



DANISH PATIENT
SAFETY AUTHORITY

How do we supervise eHealth in Denmark

Parallel session H

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Variations of eHealth

- Offers and options online
- App´s without contact to healthcare professionals (stand alone with software)
- App´s with contact to healthcare professionals



Placing the user and the provider

- eHealth managed in favor of the Danish citizens by people *outside* Denmark
- eHealth managed in favor of the Danish citizens by people *within* Denmark





Guideline 9719 of November 8th 2005 concerning the responsibilities and liabilities related to the doctors use of telemedicine

- The definition of telemedicine: An opportunity for a specialist, who is not physically present around the patient, to be included in the patient's diagnostics and treatment. This is done by the use of video, pictures, sound and test results.
- The guideline above applies to procedures concerning specialist assessment and treatment etc. **in Denmark**.
- In case of Danish healthcare professionals use the specialist assessment for diagnostics, treatment, etc. which **is obtained outside Denmark**, the Danish doctor is in charge of the patient care, and will always, without exception, be responsible for the treatment, keeping the medical record etc.



Internet based eHealth

Diagnostics outside Denmark by the use of x-rays, CT- and MR-scans recorded in Denmark.

1st example:

MR-scan is recorded in a Danish hospital and send to a doctor in India, who does the diagnostic assessment, which is reported back to the hospital in Denmark.

<https://www.retsinformation.dk/Forms/R0710.aspx?id=10132>

→ The Danish Patient Safety Authority is the supervising authority.



Internet based eHealth

An ordering of prescription-only medicine on a website in Danish, which use an unidentified doctor in UK and a pharmacy in London.

2nd example: "121doc" (an e-labelled company)

Metformin Teva 500 mg/tablet 90 pcs = 295 DK kr./ Danish pharmacy price: 90 pcs = 32,85 DK kr.

VIAGRA Pfizer 100 mg. 4 pcs = 583 DK Kr./ Danish pharmacy price: 4 pcs = 316,45 - 549,75 DK Kr.

<https://www.121doc.com/dk/>

No guarantee for a professional supervision!

§25 about foreign prescriptions (EO 1671 of 12/12/2013 (executive order of prescriptions) as a link in the implementation of the EU legislation:

"It is illegal to receive medicine purchased in or dispatched from a non-EU or non-EEA country."

Supervisory problem: there are a wide variation of the professional standards among the EU/EEA countries.



Apps for diagnostics and communication with healthcare professionals

3rd example:

If a patient wants to have a quick medical consultation, the insurance company "TRYG" has an app for that purpose.

http://www.tryg.dk/tryg-plus-fordele/tryg-laegehotline?utm_source=lm.facebook.com&utm_medium=referral

→ The Danish Patient Safety Authority is the supervising authority



Apps with *stand alone software* for diagnostics and treatment

4th example:

Image analysis of birthmarks/moles.

Medical equipment

Does *not* need a permit from the Danish Medicines Agency

A demand for CE-labelling

The Danish Medicines Agency is in charge of the supervision of medical equipment that is brought to the Danish market.

<https://laegemiddelstyrelsen.dk/da/om/kampagner/test-med-fornuft/#>



A new clarification in Denmark

eHealth:

A company, which offers doctor consultations via the internet or an app, is considered a treatment facility.

This applies to the company even if there is no office address, where they receive patients undergoing treatment and even if they do not drive out to treat patients.

In other words: Regardless of whether or not the contact between the doctor and the patient is solely by phone or in writing (typically e-mail exchanges).

EO 615 of **May 31st 2017** about registration and supervision of public and private treatment locations etc. §2, section 1.

Guideline 9653 of **July 5th 2017** about registration and supervision of public and private treatment locations, including disclosures of supervision reports etc. Section 1.3.



Overview: Supervision of eHealth in Denmark

Type of e-Health	Located in Denmark	Located outside Denmark
<p>Internet services With communication between healthcare professionals and patient</p>	<p>Supervision: Danish Patient Safety Authority</p>	<p>+/- Supervision, Danish Patient Safety Authority If used by Danish healthcare professionals they are directly responsible for the entire treatment and they become supervisory objects.</p>
<p>App's Stand alone software, possibly with generalized counselling.</p>	<p>Supervision: The Danish Medicines Agency Is regarded as medical equipment subjected to the supervision from the the Danish Medicines Agency.</p>	<p>No supervision EU: Needs to be certified in the country, where the app is used.</p>
<p>App's With communication between healthcare professionals and patient</p>	<p>Supervision: Danish Patient Safety Authority</p>	<p>+/- Supervision, Danish Patient Safety Authority If used by Danish healthcare professionals, they are directly responsible for the entire treatment and they become supervisory objects.</p>

Briefing of a foreign supervising authority when it is not possible to intervene!



Questions and dialogue!

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