



20-6-17

## Agenda of the EPSO E-Health Working group – July 3<sup>rd</sup> Tallinn, Estonia

Location: Offices of Terviseamet , Paldiski mnt 81, Tallinn

Documents and information for this working group:

- Starting document of the EPSO Supervision and E- Health working group(160621 EPSO e-Health working group doc 1.0 160620)  
<https://www.dropbox.com/s/zy8yy6p2fm06fku/160621EPSO%20e-%20Health%20working%20group%20doc%201.0%20160620.pdf?dl=0>  
(this document is also available at our below copied website)
- E- Health presentation Tove Gemzell in London 25 -4-2017;  
<https://www.dropbox.com/s/vc2gzoxkmmzscs/eHealth%20extra%20session%2025april%20London%20Gemzell.pptx?dl=0>  
(this document is also available at our below copied website)
- Questionnaire on supervision of e-health clinics- for the EPSO e-Health working group meeting in Tallinn (3-7-2017) – this document includes draft answers for CQC based on the presentation of James Clemence in London 25/4/17;  
<https://www.dropbox.com/s/f3kxgjjwjp4fdmep/170614%20Questionnaire%20for%20the%20EPSO%20e-health%20working%20group%20jv.docx?dl=0>
- more information on the EPSO website : <http://www.epsonet.eu/ehealth.html>
- Invitation to this working group by Tove Gemzell (see below).

### 10.00 – 10.30

- Welcome by Tove Gemzell
- Introduction **-who is who,**
- **Agenda setting** – suggestions for changes in the Agenda,

### 10.30 – 12.00 Discussion about the Questionnaire for the EPSO e-Health working group based on the experiences with or ideas about supervision of e-health clinics by supervisory organisations in England ( CQC), Sweden (IVO), Estonia (Terviseamet)

- introduction by Paul Burdon on supervision on online clinics in England:
  - What do we mean by digital providers?
  - The size and scale of the market in the UK
  - What CQC has done
  - How we inspect
  - Common themes from inspection
  - Enforcement action taken
  - The challenges we face in this arena

-introduction by Tove Gemzell on idea about supervision on online clinics in Sweden;

-introduction on experiences with online clinics in Estonia – Helen Staak Tehnopol –  
“Connected Health” Specialist.

**12.00 – 14.00 Lunch** (at your own costs)

**14.00 – 15.00- Discussion about the topic of ‘medical devices’ and supervision**

Taking into account the priorities of the Estonian EU Presidency, the Estonian Health Board represented by Eve Pilt and Tagne Ratassepp will introduce the subject of discussion in the eHealth Working group in the afternoon:

**- introduction to the topic of “Picture Archiving and Communication Systems (PACS)”.**

Basically, a PACS workstation is specifically designed to be networked with a wide variety of diagnostic imaging systems, e.g. X-ray, nuclear medicine, magnetic resonance imaging (MRI) or ultrasound, as well as laboratory or hospital information systems. It does not contain controls for the direct operation of a diagnostic imaging system and is designed to receive, archive, and transmit data both on-line and off-line. It is usually located at a site remote from imaging systems and is configured to provide limited or extended capabilities to further process, manipulate and / or view patient images and information collected from diagnostic Imaging systems)

**According to the “MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES”, PACS are medical devices**

If this is indeed the case the Estonian Health Board has a number of questions on this topic and wants to share these questions with the EPSO E-health working group . The participants in the EPSO working group could discuss the following questions:

- a. Do you ( in your country) also considers PACS as a medical device ;
- b. Do you as supervisory organisation supervise these PACS? and if the answer is yes:
- c. How do you manage to supervise this?
- d. Knowing that it might be a surprise to the creators of a PACS system that their system is a medical device, how do you inform the system's creators that they are making a medical device?
- e. The participants in the EPSO working group could also discuss the question whether you think that PACS should be monitored as medical devices,
- f. whether the current legislation in your country offers sufficient tools to supervise these PACS.

**15.00 – 15.45 Follow up** discussion on **how to proceed further with the three cases submitted by working group members from Denmark (Anette Lykke Petri) Estonia ( Eve Pilt and Laine Mokrik)**

and the Netherlands ( Wouter Meijer) ( see for these cases our webpage <http://www.epsonet.eu/ehealth.html> ) .

These cases are for certain offering interesting views , questions and best practices about e-Health and supervisory practice . However we did not find enough time in Stockholm to discuss these cases. Therefore we did not find a procedure to study and use and conclude on those cases .

We therefore suggest to think further about a procedure to discuss these cases in the near future in the context of finding topics for common policy guidelines to use by supervisory organisations in their supervisory practice of online clinics or otherwise.

**15.45-16.00 Commitments and Agenda setting** for a possible next EPSO e-Health working group meeting in the Netherlands , The Hague , Wednesday 11<sup>th</sup> of April 2018.

**16.00 closing of the working group by working group chair Tove Gemzell**

INVITATION by TOVE GEMZELL chair of the EPSO e-Health working group

***Dear e-Health working group***

***Welcome to the E-Health working group meeting in Tallinn, Estonia.***

*Since our last – regular- working group meeting on the 28<sup>th</sup> of September 2016 in Stockholm some interesting events and developments have taken place.*

*Developments to mention here are the following.*

*We had a - last minute- extra working session in London on the 25<sup>th</sup> of April 2017 and used this meeting to discuss ongoing developments and possible focus for our working group.*

*In England , in particular in the field of online hospitals, there has been a large activity to secure patients safety.*

*In Sweden there has been quite some negative attention in the media about online care providers who are wrongly prescribing medications such as antibiotics. The Swedish Health and Social Care Inspectorate is now discussing how to approach these online care providers.*

*During the upcoming meeting of the E-Health working group we plan to **focus on summarizing our experiences in the area of supervising online clinics and try to build and do suggestions for a common approach for supervision of on-line health providers cross border.***

*The challenge for our working group will be to identify :*

- ***specific risk areas for online providers, and***
- ***to find if possible common standards for supervision cross border or for national supervision in cooperation with other national supervisory agencies and***



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- to find **similar ways -in our various countries- to approach the online providers.**

*The final aim of our group is to produce a report of our findings based on the material and knowledge gathered together on the above listed topics.*

*The Report is planned to be distributed to all EPISO member countries. The Report can possibly later be used in the process of finding a common policy and policy recommendations for the various EPISO countries. If appropriate the Report can be used to reach cross-border agreements in the EU context.*

*It would be very helpful if you could have a look from your perspective at the questionnaire with the draft answers from CQC. If possible provide the answers to the same questions on behalf of your organization.*

*Best regards*

*Tove Gemzell*