to the IT system which did not function properly (i.e. frequent interruptions of service). The email system is described as slow, and the IT system was described as unreliable and subject to frequent interruptions.

Some respondents found the physical environment not helpful, as the open plan layout does not support confidential conversations.

The office in Copenhagen is situated apart from the Ministry for Health, and from other institutions, which helps DHMA to maintain an independent focus. The central office is also separately located from the regional offices (North and South), although the regional office for the central region is co-located in the same premises as the central office.

The dispersed location of the other two regional offices makes it necessary to organise several co-ordination meetings between the central office and the regional offices (e.g. the Task Force and 'internet working group meetings').

The closure of two former regional offices and integration of functions has helped to promote closer working. However, some staff based in the former regional offices have much further to travel in discharging their statutory responsibilities.

The various databases at the regional and the central offices have separate electronic processing systems, which gives rise to the need for electronic transfer of information between offices. Staff take appropriate steps to reduce duplication of work, create efficient work flows and arrange weekly meetings to ensure rapid progress of investigations.

Co-operation between the regional offices of DHMA, and between DHMA and the National Agency for Patients´ Rights and Complaints, is still being developed. This is also the case with co-operation between DHMA and other stakeholders. Efficient sharing of electronic information does not seem to be available either within or between organisations.

DHMA tries to find safe and efficient ways to overcome barriers to communication but from the interviews with staff it becomes clear that communication systems and relatively complex structures of communication and collaboration do take time to establish.

Information about incidents, complaints, accreditation results and performance of service providers etc. is available to DHMA.

DHMA has advised that information concerning, e.g. a hospital or a health care professional, is held in a single record and that the perceived risks are taken into account by the Task Force, a suitable managerial tool to process this information, a system to support priority setting, and an electronic alert system, next to a human alert system, is still missing.

Chapter 7 Conclusions and recommendations

Conclusions chapter 7

7.1 Have access to suitable and adequate facilities and equipment that support the delivery of its function. This includes IT systems, databases and relevant documentation.

Access to facilities and equipment that supports the work of DHMA should be appropriate to the needs and requirements of the organisation. It is necessary to ensure that information and communication systems flow seamlessly between the central and regional offices. IT systems and data bases seem to lack integration, operational stability and professional accessibility. The organisation relies on IT to process sensitive information. It must take whatever steps are necessary to ensure the system is functional and fit for purpose.

An important first step is already in progress: all information about incidents, complaints, accreditation results and performance of service providers etc. which is available to DHMA is filed on the same place, e.g. a hospital or a health person. This makes it possible for DHMA and the Task Force to assess and take the perceived risks into account.

Recommendations chapter 7

29.0 DHMA's supervisory body should focus as a priority on a professional exchange of information within and between the regional and central offices, and organise sufficient financial recourses to build a stable and adequate IT communication system.

30.0 DHMA should focus on a suitable managerial tool to process the available internal and external information to support priority setting by using this information, and developing an electronic alert system alongside a human alert system to manage investigations, near misses, adverse events and other possible risks in the Danish Healthcare system as a whole. DHMA should utilise available information from other parts of the Danish Healthcare system as necessary, and the database should be developed in co-operation with the relevant parties.

Chapter 8

Are DHMA's inspection methods, procedures and follow-up arrangements appropriate and transparent, and do they achieve the necessary outcomes?

The supervisory body should:

- ensure that the methods and procedures it uses for its planned inspections are those that are defined in legislation or documented in its policies and procedures;
- ensure that the methods and procedures it uses for incident inspections, are those that are defined in legislation or documented in its policies and procedures;
- set out in a way that is transparent and clear the methods and types of inspections in case of supervision of individual health personnel (disciplinary cases);
- have sound inspection planning arrangements in place. Planning and prioritization processes should be documented;
- set clear terms of reference and objectives for its inspection activities;
- have quality assurance procedure in place that assure the consistency of judgments across Teams;
- set Standards for the delivery of its supervisory functions. The Standards should include Standards for the documentation of observations, the results of testing, information and data obtained during the course of inspections to ensure that they are recorded in a timely, consistent and professional manner to prevent the loss of relevant information. All documentation should be appropriately referenced, signed off and cross-referenced;
- use Standardized techniques for sampling and inspection. These should be documented in circumstances where the absence of such instructions could jeopardize the efficiency or outcome of the inspection;
- describe in detail the use of unannounced inspections and the legal framework for such visits; and
- have arrangements in place for the follow up of its inspection findings.

8.1 Ensure that the methods and procedures it uses for its planned inspections are those that are defined in legislation or documented in its policies and procedures

The legislation requires DHMA to make annual planned unannounced visits to inspect the health conditions in nursing homes. For these unannounced planned inspections a comprehensive set of procedures is available in the document called: 'Guidance on supervision of nursing homes, sheltered housing estates and similar housing units'

DHMA has methods and procedures in place for inspections based on regulations for nursing homes (section 219), private clinics (section 215a) cosmetic clinics (chapter 25, Act on Health Personnel). DHMA has a legal obligation to act on a proactive basis in respect of these services.

In other services such as public hospitals, and other providers, there is no legal obligation, but a legal option to act, (section 215b). There has always been an obligation to supervise the whole sector but only on a reactive basis.

In those cases, although some guidelines for organisational supervision are available in the quality system, no specific documents, or at least no overall methods, procedures and arrangements were mentioned by respondents in the interviews with the Peer Evaluation Team. No reference was made to these procedures and guidelines regarding public hospitals.

8.2 Ensure that the methods and procedures it uses for incident inspections, are those that are defined in legislation or documented in its policies and procedures

Most incident investigations begin at regional level and are, via the Task Force, referred to the central level or to co-operation with the central level. In accordance with the Task Force Rules regional offices must refer cases which meet one or more of the criteria described to the Task Force. The Task Force makes a plan with next steps for investigation of these cases. This plan must be followed. All major incident inspections are done in collaboration between the relevant regional office and the central office. For incident inspections there are appropriate internal procedures in place at the regional and at central level.

The DHMA website does not provide detailed information about the working methods and procedures, and the possible outcomes of interventions. Procedures about how DHMA responds to serious incidents are not publicly available.

The National Agency for Patients' Rights and Complaints (Patientombuddet) is obliged by legislation to share information on incidents with DHMA. DHMA has direct access to the adverse event reporting system and can pick up on patient safety issues. This system is separate to the complaints system and all adverse events are

anonymised by the reporting organisation. This information is distributed to the entire health sector, including DHMA.

According to section 200 of the Health Act information on individuals included in a report on adverse events is confidential and can only be disclosed to a prescribed group of persons. This information is not disclosed to DHMA. Therefore the information cannot be used for incident inspections. Nevertheless the information can indirectly be used to select risk areas for supervisory activities. DHMA uses the information from adverse events to generate binding guidance.

A system for the reporting of adverse events relating to medical devices is in place between Sundhedsstyrelsen and the National Agency for Patients' Rights and Complaints (Patientombuddet).

A working group meets twice each year (biannually) to consider adverse events. This group discusses how information on adverse events could be utilised to support the development of guidelines. However, it was felt by some respondents that the National Agency for Patients' Rights and Complaints (Patientombuddet) could be better and more formally involved in the development of DHMA's recommendations and guidelines.

8.3 Set out in a way that is transparent and clear the methods and types of inspections in case of supervision of individual health personnel (disciplinary cases)

In cases of supervision of individual health personnel (professional misconduct) a set of legally based methods and procedures is in place. These methods and procedures are based on the concept that DHMA is the final resort before formal legal intervention, (see also Chapter 11). The expertise of DHMA is critical to this procedure, which is usually a follow up from a complaint with the National Agency for Patients' Rights and Complaints (Patientombuddet).

The administrative procedures in respect of individual cases have been revised and are stated in legislation. Formerly there was a formal right of appeal of a decision by DHMA to the Ministry. These cases took a very long time to resolve. The impact of the appeal was limited in that it did not result in a review of the judgement. Subsequently, parliament changed the legislation so that an appeal to the Ministry, or to any other public authority, was no longer possible. The current legislation places the final administrative judgement within DHMA. This situation has been criticised by various parties.

Other parties and political pressure groups have lobbied for stricter sanctions and improved procedures.

Some parties referred to a gap between what the public considers supervision should be and what DHMA provides. It was stated more than once that what DHMA does is

not sufficiently understood by the general public. It was mentioned that in some individual cases DHMA had not reacted quickly enough, despite holding information that highlighted significant concerns about poor performance and / or patient safety.

Regarding the procedures, in these cases, most of the respondents referred to delays between information being made available to DHMA and it being processed and translated into appropriate action and decisions.

Contrary to the information that was obtained from the interviews, the Peer Evaluation Team researched a significant number of individual cases and found the procedure in these cases well documented, transparent and available to the involved personnel.

The Peer Evaluation Team is of the view that the procedures conform with the principles of best practice in respect of a comprehensive legal process. The procedures are not published on the DHMA website, but some general information regarding the procedures is available on the web.

In individual cases the Peer Evaluation Team found that the written procedures were strictly followed. In all cases DHMA had acted in accordance with an appropriate procedure with respect for the persons involved, and with due regard for the importance of the case for society, whilst acknowledging and respecting the rights and interests of individual doctors, nurses and the health organisations involved.

The right of representation for individuals and services which are subject of disciplinary procedures is well organised. The Peer Evaluation Team did not find any problem with individual representation in respect of specific investigations. The meetings between the health personnel and the Board were well documented and the notes were presented to for factual accuracy checking and comments.

The individual cases were considered by a DHMA panel which was not involved in the original investigation. As far as the Peer Evaluation Team could see the decision panel was working impartially and with discretion, and was open to arguments brought forward during the representation and in the relevant documents.

Based on the information of the individual cases the Peer Evaluation Team found no evidence of conflicts of interests whatsoever. However, for external parties including the individuals involved in investigations, and their representatives, this might not always be easy to see from the outside. The individuals do not see other cases and do not have any possibility for administrative appeal.

The possibility to initiate an administrative appeal is prevented by explicit legislative rules. The individual health care professionals have no option but to trust the representatives of DHMA in their objectiveness. The final decisions seem to be taken with care, taking into consideration all relevant interests.

The Peer Evaluation Team found no evidence of unreasonable delay. All relevant steps were taken in a timeframe of two to four weeks. The Peer Evaluation Team

finds this timeframe relatively short but appropriate, and in the cases evaluated never too short. In all cases there was an option to ask that a case be deferred, which was usually granted. If a short deferral of two weeks was granted the reason for this was clearly explained and was never applied without good reason, usually only in cases with a long history, and cases that could not benefit from an extended timeframe.

In most cases there was a possibility to refer to previous proceedings. If this was not possible the facts of the case were presented clearly and described in detail. The Peer Evaluation Team did not see any circumstance where the possibility of 'being taken by surprise' could have occurred.

In all procedures reviewed by the Peer Evaluation Team the necessary steps were taken with a high degree of promptness, but always with due diligence. In some cases DHMA could have taken a bit more time, but the Peer Evaluation Team did not find any circumstances in which a doctor, nurse or other person was required to attend at an unreasonable period of notice.

The Peer Evaluation Team found a clear policy and procedure for managing cases where no further action was taken, and informing the relevant people about this. This procedure was followed in all cases examined. We saw, and were informed, that the co-ordination of these cases had improved over the previous year.

In the past there was little communication about cases dropped between the investigations of the regional medical officers and the central organisation. As a result, information about a doctor, nurse or institution held at various places within DHMA could be held separately, and not connected. The Peer Evaluation Team was told that this cannot happen any longer, as the cases are logged by name and by institution, and are tracked internally. The Peer Evaluation Team found that investigations were not dropped or discontinued without good reason.

Some decisions could, in the opinion of the Peer Evaluation Team, be subject of legal challenge to make sure that a final decision was taken regarding withdrawal of authorisation. In all cases the Peer Evaluation Team found that it was fully clear that the individual had been prevented from being or continuing to be a danger to patients. Taking these cases to court would have had no added value with regard to public protection.

In some cases a public prosecution would have resulted in greater publicity for the individual doctor or nurse exposed through media reporting of the findings. However, taking these cases into court would have created extra work for DHMA, cost time and money for the State and for the individuals concerned, with little or no additional impact.

The number and the kind of sanctions in those cases seen by the Peer Evaluation Team seem to be within a balanced and proportionate range, and always have an appropriate motivation.

The follow up in the individual cases which the Team reviewed (35 random cases) was appropriate, no unexplained delay, appropriate information and, if necessary, explanation provided to the people directly involved in the case (doctor, nurse, institution).

The investigations and the outcomes of the individual cases are not published on the DHMA website. However the sanctions in all individual cases are published.

In regard to involvement of the press, information to the public, information to other stakeholders, feedback to institutions, feedback to people directly or indirectly involved in the procedures (colleagues, whistle-blowers) the Peer Evaluation Team found that, except through the DHMA website and through regular contact, no response was provided through other channels.

DHMA advised that it prefers to handle and resolve health risks and medical problems in individual cases without public involvement and possible scandal for either the professionals or the institutions involved.

Involvement of stakeholders and other parties in reaction to the outcomes of individual cases (professional misconduct) is not a standard procedure.

The Peer Evaluation Team found that more could be done to communicate outcomes of investigations in individual case supervision, (see also chapter 10).

8.4 Have sound inspection planning arrangements in place. Planning and prioritization processes should be documented

DHMA uses the Task Force to set priorities, by agreeing performance targets and processing time to handle individual cases. The purpose of the Task Force is to ensure seamless progress of investigations, particularly cases where health professionals potentially pose a risk to patient safety. The Task Force deals primarily with individual cases, whether they arise from technical problems or fitness to practice problems.

Organisational issues with broad implications related to difficult or nationwide concerns are also referred to the Task Force. Similarly, certain screened cases where the decision is criticised by the National Agency for Patients' Rights and Complaints (Patientombuddet) are also sent to the Task Force to decide on timing and procedure.

The Task Force has the relevant staff from each of the four participating units within DHMA. In general this leads to selection and time setting of 3 categories:

Category 1: the relatively simple cases where, on the basis of a decision of the Disciplinary Board or Dental Board, there is concern that a doctor's or dentist's practice presents a risk to patients.

Category 2: the more complex cases where a doctor / dentist repeatedly has been criticised by the Disciplinary Board or has received criticism with a warning.

Category 3: the cases of more complex and very serious nature, and cases where the investigation requires special attention.

DHMA has - except for this Task Force procedure- no structured prioritisation process in place in respect to complaints that are notified to DHMA by the National Agency for Patients' Rights and Complaints (Patientombuddet), (see chapter 4.8). DHMA does not investigate the complaint itself, but will consider any patient safety problem that it might represent.

DHMA usually waits for the outcome of the National Agency for Patients' Rights and Complaints (Patientombuddet)'s investigation before taking further action.

The interval between receiving and deciding on complaint investigations - by the National Agency for Patients' Rights and Complaints (Patientombuddet) may be a significant factor in progressing investigations by DHMA. This time interval may contribute to delays in progressing investigations, as the time taken to receive and use information from the National Agency for Patients' Rights and Complaints (NAPRC), is too long.

The Peer Evaluation Team was advised that the time gap between the complaint entering the system and the decision or final outcome of the National Agency for Patients' Rights and Complaints (Patientombuddet), which can, in some cases, take years, makes it difficult for DHMA to act in these cases.

DHMA needs to be proactive in investigating specific issues emanating from complaints made to the National Agency for Patients' Rights and Complaints (Patientombuddet). Information about incidents, complaints, accreditation results and performance of service providers etc. is available to DHMA but is not being processed using a suitable managerial tool. This is a significant barrier to identification of serious cases and, therefore a serious barrier to priority setting (prioritisation of inspection tasks). However, the relatively new system of registration of cases by name of the doctor and by name of the institution helps to ensure that all concerns regarding the practice of an individual or institution are recognised and will be investigated appropriately. The Peer Evaluation Team saw some evidence that this new registration system is working.

The Peer Evaluation Team was informed that more work could be done to ensure more efficient and effective sharing of information with the National Agency for Patients' Rights and Complaints (Patientombuddet) to make sure Sundhedsstyrelsen is able to identify individuals or organisations who represent a risk to patient safety.

8.5 Set clear terms of reference and objectives for its inspection activities

There is no strategic plan is in place for supervision. Since almost all recourses (80-90 %) are bound by the legal obligations, DHMA is of the opinion that there is not

much room for a strategic plan. It was stated that it seems unrealistic to have a strategic plan. Instead of a strategic plan, DHMA prioritises tasks which are shared between the central office and the Board.

The list includes a limited number of prioritisation areas (focus areas) and does not include reference to the aims and objectives of the organisation. It has limited scope regarding the personnel involved, and does not focus on longer term areas of importance. The main characteristic of this plan is practical, with a limited overall impact.

Plans for unannounced inspections in nursing homes tend to be based on what was undertaken in the previous year. The Peer Evaluation Team was advised that the other two areas of planned inspection (private clinics and cosmetic clinics) are subject of annual work plans. The inspection of cosmetic treatment lies with the regional medical officers (now Public Health Medical Officers) and involves supervision to the extent they deem necessary.

As a result of the legal requirement to undertake obligatory planned inspections of private clinics this work is carried out on different terms compared to the inspection in the public sector. Private clinics are under intensified scrutiny compared to public hospitals.

For many years the regions produced an annual report, but this had ceased when the regions were merged within DHMA. The Southern regional office has developed an annual report for 2013-14, but this did not include reference to what supervisory work should be taken forward in future years.

The same was the case with the annual report which was formerly provided by the central office of DHMA. The Peer Evaluation Team was informed that as a result of financial exigencies these reports are no longer published.

It would be preferable if DHMA were to develop a strategic plan in relation to supervision which could be updated annually and placed in the public domain.

8.6 Have quality assurance procedure in place that assure the consistency of judgments across teams

At the central office specific policies and procedures for consistency checking were not available to be shared with the Peer Evaluation Team.

The Task Force will help to assure consistency of decision taking between the centre and the regions, but only in respect of the cases referred to it. Not all cases are referred to the task force. The referral procedure varies in the three regions depending on custom and practice.

Staff in the regional offices work in teams; individual inspectors are usually attached to one of the four teams. Individual inspectors do not deal with everything that forms part of the regional agenda.

8.7 Have a set of Standards for the delivery of its supervisory functions. The Standards should include Standards for the documentation of observations, the results of testing, information and data obtained during the course of inspections to ensure that they are recorded in a timely, consistent and professional manner to prevent the loss of relevant information. All documentation should be appropriately referenced, signed off and cross-referenced

Some Standards, mainly related to the mandatory tasks of DHMA, such as inspection of private clinics, nursing homes, surveillance on proper data collection regarding the prescription of medicines by doctors and specialists, are available for the delivery DHMA's supervisory functions.

There is clear guidance for some processes such as radiation and medicines use. Another division of DHMA develops national clinical guidelines to be used in the health care system. These clinical guidelines have little impact on supervision.

The supervisory arm of DHMA publishes binding guidelines on patient safety issues as standards for the supervisory function. These standards are published on the website and have a great variety of different topics and subjects regarding patient safety issues, from various perspectives.

In preparing for and carrying out inspections, there is no set handbook, but for the obligatory planned inspection tasks, appropriate processes are described in guidelines. For the other supervisory tasks, no instructions are in place.

In general there are no comprehensive DHMA Standards for the supervisory functions (standards for the documentation of observations, the results of testing, information and data obtained during the course of inspections, to ensure that they are recorded in a timely, consistent and professional manner to prevent the loss of relevant information). This means that there is also no system in place to guarantee that documentation is appropriately referenced, signed off and cross-referenced.

8.8 Use standardised techniques for sampling and inspection. These should be documented in circumstances where the absence of such instructions could jeopardise the efficiency or outcome of the inspection

Some standardised techniques are available in respect of the legally mandatory tasks of DHMA.

There is no overall quality system available on the website for using standardised techniques for sampling and inspection.

The standards for planned inspections in cosmetic treatment, private clinics and nursing homes include instructions on some aspects of these topics.

8.9 Describe in detail the use of unannounced inspections and the legal framework for such visits

Unannounced inspections are used mainly in the field of nursing homes, as in this field it is a legal obligation to only use unannounced inspections. For these inspections instructions are available.

As the law does not allow any flexibility, the Danish legislation allows the use of unannounced inspections only in specific cases, (see chapter 1), there is no professional discretion to facilitate a mix between unannounced and announced inspections.

In case of incident investigations inspections can be unannounced. In these cases instructions and standard letters are available to the staff but are not publicly available.

In general there is no description of unannounced inspections in fields other than those referenced above.

8.10 Have arrangements in place for the follow up of its inspection findings

In terms of follow up on an inspection, this appears variable and depends on the recommendations and what is found at an inspection.

Follow up instructions are part of the guidance documents available for nursing homes, private clinics and cosmetic treatment.

For nursing homes the following text is published in the guidelines:

> The Medical Officer of Health should, as appropriate, ensure that nursing unit / municipal authorities follow up on any censure, health conditions that may be found in the health supervision visits.
> By deficiencies found Medical Health Officers must assess the degree of severity and how quickly the situation should be rectified. Depending on the nature of the institution must assess whether it is sufficient to ask the nursing unit for written feedback on the measures undertaken to remedy the deficiencies, or about to be made return visits, for example, after a month, to ensure that the situation is resolved satisfactorily.
>
> At the next inspection check that identified deficiencies have been corrected.
> If the supervision is very bad conditions, informed the municipal authorities forthwith.
> If the Medical Health Officer for supervision becomes aware of failings, not related to the health conditions drawn the operating authority's attention to the problem.
> It is the municipal authority's responsibility to be rectified any criticism, health conditions that may be identified during the health professional inspection. Medical Officer has no power to issue orders to municipalities that do not follow up on identified shortcomings.

For Cosmetic treatment a different text is included in the guideline:

> If it turns out in the return visit that the medical officers requirements are complied with…treatment sites will be transferred to routine visits as usual. If medical officers consider that the requirements are not met the official physicians will contact the supervisors for an assessment of the way forward. Under Executive Order on cosmetic treatment § 25, the authorized health care professional who have not complied with the requirements asked by Board of Health will be deleted from the register together with any assistants. If it is decided that the outcome of the requirements are not met the supervisory party will hear the decision in advance.

A systematic or structured follow up instruction, including a systematic approach of sanctions, was not found by the Peer Evaluation Team.

The follow up is an integrated part of the reports for all planned inspections (private clinics, nursing homes, cosmetic treatment). These reports are all publically available on the DHMA website. In incident inspections the follow up is always stated in the report.

Chapter 8 Conclusions and recommendations

Conclusions chapter 8

8.1 Ensure that the methods and procedures it uses for its planned inspections are those that are defined in legislation or documented in its policies and procedures;

The methods and procedures used by DHMA for planned inspections are defined in legislation and documented in policies and procedures.

There are policies and procedures in place covering mainly the compulsory tasks explicitly defined in the legislation. But, there is no comprehensive description covering all aspects of DHMA's supervisory work.

The procedures used in the investigation of supervisory cases are clearly defined and adequate, but are not in full publicly available for stakeholders and supervised bodies.

8.2 Ensure that the methods and procedures it uses for incident inspections, are those that are defined in legislation or documented in its policies and procedures;

There is no overall system to cover incident inspections and adverse events. Some elements are in place, including co-operation with the National Agency for Patients' Rights and Complaints (Patientombuddet), but this is not used systematically to identify risk and set priorities for investigations. There is a potential for delay when presented with information that could be an indication of the need for a proactive supervisory response such as complaints, incidents, adverse events, accreditation results, performance of service providers etc. The establishment of the Task Force in 2013 seems to have improved the process of prioritisation and co-ordination of complex investigations.

8.3 Set out in a way that is transparent and clear the methods and types of inspections in case of supervision of individual health personnel (disciplinary cases);

Information from individual health personnel (disciplinary cases) is processed within the supervisory arm of DHMA swiftly and without unreasonable delay. The findings of investigations are communicated to those directly involved. The outcome of supervisory investigations (sanctions) are communicated to the wider public by publication on the DHMA website. The transparency and clear reporting of the methods and types of inspection and outcomes of individual cases could be improved. Communication of the outcomes of individual cases to the press, the public and to other stakeholders could be improved. More could be done

to publicise the proactive work of DHMA, and the impact of the risk based approach to supervision.

8.4 Have sound inspection planning arrangements in place. Planning and prioritization processes should be documented;

DHMA uses the Task Force procedure as an instrument in the planning and prioritisation process, mainly to set priorities by using performance targets and time slots. The Task Force deals primarily with investigation of individual cases, although organisational issues with broad implications related to difficult or national issues also are addressed to the Task Force. DHMA has - except for this Task Force procedure- no structured prioritisation process in place in respect to the complaints that are notified to DHMA by the National Agency for Patients' Rights and Complaints (Patientombuddet). DHMA usually waits for the outcome of the ombudsman's investigation before taking further action. Between receiving and deciding on these complaints - by the National Agency for Patients' Rights and Complaints (Patientombuddet) - there is a too long time gap. DHMA has no general policy in place to make use of this time gap to act on specific issues regarding these complaints.

Complaints are not prioritised by the National Agency for Patients' Rights and Complaints (Patientombuddet).
Before the Task Force was established DHMA coded all referrals as either red, amber or green, depending on the degree of complexity and risk of the complaints, to ensure that the most serious matters receive priority within the health and supervisory tasks of DHMA (see for prioritization also chapter 8.4).

Information about incidents, complaints, accreditation results and performance of service providers etc. is not being processed using a suitable managerial tool. This is a significant barrier to priority setting (prioritisation of inspection tasks). More work could be done to ensure efficient and effective sharing of information to make Sundhedsstyrelsen able to identify individuals and organisations which present as high risk.

8.5 Set clear terms of reference and objectives for its inspection activities;

There is no strategic plan and no clear terms of reference and objectives for DHMA's inspection activities.

8.6 Have quality assurance procedure in place that assures the consistency of judgments across teams;

The Task Force is the main procedural instrument to ensure consistency of judgment within the supervisory functions of DHMA. As not all cases are

referred to the Task Force, the assurance procedures are not comprehensive or complete.

Staff in the regional offices work in teams which ensures that there is within these teams, some assurance of consistency. Systematic policies and procedures for consistency checking were not available at the central office.

8.7 Set Standards for the delivery of its supervisory functions. The Standards should include Standards for the documentation of observations, the results of testing, information and data obtained during the course of inspections to ensure that they are recorded in a timely, consistent and professional manner to prevent the loss of relevant information. All documentation should be appropriately referenced, signed off and cross-referenced;

Standards for delivery of supervisory functions - mainly in the field of the mandatory tasks of DHMA, such as inspection of private clinics, nursing homes, surveillance on proper data collection regarding the prescription of medicines by doctors and specialists, are available for the delivery of DHMA's supervisory functions. For these obligatory planned inspection tasks, processes are fully described in guidelines.

Standards for mandatory tasks include instructions on topics such as how to plan, organise, conduct and complete the inspection visit, how to review written material and how to prepare for and consult on a report, and how to follow up on a visit.

There is also clear guidance for some processes such as radiation and medicines use. For the other tasks no instructions are in place.

8.8 Use Standardized techniques for sampling and inspection. These should be documented in circumstances where the absence of such instructions could jeopardize the efficiency or outcome of the inspection; Standardized techniques for sampling

The Peer Evaluation Team did not see evidence of a complete set of DHMA Standards for the delivery of its supervisory functions (standards for the documentation of observations, the results of testing, information and data obtained during the course of inspections, to ensure that they are recorded in a timely, consistent and professional manner to prevent the loss of relevant information).

This means that there is no overall system in place to guarantee that documentation is appropriately referenced, signed off and cross-referenced.

8.9 Describe in detail the use of unannounced inspections and the legal framework for such visits;

The use of announced and unannounced inspections is described in the instruction/ guidelines for cosmetic treatment. The unannounced character of the legally obliged inspections of nursing homes is mentioned in the guidelines for nursing homes.

A standard procedure for unannounced inspections, based on the legal framework and the specific sections of the relevant legislation, is available and can be used accordingly. However, general guidance for the choice between announced and unannounced inspections is not in place and no general or overall description of the use of unannounced inspections and the legal framework for such visits is available.

8.10 Have arrangements in place for the follow up of its inspection findings.

Various follow up instructions for inspection findings are part of the guidance documents available for nursing homes, private clinics and cosmetic treatment. A systematic or structured follow up instruction, including a systematic approach of sanctions, is not in place.

Recommendations chapter 8

31.0 Clear terms of reference and objectives should be set for all inspection activities. This information should be available to all staff and also to the public, and should be accessible on the DHMA website.

32.0 DHMA should use standardised techniques for sampling and inspection. These should be documented in circumstances where the absence of such instructions could jeopardise the efficiency or outcome of the inspection.

33.0 DHMA should describe in detail, and for all categories of service, the use of unannounced and announced inspections and the legal framework for such activities.

34.0 DHMA should have systematic communication arrangements in place for reporting its inspection findings.

35.0 DHMA should audit its activities to ensure that methods which it uses are in accordance with the legislation and as documented in its policies and procedures.

36.0 All documentation should be appropriately referenced, signed off and cross-referenced.

37.0 Information about incidents, complaints, accreditation results and performance of service providers etc. which is, in principle, available to DHMA should be made available by using a suitable managerial tool for intelligence gathering and collation of relevant information.

38.0 An independent panel of external experts should be established to support DHMA in taking forward its supervisory functions.

Chapter 9

Does DHMA communicate the objectives and outcomes of its inspection activity to those subject to inspection in a way that is clear and timely; giving them the opportunity to comment on findings and recommendations?

The supervisory body should:

- clearly communicate the objectives and purpose of its inspections to those subject to inspection.
- clearly set out the consequences of non-compliance with supervisory measurements and requirements and its expectations in terms of response to its recommendations.
- give those subject to inspection the opportunity to comment on the findings, conclusions and recommendations set out in the inspection report.

The objectives and purposes of the supervisory work related to the tasks defined specifically in the legislation are published on the website (www.sst.dk), with reference to relevant legislation. The possible consequences of non-compliance are also presented on the web site. But the policies and procedures used by DHMA are not published likewise.

All draft reports are sent to individuals and organisations for factual accuracy checking prior to publication.

Some respondents felt that the web site was difficult to use, thus making it difficult to access the relevant information. Some also found DHMA taking a relatively passive role in communicating the findings of inspections and investigations, e.g. by not being proactive in making information available to the public.

The Peer Evaluation Team found some truth in the statement that the website is difficult to handle. The Team also had difficulties in easily finding the right information on the (English and Danish) sites.

Representatives for organisations of health personnel claimed that DMHA does not communicate the objectives and purposes of its actions when investigating individuals in supervisory cases.

The cases reviewed by the Peer Evaluation Team showed to the contrary that DHMA was clear about objectives and purposes of its actions when investigating individuals in supervisory cases, (see also chapter 8.3).

Chapter 9 Conclusions and recommendations

Conclusions chapter 9

9.1 Clearly communicate the objectives and purpose of its inspections to those subject to inspection.

DHMA fulfils the basic legal requirements when communicating the outcomes of inspections or investigations. However, there is potential for improvement in communicating the outcomes of investigations with involved individuals, with organisations and with the wider society, including the press.

9.2 Clearly set out the consequences of non-compliance with supervisory measurements and requirements and its expectations in terms of response to its recommendations.

The guidelines for the statutory obligations of DHMA (inspections of nursing homes, private clinics, cosmetic treatment) are clear, setting out the requirements and expectations in response to its recommendations and the consequences of non-compliance with supervisory measurements. Also, in individual cases, where health professionals pose a risk to patient safety, the requirements and expectations in response to its recommendations, and the consequences of non- compliance with supervisory measurements is clearly presented to the person concerned. For other inspections (see chapter 8.2), no general instructions are available. This leads to the conclusion that for these parts of the supervisory tasks the requirements and expectations in response to DHMA's recommendations could be clearly presented to the persons involved, but if this is happening it is not based on a general instruction to do so.

9.3 Give those subject to inspection the opportunity to comment on the findings, conclusions and recommendations set out in the inspection report

According to the guidelines for the inspection tasks of DHMA (nursing homes, private clinics, cosmetic treatment) guidelines and instructions are available which clearly set out the instructions for monitoring the report and the reporting format. It clearly mentions the requirement to submit these documents to the nursing unit etc. for any comments. A timetable for feedback and factual accuracy checks is included in the instructions.
In the individual cases, cases where health professionals pose a risk to patient safety, DHMA provides an opportunity to the individual to correct errors of fact on the draft findings. Measurements and outcomes of the case are clearly presented to the person or persons concerned.

Recommendations chapter 9

39.0 DHMA should develop a comprehensive strategy for both internal and external communications, and make its policies and procedures available on the website.

40.0 DHMA should ensure that health personnel involved in supervisory cases are aware of the procedures and what DHMA expects from them.

41.0 DHMA should develop a policy on the circumstances in which sensitive personal information will be kept confidential, indicating when and how information from inspections and investigations will be disclosed to the general public.

Chapter 10

Is DHMA open and transparent and does it make its findings available to stakeholders and the public?

The supervisory body should:

- make details of its processes and the findings of its inspections and activities available to the public and other stakeholders; in so doing it should ensure that its reports are written and published in formats that are user friendly and accessible.
- have a policy and guidelines in place setting out its approach for the publication of the results of its inspections.

DHMA makes most of the findings of its inspections available on the internet.

All reports from planned inspections (private clinics, cosmetic clinics and nursing homes) are published on the website.

All major inspections in public hospitals, e.g. “code-case”, “Glostrup” and “ 1813” are also published on the website. In individual cases, the sanctions to the health personnel are also published on the DHMA website.

Information that is not openly accessible is not published on the website. In individual cases this information is sent directly to those concerned.

If not directly required by legislation, information related to personal data is not actively published, but may be provided in response to a request made under the Danish Freedom of Information Act.

The public can use the Freedom of Information Act (FOI) to ask for access to information from documents, but are not consulted with or actively engaged in setting inspection goals in general.

The annual themes DHMA uses to shape its inspection programme, e.g. mental health issues in care homes, comes mainly from the staff and is not based on open communication with stakeholders and the public. It was noted that overarching reports, previously published, are no longer routinely provided by DHMA.

The Peer Evaluation Team was advised that all knowledge from inspections and adverse events is used to generate nationally binding guidelines. These guidelines

are an interpretation of how health personnel can conduct themselves with care and consideration, as they are obliged to in accordance with section 17 of the health personnel act. The guidelines are published on the website. An overview of the guidelines shows that various topics and subjects have been assessed in this way.

No evidence was made available of a policy or guidelines on how DHMA is using data from supervisory work for learning purposes, and quality improvement in the health sector, in a systematic and strategically planned way. Prior to most inspections, information is not generally received from the public. The DHMA does not use social media as a source to obtain information and intelligence from the public.

The reporting system for adverse events did originally sit within DHMA but was transferred some years ago to the National Agency for Patients' Rights and Complaints (NAPRC). This knowledge on adverse events is used by DHMA to produce the above mentioned guidelines. As DHMA is not any longer responsible for the handling of adverse events, this information, or a link to this information and how adverse events are now handled by the National Agency for Patients' Rights and Complaints (Patientombuddet), is not available on the DHMA website.

The processes for preparing and carrying out inspections are, at least for most of the legally prescribed tasks of DHMA (planned inspections private clinics, nursing homes and cosmetic treatment), described in the various policies and procedures. The descriptions of the inspection processes are not available on the website.

Besides, there are clear guidelines including processes such as radiation and medicines, but there is no set overall handbook for all processes available.

Working methods, for instance on how to investigate incidents, is partly available on the website, but not in full. Information regarding standards and norms, except for the binding guidelines on specific topics, is not available on the DHMA website, and is not communicated openly to the public, press and stakeholders (public hospitals etc.).

Prior to inspection of nursing homes or cosmetic private clinics a set of standards, is developed before DHMA visits the clinics, e.g. for gynaecology or eye diseases. The same happens with inspections at nursing homes. These standards could be provided to the public and to the supervised institutions on the DHMA website but are not currently available.

An annual report on themes is published. Individual reports are only published for care homes. Nursing homes are required to post their supervision reports on their own websites and on the website of the Social Service Board, (Socialstyrelsen). The outcome of the inspection of nursing homes could also, as a service to the public and from a transparency point of view, be made available by DHMA on their website. This information is however not systematically available on the DHMA website.

The communication and follow up methods after an inspection are variable and depends on the findings and recommendations of an inspection. This is part of a set of various and per category different internal procedures, which are not fully available on the DHMA website (see also chapter 8.10).

A systematic or structured follow up instruction, including a systematic approach of sanctions was not found by the Peer Evaluation Team.

In specific cases the central office of DHMA and the regional inspectors are not operating proactively in communicating with stakeholders, press and public. Proactive communication with the press includes a press strategy which identifies and makes appropriate use of the relevant elements of DHMA policy.

The media has a tendency to look only at the national part of the authority (DMHA) after a scandal has become public.

Chapter 10 Conclusions and recommendations

Conclusions chapter 10

10.1 Make details of its processes and the findings of its inspections and activities available to the public and other stakeholders; in so doing it should ensure that its reports are written and published in formats that are user friendly and accessible.

DHMA could improve communication with the public, with stakeholders, with the National Agency for Patients' Rights and Complaints (NAPRC) (Patientombuddet), with the Ministry of Health and with Members of Parliament.

There is need for a better communication strategy. Public expectations are high and may exceed what can be achieved within available resources. It is necessary therefore to make clear what DHMA is doing, can continue to do, as well as what is not being done, and why.

More public involvement in the work and more and better co-ordination with a broader range of organisations is necessary to make sure that information is shared appropriately with key stakeholders.

10.2 Have a policy and guidelines in place setting out its approach for the publication of the results of its inspections.

An overall approach for publication of inspection results and a proactive policy for setting communicating with stakeholders, press and public would strengthen elements of the DHMA’s approach to supervision.

Recommendations chapter 10

42.0 *DHMA needs to communicate with the general public the key tasks and goals of the supervisory organisation, and also be clear as to what can and cannot be done, and why, and what could be done if additional resources became available. The communication strategy should identify the specific legal obligations and restrictions for the regulator.*

43.0 DHMA should, in co-operation with relevant stakeholders, develop a strategy for elaborating and distributing supervisory data for improvement purposes in the health sector.

44.0 DHMA Procedures for supervision of health care providers should be available.

45.0 DHMA could inform the public about the outcomes of investigations including the imposition of sanctions, by informing the press more actively and by taking more time to explain why how and to what extent DHMA is being proactive in this field.

46.0 DHMA should set out findings of investigations where they have taken action and also any investigations which are concluded but have not resulted in imposition of a sanction.

Chapter 11

Is DHMA's approach to issuing of disciplinary sanctions appropriate

The supervisory body should:

- have appropriate processes in place for the issuing and management of disciplinary sanctions.

DHMA's approach to issuing disciplinary sanctions is set out in section 215 of the Health Care Act, and in different sections in Act relating to authorisation of health personnel etc.

The work related to disciplinary sanctions is performed according to strict procedures based upon legal requirements. The Peer Evaluation Team accessed sets of case records selected at random from 2013. In all cases investigated (35 cases), the procedures were followed, the relevant personnel were invited to meet with DHMA together with a legal or other representative of their choice, written notes were made from the meetings and these notes were presented for factual accuracy checking before decisions were made. The Team also noted that disciplinary cases were dealt with without undue delay.

Sanctions were appropriate: within a balanced and proportionate range, with due regard to protecting the public, a focus on prevention of (further) harm and with prevention of unnecessary reputational damage towards the medical personnel involved.

The procedures followed are not described in detail on the DHMA website. But there is general information available on how DHMA deals with these cases.

Prior to 2011, staff felt that the power to issue sanctions was limited. The changes to the legislation in 2011 had the effect of extending the authority of DHMA in this important area.

Decisions made in relation to individual doctors may only be challenged through court and a number of decisions to impose a sanction have been referred to the legal system. The absence of an internal administrative complaint procedure is based upon explicit legal rules.

See for a more detailed description of the findings of the Peer Evaluation Team in individual cases chapter 8.3.

Chapter 11 Conclusions and recommendations

Conclusions chapter 11

11.1 Have appropriate processes in place for the issuing and management of disciplinary sanctions.

The procedures followed in disciplinary cases comply with the legal requirements. The lack of administrative complaint procedures is outside the authority of DHMA. Not least due to the lack of administrative complaint procedures, DHMA has to demonstrate a higher order of compliance with its internal administrative procedures in all such cases.

Disciplinary sanctions are an integral part of the DHMA strategy in individual disciplinary cases. The sanctions used are appropriate and relate to the particular circumstances of the specific case. These sanctions are not part of a structural system or a well-defined policy. However, the results are, in general balanced and proportionate. Also, sanctions in other cases do not rely on a sophisticated system approach, but in these cases the outcomes seem appropriate to the circumstances. DHMA does not have a well-defined system in place for the issuing and management of disciplinary sanctions. Nevertheless, the outcome is in accordance with good practice.

Recommendations chapter 11

47.0 DHMA should consider establishing an advisory panel that could assess and review the procedures and practices followed by DHMA in cases related to disciplinary sanctions.

48.0 DHMA should consider making the policies and procedures followed in these cases more publicly available to interested parties, including the public.

49.0 DHMA should continue to report the outcomes of disciplinary cases and the consequences in terms of prevention of harm. DHMA should take steps to promote public safety, including any measures required to address risk factors which may require notification to other service providers.

Chapter 12

Does DHMA have the necessary mechanisms in place to enable its impact and contribution to the improvement of the quality of care and patient safety to be measured and assessed?

The supervisory body should:

- have a policy and process in place for measuring the impact of its work
- regularly consider and assess how its inspection activity may contribute to the improvement of quality of care and patient safety.

The impact of DHMA's inspections on the standard of nursing home provision seems to be evident. However, there has been no formal evaluation of the work DHMA undertakes of the impact of its activities. The evaluation which was performed focused on the process and not on the outcomes of the inspections.

The Ministry of Health has set a requirement for an evaluation of the new planned supervisory approach regarding private clinics to be undertaken in three years' time.

There are no plans to carry out research into the impact of the inspection process. DHMA was unable to confirm whether anyone was undertaking independent research on the impact of supervision.

It is possible to produce over-arching reports on cosmetic clinics, nursing homes and private hospitals, if the approach adopted across Denmark was standardised.

The process for the inspection of private doctors has been developed to enable evaluation.

Chapter 12 Conclusions and recommendations

Conclusions chapter 12

12.1 Have a policy and process in place for measuring the impact of its work

DHMA has no policy and procedure or formal evaluation mechanisms in place to measure the impact of its work, or to audit the results of its inspection activities.

12.2 Regularly consider and assess how its inspection activity may contribute to the improvement of quality of care and patient safety

No plans are in place to carry out research as to the wider impact of the obligatory inspections.

Outside the obligatory inspection fields there are also no processes available to carry out overall evaluation on how inspection activity may contribute to the improvement of the quality of care and patient safety.

Over-arching reports such as reports on cosmetic clinics, nursing homes or of private hospitals are not being produced on a regular basis.

Evaluation of other mechanisms such as inspection of private doctors is not actively or systematically organised.

Recommendations chapter 12

50.0 DHMA should have a process to measure and report on the impact of the work of the supervisory arm of the organisation.

51.0 DHMA should systematically evaluate the result of its activities by completing impact assessments which will enable decisions to be taken about future priorities and appropriate use of limited resources.

52.0 DHMA should consider whether it has sufficient capacity and resources to undertake the full range of supervisory activities required and should identify any gaps to the Department of Health for further consideration.

53.0 DHMA should consider re-establishing the practise of publishing overarching reports of quality, safety, and outcomes of its inspection activities.

Chapter 13

In developing its plans, inspection approaches and findings does DHMA engage with stakeholders, patients and other review bodies?

The Supervisory body should:

- ensure that in taking forward its role it engages with patients, the public and other stakeholders; seeking their views and experiences.
- work in collaboration with other review bodies to share experiences and identify noteworthy practice.
- share its knowledge in relation to patient safety issues with health organisations.

13.1 Ensure that in taking forward its role it engages with patients, the public and other stakeholders seeking their views and experiences.

There are a number of important stakeholders in the system who need to communicate effectively with DHMA, for example the National Agency for Patients' Rights and Complaints (Patientombuddet), the Regional and Municipal Authorities, service providers such as private clinics and hospitals, and umbrella organisations representing the interests of the public.

There are regular meetings with the National Agency for Patients' Rights and Complaints (Patientombuddet).

DHMA receives a copy of all complaints (5,000 complaints per annum) when they are reported to the National Agency for Patients' Rights and Complaints and when they are solved / decided on by this Agency.

Complainants are aware that a copy of their complaint is sent to DHMA, as in all decisions made by the National Agency for Patients' Rights and Complaints (Patientombuddet) it is stated that DHMA receives a copy (see for communication also chapter 10).

DHMA advised the Peer Evaluation Team that individual complaints do not receive attention from DHMA but that they look at the patient safety issues that a complaint might represent.

Between receiving and deciding the outcome of complaints investigations, by the National Agency for Patients' Rights and Complaints (Patientombuddet), - there is a

time gap. DHMA has no general policy in place to make use of this interval to act on specific patient safety issues regarding these complaints.

The complaints are not prioritised by the National Agency for Patients' Rights and Complaints (Patientombuddet).

Before the Task Force was initiated DHMA coded all referrals as either red, amber or green, depending on the degree of complexity and risk of the complaints, to ensure that the most serious complaints received priority within the health and supervisory tasks of DHMA, (see for prioritization also chapter 8.4).

DHMA has the legal obligation to inform and offer guidance to competent authorities and to the public, as stated in Health Act section 213 and 214, and to set guidelines in accordance with § 17 of Consolidated Act No. 877 of 4 August 2011 on the authorisation of health personnel and on professional health activities (the Authorization Act).

DHMA advised that they devote a lot of time to this task, e.g. the handling of medication, the responsibilities of health personnel, the rights of patients, and many questions concerning patient safety in general.

DHMA may issue authority letters to the involved hospital departments and clinics, engage in meetings with those responsible for the services to require them to take specific action, provide seminars for various health personnel groups and issue binding guidance specifically to instruct staff to behave in a certain way.

Sharing information with other health organisations was mentioned by more than one respondent as an active task of DHMA, but not everyone agreed that this happens on a planned or systematic basis.

A major consideration is the need to improve internal communication and co-ordination within DHMA, particularly between the central and the regional offices. There are unresolved tensions which are impacting on the way the organisation delivers its supervisory functions. Until these matters are resolved the organisation will continue to have difficulty in co-ordinating its response to major concerns, (see for the relations between the centre and the regions also chapter 5 and 8).

DHMA stated that it has a policy on user involvement. Nursing home inspections includes inspectors having direct contact with residents.

DHMA consults with the public and with user / interest groups to help inform the approach to inspection. Examples of regular consultation were cited by several respondents.

Some respondents stated that there are good working relationships between them and the DHMA, and there is no barrier to further improving relationships or to sharing information appropriately.

One agency felt that they could be involved to a greater degree in the development of guidelines.

A group meets twice each year to consider adverse events and how information on adverse events is utilised to support the development of guidelines. See for adverse events reporting and cooperation, chapters 7.3 and 10.

DHMA engages with the medical societies who have been involved in the development of indicators.

The Patient Association confirmed that it works collaboratively with DHMA on a number of levels, including providing representation to steering and working groups. They reported that co-operation had been enhanced, with a national conference being held in 2011 and another planned for 2014.

Some respondents - especially those who are also working with the broader DHMA organisation - felt that there is a perceived conflict of interest in that DHMA is part of a wider agency which acts to defend the healthcare system whenever it is subject of public criticism, hence the potential for DHMA to be seen as part of the healthcare system, rather than being independent of it.

Not all findings are made public and those which do become public are usually brought to attention of the public by media reporting. DHMA advised that they make about 80% of all their work public. Individual cases are not published, but all sanctions are published. The media do not have any influence on what is published but can access information within the legislation (Freedom of Information Act) and publish it separately. Some respondents stated that DHMA needed to have a better approach to communicating its role and responsibilities to the people of Denmark.

Chapter 13 Conclusions and recommendations

Conclusions chapter 13

13.1 Ensure that in taking forward its role it engages with patients, the public and other stakeholders; seeking their views and experiences.

There are a number of important stakeholders in the system who need to communicate effectively with DHMA, for example the National Agency for Patients' Rights and Complaints (Patientombuddet), the Regional and Municipal Authorities, service providers such as private clinics and hospitals, and umbrella organisations representing the interests of the public.

There are regular meetings with the National Agency for Patients' Rights and Complaints (Patientombuddet). DHMA has a strategy in place to engage with patients, interest groups, stakeholders and the public. DHMA has good working relations with a limited number of organisations such as Patientombuddet, medical and patient organisations.

Guidelines and indicators, as well as adverse events signals are being developed.

DHMA has a policy on user involvement.

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, for instance, other networks including social media.

13.2 Work in collaboration with other review bodies to share experiences and identify noteworthy practice.

Work in collaboration with other review bodies, as well as accreditation bodies, and with community based organisations, is not systematically organised.

13.3 Share its knowledge in relation to patient safety issues with health organisations.

DHMA is well prepared and actively involved in sharing its knowledge with other health related organisations such as municipalities, organisations of psychiatrists, nurses, nursing assistants, etc.

DHMA has a policy in place to share information by using authority letters, meetings, organising seminars, producing binding guidance, working with scientific organisations and other relevant stakeholders.

DHMA has the legal obligation to inform and offer guidance to competent authorities and to the public as stated in Health Act section 213 and 214, and to set guidelines in accordance with § 17 of Consolidated Act No. 877 of 4 August 2011 on the authorisation of health personnel and on professional health activities (the Authorisation Act).

DHMA commits a significant amount of resource to this task e.g. the handling of medication, the responsibilities of health personnel, the rights of patients and many questions concerning patient safety in general.

DHMA issues authority letters to the involved hospital departments and clinics, various meetings with those responsible for the services to make them take action, seminars for various health personnel groups and binding guidance to specifically to instruct staff to behave in a certain way.

Sharing information is an active task of DHMA but does not always happen in a planned, systematic and coordinated way.

A major consideration is the need to improve internal communication and co-ordination within DHMA, particularly between the central and the regional offices. There are unresolved tensions which are impacting on the way the organisation delivers its supervisory functions. Until these matters are resolved the organisation will continue to have difficulty in coordinating its response to major concerns, (see for the relations between the centre and the regions also chapter 5 and 8).

Recommendations chapter 13

54.0 DHMA should review the arrangements by which it engages with patients, patient organisations and with the general public.

55.0 DHMA should examine its approach to engagement with the media, particularly in respect of serious concerns and high profile investigations.

56.0 DHMA should benchmark with other similar supervisory organisations in developing a robust communications and publication strategy.

57.0 DHMA should consider how best to make use of the information it collects and processes to inform the public about key trends and developments in respect of healthcare and associated supervisory activities.

Epilogue

This peer evaluation was conducted by a team of highly skilled and experienced EPSO members (in co-operation with the EPSO secretariat) who have in addition to their substantive positions in their respective organisations invested personal time and energy into this project, without any self-interest except for learning from each other and from the Danish Board of Health and the Danish healthcare system.

Working with this group was a worthwhile experience, although two of the original six members were unable to complete the process for health and other reasons. We are very grateful for their specific contributions to the development of the final product of the Peer Evaluation Team.

The support group that was identified by EPSO at the start of this project did not have to do a lot of work, but was nevertheless a very useful backup for the activities of the Peer Evaluation Team. The Team was happy to know that other experienced and qualified EPSO members could assist if necessary.

EPSO is privileged and grateful to have been in a position to organise and support this work; with special thanks to the Danish government who chose EPSO as partner for their work with the Danish Health and Medicines Authority, and who supported the Peer Evaluation Team more than could have been asked for.

Jooske Vos EPSO

EPSO
European Partnership for Supervisory Organizations in Health Services and Social Care

The European Partnership for Supervisory Organizations in Health Services and Social Care (EPSO) is an informal group of governmental and government-related organizations involved in law enforcement, supervisory activities, monitoring and accreditation, related to Health Services and Social Care in European countries or regions, including EFTA (European free trade area) countries.

EPSO aims to:

- improve co-operation amongst supervisory bodies to ensure the quality of inspection, supervision and monitoring of health services and social care;
- improve the exchange of ideas, outcome of research, information and good practice;
- facilitate the exchange of experience between interested organisations including directives, regulations, standards and guidelines;
- promote co-operation on topics such as education and dissemination of knowledge; and
- as a result of these activities EPSO aims to improve the quality of health care and social care in Europe including EFTA countries.

Specifically EPSO is focused on:

- Building up a network by exchange of information and co-operation between European colleagues in supervisory organisations, in order to develop mutual confidence and trust in the resolution of matters of health and social service supervision. In the case of cross border health care of patients as well as health care personnel, the network will facilitate the exchange of information about quality and safety of health care institutions and health care personnel. The members of the network will work together if this is deemed desirable or necessary in the interest of cross-border healthcare.

- Improvement of the quality of supervisory activities in health & social care within the European Community including the European Free Trade Area (EFTA countries) by improving informal and formal exchange of information between European colleagues in supervisory organisations, good and bad practice, outcome of research, promotion of joint co-operation on specific terms of health care, education and dissemination of knowledge and other ways to connect between the supervisory organizations and the organizations involved in quality control on health services as well as connecting individual members in the various countries or regions in order to improve the exchange of ideas and good practice in health & social care in Europe.

- Promotion of the adoption of good practice, in respect of the principle of the European 'home authority'. This involves facilitating the exchange of experience between interested organisations, for example exchange of directives, regulations, standards and guidelines.

- The support of EPSO working groups on specific topics such as Risk assessment methods in healthcare and Social care regulation; Restraints and Coercive methods in Health and Social Care; Economic regulation in Health and Social Care; Partnership of inspectorates working together on methods of inspection; activities such as debates and working group activities on the Ageing and Active Ageing;
- Support and organising of educational activities based on good practise of supervisory organisations regarding health and social care;
- Conduct and organising of Peer Evaluation activities in EPSO member countries.

Overview of Aims Actions and Output of EPSO

Aim	Action(s)	Output
Strengthen the exchange of knowledge and experiences between national supervisory bodies	Two conferences every year	Documents and presentations published on internet
Develop and discuss regulatory issues of common interest to several countries	Establish working groups in defined areas for time limited work	Reports published on internet
Enhance quality of supervisory activities	Maintain a system for Peer Evaluation of supervisory bodies	Report presented to the relevant national authority and published on internet
Enhance quality of supervisory activities	Develop Educational Activities on request	Educational material published on internet

Appendix 2

The EPSO Peer Evaluation Team and Reference team

- Jan Vesseur (President of Peer Evaluation Team),
  Chief inspector for Patient Safety, Health IT and International affairs of the Netherlands Health Inspectorate IGZ;
- Geir Sverre Braut, (Member of the Peer Evaluation Team),
  President of EPSO and former Deputy and Acting Director General Norwegian Board of Health Supervision;
- Glenn Houston (Member of the Peer Evaluation Team),
  Chief Executive at RQIA The Regulation and Quality Improvement Authority Northern Ireland;
- Jooske Vos (Member of the Peer Evaluation Team),
  Director Eurinspect and General Secretary of EPSO;
- Mandy Collins(Member of the Peer Evaluation Team- partially) Former Deputy Chief Director of the Wales Health inspectorate;
- Neil Prime (Member of the Peer Evaluation Team- partially);Former Head of Analytics, Intelligence Directorate Care Quality Commission, England;
-

Members of the Reference Team

- César dos Santos Carneiro, Head of Department of Studies and Economic Regulation ERS Portugal;
- Helge Høifødt, Assistant Director of Department of Administration, the Norwegian Board of Health Supervision.

MINISTRY OF HEALTH

Appendix 3

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Date: 24 June 2013
Section: Sundhedsjura og lægemiddelpolitik
Case Officer: SUMMSB
Case No.: 1303064
Doc No.: 1242955

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

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 Glostrup 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.

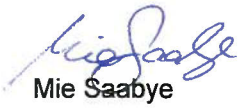
Practical issues

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

Appendix 4

Overview of the main documents considered by the Peer Evaluation Team and involved in the peer evaluation

Legislation

- Overview of the history of the legislation regarding healthcare professionals at risk
  - 1 Jan 1933 Act no 182 of June 1932 on the Health Sector's Central Administration and Act no 72 0f 14 March 1934 on general practitioners;
  - 1 Jan 1956 Act no 168 of 24 May 1955 on Amendment of Danish Act on General practitioners;
  - 1 July 2000 Consolidated Act no 215 of 9 April 1999 on the Health Sector's Central Administration etc. as amended by Act no 258 of 12 April 2000;
  - 1 January 2007Act no 546 of 24 June 2005 The Danish Health Act;
  - 1 January 2007 Act no 547 of 24 June 2005 on Complaints and the Possibility of Seeking Damages in the Health Sector;
  - 1 January 2007 Act no 451 of 22 May 2006 on Registration of Healthcare Professionals and on Healthcare Activities ;
  - 1 January 2011Act no 706 of 25 June 2010 on e.g. Amendment of Act on Registration of Healthcare Professionals and on Healthcare Activities;
  - 1 July 2013 Act no 361 of 9 April 2013 on. Amendment e.g. of Act on registration of Healthcare Professionals and on Healthcare Activities.

- Overview of the history of legislation regarding Organisations at risk
  - 1 January 1933 Act no 182 of 23 June 1932 on the Health Sector's Central Administration and Act no 72 of 14 March 1934 on General Practitioners entered into force 1 Jan 1935;
  - 1 January 2002 Act no 490 of 7 June 2001 in Amendment of e.g. Act on Public Health Medical Officers etc.;
  - 1 January 2007 Act no 451 of 22 May 2006 on Registration of Healthcare Professionals and on healthcare Activities;
  - 1 January 2012 Act no 607 of 14 June 2011 on Amendment of the Danish Health Act;
  - 1 July 2013 Act no 361 of 9 April 2013 on Amendment e.g. of the Danish Health Act.

- The Danish Health Act, title XVII, on Government authorities etc. Part 66, paragraphs/ sections 212- 221, regarding the Danish Health and Medicines Authority (DHMA);
  Sundhedsloven – The Danish Health Act sections on patients' rights, forensic tasks, penal provisions etc.;
- Other Relevant Legislation such as:
  Authorisationsloven –Authorisation Act;
  Bekendtgørelse af lov om anvendelse af tvang i psykiatrien Retssikkerhedsloven –Act on the use of coersion in psychiatry;
  Retssikkerhedsloven inspektioner (tilsynsbesøg)-The Law on inspections '

General documents

- **Annual Report 2012;**

- **Resultatkontrakt 2012, 2013 and 2014** between The Health and Medicines Authority and the Ministry of Health;

- **Supervision Strategy 2010-2015** –Tilsynsstrategi 2010-2015;

- **Udvikling af Administrativ Ledelsesgruppe for Embedslægeinstitutionerne (ALG) til et Strategisk Kontaktforum (SKF);**

- **Dansk Standard DS/EN ISO/IES** 17020, 4 udgave, 2012-05-21;

- **Guidance document on Requests for access to public information** in accordance with the Acts on Public Administration, Information and Privacy Act (Aktindsigtsanmodninger iht. Forvaltningsloven, Offentlighedsloven og Persondataloven);

- **Memorandum on Public Health Medical Officers 12 April 2013;**

- **Memorandum on Proactive Supervision 23 August 2013;**

- **Report from Danish Audit Office for Budgeting and Accounting:** Beretning til Statsrevisorerne om kvalitetsindsatser på sygehusene – February 2012 – Document regarding the following questions :
  - Is there a link between the national quality initiatives and hospital wards work to ensure and develop the quality?
  - Do the national quality initiatives support the work of hospital wards to safeguard and develop the quality?
  - Are the Ministry of Health and the Regions following up on the national quality initiatives which help to ensure and develop the quality?

- **Report the Danish Audit Office for Budgeting and Accounting :** Tilsyn med private leverandører af mammografiundersøgelser (Notat til Statsrevisorerne om tilsyn med private leverandører af mammografiundersøgelser- May 2012);

- **Report from the Danish Audit Office for Budgeting and Accounting:** Cases on price, quality and treatment in private hospitals regarding:
  - use of mammography equipment in violation of orders;
  - poor quality of mammography screening;
  - lack of detection of breast cancer in clinical mammography)(Opfølgning i Sagen om pris, kvalitet og adgang til behandling på private sygehuse (beretning nr. 15/2008) – January 2011).

Procedural documentation and Guidance and Monitoring documents

- Supervision measure points dermatology 04.10.12 –Consultation Draft;

- Guidance document regarding cosmetic treatment;

- Guidance document on supervision of nursing homes , sheltered housing estates and similar housing units;
- Task Force forretningsorden –Task Force Procedures;
- Guidance document on Notification of unannounced visits – (Varsling af uvarslet besøg);
- Concept for yearly appraisals;
- Other relevant binding guidelines on various topics such as delegation of privileged healthcare tasks, cosmetic treatment, registration and supervision of certain private hospitals , prescribing medication management , new treatments in healthcare , legal status in nursing homes and many other topics;
- Various other policy documents and organisation and guiding documents;
- Overview of other relevant documents on department level.

Specific case information received from the Danish Ministry of Health

- Doc 1 Opsummering af Mejlhede-sagen – 23. august 2013;
- Doc 2 Short summary of the DHMA focus on the radiology area – 23. august 2013;
- Doc 3 Short summary of the mammography case – 23. august 2013;
- Doc 4 Short summary of the Herlev Case– 23. august 2013;
- Doc 5 Short summary about the use of misoprostol in birth inducement– 23. august 2013;
- Doc 6 Proactive Supervision– 23 august 2013;
- Doc 7 Short summary about the psychiatry department in Glostrup;
- Document regarding an Unannounced visit to Glostrup - tilsynsbesøg på Glostrup Privathospital;
- 2 findings of the Danish Parliamentary Ombudsmand (Folketingets Ombudsmand Jørgen Steen Sørensen):
    - Levendefødte, uafvendeligt døende børn efter aborter skal have Omsorg – 9 Maj 2012 (J.nr. 12/00236);
    - Sygehuslægers journalføringspligt – 25 oktober 2010 (J.nr. 2008-2276-420).

European Partnership for Supervisory Organisations in Health Services and Social Care

Statement of Integrity

The undersigned, members of the independent EPSO Peer Evaluation Commission have been appointed by the Danish Health Ministry to undertake a Peer Evaluation of the Danish Health and Medicine Authority (Sundhedsstyrelsen), in accordance with the example of the Peer Evaluation of the Norwegian Board of Health Supervision (Statens helsetilsyn), presented by EPSO in 2012.

We hereby declare that:

- A Peer Evaluation is an evaluation of the supervision function of a supervisory body by peers who have knowledge, experience and skills in the field of supervision or regulation of healthcare, which means that the evaluation of the professional activities of a specific supervisory body is performed by members of the same profession or by members who are professionally active in the same field of activities;
- A Peer Evaluation may be undertaken by or on behalf of the EPSO board, which implies that during the course of a Peer Evaluation any member of the EPSO board who is an employee of the specific supervisory body subject of the evaluation or who has a direct interest (either business or professional)with that supervisory body, will suspend his or her activities as a board member during the course of the Peer Evaluation;
- As a member of the Commission we do not have any personal, financial or business interest or knowledge that could become a conflict of interest with that specific supervisory body or with anyone employed by that supervisory body.

Names	Signatures	Date	Place
Jan Vesseur			
Geir Sverre Braut			
Mandy Collins			
Glenn Houston			
Neil Prime			
Jooske Vos			

European Partnership for Supervisory Organisations in Health Services and Social Care

Declaration of confidentiality:

We, the undersigned, members of the independent EPSO Peer Evaluation Commission to evaluate the Danish Health and Medicine Authority (DHMA), further referred to as the Commission,

hereby declare that -

- we agree to respect the confidentiality of the work and resulting reports both during and after the time in which EPSO has requested us to undertake tasks related to this request of the Danish Ministry of Health;
- we agree that we will neither divulge nor disseminate the findings to, nor will we discuss them with, any third party (including the media) unless there has been express and prior consultation and agreement in writing from the EPSO secretariat or the EPSO board in agreement with all members of the Commission;
- we understand that the reports, generated by the peer evaluation, remain the property of EPSO, which has sole right of decision as to who will receive the report of the Commission and at what time and in what form. The Commission may decide to present some interim findings in a verbal report.. The Final report will be presented to the Danish Ministry of Health and to the stakeholders and participants in the work of the Commission.
- we understand that EPSO as part of an independent foundation based on Dutch law, may decide to make these reports public, or to give access to them, on request, under the rules on access to documents under Dutch law.

Names	Signatures	Date	Place
Jan Vesseur			
Geir Sverre Braut			
Mandy Collins			
Glenn Houston			
Neil Prime			
Jooske Vos			

Appendix 6

Overview of the recommendations of the report

Recommendations chapter 1

1.0 *DHMA must organise a clear division between the supervisory tasks and its other statutory responsibilities.*

2.0 *The supervisory task should be clearly identifiable and balanced and defined by statute in such a way that it allows DHMA to make the best use of all available resources. DHMA should determine its supervisory priorities by focusing its activities in areas which will best serve the interests of patients and the wider public.*

3.0 *DHMA must have a clear and appropriately resourced strategic plan setting out the key objectives of the supervisory arm of the organisation and how its performance will be measured over time. This strategy has to clarify and define the boundaries of the supervisory tasks of DHMA and incorporate a risk based approach to priority setting (see for priorities chapter 8.4).*

4.0 *DHMA must determine its core priorities and how it will use its limited resources to best effect in providing the Minister, elected representatives and the general public with assurance as to the quality and safety of healthcare provisions across Denmark. It must determine priorities by focusing on activities in areas which will best serve the interests of patients and the wider public (see for priorities chapter 8.4).*

5.0 *DHMA needs to be clear as to the limitations of its role and responsibilities so that the organisation can concentrate resources on its primary duties and tasks. There ought to be clear procedures related to where DHMA has an "obligation to act" and where DHMA has an "opportunity to act". If no distinction is made between these categories and the obligation to act is specified in legislation, DHMA will have no opportunity to exercise professional discretion as to the broader scope of its tasks. The division between opportunity and obligation to act must rely upon sound interpretation of the legislation, agreed between the Ministry and DHMA and communicated with the wider public.*

6.0 *Before DHMA extends its role into proactive supervision of public hospitals, it must be confident that it has robust systems and processes in place to discharge all of its core functions.*

Recommendations chapter 2

7.0 The procedures for reporting and communicating the outcomes of supervisory tasks should be defined and made transparent.

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

9.0 A comprehensive media strategy which describes how DHMA will communicate the outcomes of supervisory tasks should be put in place as soon as possible.

Recommendations chapter 3

10.0 DHMA should review the policies and procedures for confidentiality and data protection for both electronic data and written records to make sure they are comprehensive and complete.

11.0 DHMA should have a policy and procedure for reporting and responding to any incident of loss of sensitive confidential information.

12.0 DHMA should make sure that employees are appropriately trained in the principles of confidentiality, record management and data protection. Refresher training should be available on a regular basis.

13.0 DMHA should test the resilience of its IT security systems to ensure that the necessary safeguards are in place, and are appropriate for the nature and extent of personal confidential data and information stored and accessed. DHMA should evaluate the risk of adverse events or system failures, and take appropriate measures to prevent unlawful access involving data loss. DMHA should assess whether it has taken all appropriate steps to mitigate all identified risks.

Recommendations chapter 4

14.0 Relationships between the central and the regional offices require significant improvement. The Peer Evaluation Team considers this to be one of the most important areas for improvement.

15.0 Consideration should be given to supporting the role of the Public Health Medical Officers in the regional offices to retain responsibility as lead investigators in supervisory matters, co-ordinating investigations from initial referral through to final determination.

16.0 The lines of authority and accountability of the senior managers in each of the regional offices and in the central office requires urgent clarification.

Establishing formalised structures for corporate decision making should be considered.

17.0 *The internal structure should be revised to ensure clear division of tasks and power between the central and regional offices, and between the supervisory tasks and other tasks of DHMA.*

18.0 *DHMA should implement a coherent system to assess all new cases and to prioritise work.*

19.0 *The use of information from adverse events for supervisory purposes should be further developed.*

20.0 *There should be a clearly defined threshold for referral of cases to the Taskforce. DHMA should make this clear in any planned evaluation of the role and functions of the Task Force.*

21.0 *Consideration should be given to a system of providing effective leadership of the supervisory function across Denmark. This could be achieved by establishing a forum of senior officers with responsibility for supervisory functions.*

22.0 *DHMA can improve arrangements for sharing information with other health organisations and should concentrate on improving systems for sharing knowledge and information between the central and the three regional offices.*

Recommendations chapter 5

23.0 *DHMA should have one overall quality system in place, where policies and procedures can be accessed on the intranet.*

24.0 *Regular audits should continue to be performed to confirm that supervision is being carried out in accordance with the approved policies and procedures.*

Recommendations chapter 6

25.0 *DHMA should prepare a workforce development strategy identifying how training needs of all staff will be met in future.*

26.0 *DHMA should develop formal induction training for newly appointed staff engaged in the supervisory functions at both the central and regional offices.*

27.0 *Each employee should have regular professional supervision and appraisal with their line manager, and should have a personal development plan identifying key training needs and how these will be met by their employer.*

28.0 *In-service training linked to the supervisory functions of DHMA should be available at regular intervals to all staff engaged in these duties.*

Recommendations chapter 7

29.0 DHMA's supervisory body should focus as a priority on a professional exchange of information within and between the regional and central offices, and organise sufficient financial recourses to build a stable and adequate IT communication system.

30.0 DHMA should focus on a suitable managerial tool to process the available internal and external information to support priority setting by using this information, and developing an electronic alert system alongside a human alert system to manage investigations, near misses, adverse events and other possible risks in the Danish Healthcare system as a whole. DHMA should utilise available information from other parts of the Danish Healthcare system as necessary, and the database should be developed in co-operation with the relevant parties.

Recommendations chapter 8

31.0 Clear terms of reference and objectives should be set for all inspection activities. This information should be available to all staff and also to the public, and should be accessible on the DHMA website.

32.0 DHMA should use standardised techniques for sampling and inspection. These should be documented in circumstances where the absence of such instructions could jeopardise the efficiency or outcome of the inspection.

33.0 DHMA should describe in detail, and for all categories of service, the use of unannounced and announced inspections and the legal framework for such activities.

34.0 DHMA should have systematic communication arrangements in place for reporting its inspection findings.

35.0 DHMA should audit its activities to ensure that methods which it uses are in accordance with the legislation and as documented in its policies and procedures.

36.0 All documentation should be appropriately referenced, signed off and cross-referenced.

37.0 Information about incidents, complaints, accreditation results and performance of service providers etc. which is, in principle, available to DHMA should be made available by using a suitable managerial tool for intelligence gathering and collation of relevant information.

38.0 An independent panel of external experts should be established to support DHMA in taking forward its supervisory functions.

Recommendations chapter 9

39.0 DHMA should develop a comprehensive strategy for both internal and external communications, and make its policies and procedures available on the website.

40.0 DHMA should ensure that health personnel involved in supervisory cases are aware of the procedures and what DHMA expects from them.

41.0 DHMA should develop a policy on the circumstances in which sensitive personal information will be kept confidential, indicating when and how information from inspections and investigations will be disclosed to the general public.

Recommendations chapter 10

42.0 DHMA needs to communicate with the general public the key tasks and goals of the supervisory organisation, and also be clear as to what can and cannot be done, and why, and what could be done if additional resources became available. The communication strategy should identify the specific legal obligations and restrictions for the regulator.

43.0 DHMA should, in co-operation with relevant stakeholders, develop a strategy for elaborating and distributing supervisory data for improvement purposes in the health sector.

44.0 DHMA Procedures for supervision of health care providers should be available.

45.0 DHMA could inform the public about the outcomes of investigations including the imposition of sanctions, by informing the press more actively and by taking more time to explain why how and to what extent DHMA is being proactive in this field.

46.0 DHMA should set out findings of investigations where they have taken action and also any investigations which are concluded but have not resulted in imposition of a sanction.

Recommendations chapter 11

47.0 DHMA should consider establishing an advisory panel that could assess and review the procedures and practices followed by DHMA in cases related to disciplinary sanctions.

48.0 DHMA should consider making the policies and procedures followed in these cases more publicly available to interested parties, including the public.

49.0 DHMA should continue to report the outcomes of disciplinary cases and the consequences in terms of prevention of harm. DHMA should take steps to promote public safety, including any measures required to address risk factors which may require notification to other service providers.

Recommendations *chapter 12*

50.0 DHMA should have a process to measure and report on the impact of the work of the supervisory arm of the organisation.

51.0 DHMA should systematically evaluate the result of its activities by completing impact assessments which will enable decisions to be taken about future priorities and appropriate use of limited resources.

52.0 DHMA should consider whether it has sufficient capacity and resources to undertake the full range of supervisory activities required and should identify any gaps to the Department of Health for further consideration.

53.0 DHMA should consider re-establishing the practise of publishing overarching reports of quality, safety, and outcomes of its inspection activities.

Recommendations chapter 13

54.0 DHMA should review the arrangements by which it engages with patients, patient organisations and with the general public.

55.0 DHMA should examine its approach to engagement with the media, particularly in respect of serious concerns and high profile investigations.

56.0 DHMA should benchmark with other similar supervisory organisations in developing a robust communications and publication strategy.

57.0 DHMA should consider how best to make use of the information it collects and processes to inform the public about key trends and developments in respect of healthcare and associated supervisory activities.