**e-Health Working group – Survey-**

**Questionnaire on e-Health regarding supervisory organisations (regulators/monitoring organisations/inspectorates)**

**0. Introduction**

This questionnaire is the instrument supporting a survey among EPSO members intended to provide an overview of what interests and responsibilities health care regulators and supervisory organisations have regarding e-Health[[1]](#footnote-1). More specifically, the questions below focus on the following issues:

* Organisational approaches to supervision of e-Health;
* Main supervisory aspects of e-Health;
* New developments in the field of e-Health.

The respondents are asked to fill in the questionnaire according to the questions above, but should feel free to add any comments whenever they think it’s important to contextualize the answers.

If any doubt or difficulty occurs, please send an e-mail to mmurel@epsonet.eu

**1. Questions**

**Section A – Respondent identification**

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| Country (or region) to which the answers correspond: Finland |
| Name: Riitta Aejmelaeus/Heikki Mattlar |
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| Telephone (landline/mobile): |
| Organisation: National Supervisory Authoritys for Welfare and Health (Valvira) |

**Section B – Organisational approaches to supervision of e-Health**

1. **Is e-Health a topic that is addressed within your organization?**

**If yes, what kind of issues are being discussed/ worked on?**

* **Medical devices**
* **e-medicine**
* **M(obile)Health2 (for example medical apps)**
* **Telemedicine3 (consultations via internet etc)**
* **Prevention/promotion via e-health**
* **others**

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| Medical devices, MHealth (especially medical apps), Telemedicine, prevention, ePrescription. |

1. **What are the main areas in the field of e-Health where you conduct supervision (medical devices, mhealth[[2]](#footnote-2), telemedicine[[3]](#footnote-3), e-medicine etc.)? And if you do, where does that supervision take place (hospitals, nursing homes etc.)?**

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| Product manufacturers, hospitals and users of telemedicine services, information security. |

1. **Do you have a special department or positions or working groups inside your organization that are responsible for supervision of e-Health? If yes, what type of qualification do they have (IT- related, health management, medical doctors etc.) and how many people are working on this topic?**

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| We have 10 people in Valvira’s health technology group. We have professionals with different background (etc. technical and healthcare).  Also other sections of social and health care supervision and licensing face problems with eHealth issues considering mainly patient safety and information security. |

1. **Based on what (legal)standards, guidelines or laws does your organization practice supervision on e-Health (if applicable)?**

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| Act and regulations:  Medical Device Directive MDD 93/42/EEC  MEDDEV 2.1/6 Guidelines on classification of standalone software  Medical Devices Act (629/2010)  EC/EN 62304 Medical Device – Software Life Cycle Processes  The basic social and heal legislation that regulates patient safety and information security issues and EU-directives in this area. |

**Section C – Main Supervisory aspects of e-Health**

1. **How does your organization organize supervision of e-Health in the health care sector? For example, by visiting health product manufacturers, monitoring the implementation of new medical systems, based on claims, or other methods**

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| Inspecting product manufacturers and monitoring the implementation of new medical systems.  Inspecting hospitals and safe use of applications. |

1. **What are the main risks and benefits for the health care sector when implementing e-Health?**

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| Risks: Information security risks with patient data. Risks with incorrect rendition of data.  Benefits: More efficient healthcare by using correct data and efficient software. Increased access into services, easier data transformation and consultations. Promotion of healthier lifestyles and patient responsibility in taking care of their own health and chronic diseases. |

1. **Does your organization have good examples of (supervising) e-Health?**

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| We have supervised many services in which patient collects his own data and uses it. For example monitoring own medicine, blood pressure or blood sugar. |

1. **Do you have examples of health care organizations that experienced problems/ issues when implementing e-Health? If yes, please elaborate.**

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| Problems with data communications can cause interruptions for e-Health-services.  Problems in deciding services that can be provided by eHealt or Telemedicine. The field is a constant state of transformation. |

1. **What are the main challenges for your organization concerning supervising e-Health?**

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| There are a lot of different types of actors (companies, hospitals, big and little software vendors). Almost anyone can make and publish application with little knowledge of software development and zero-knowledge of regulations.  As a human point of view, the whole physician-patient relationship is changing. We have to ensure the patient safety and sufficient (if necessary) face-to-face communication between patient and medical staff. Regulation and guidelines for the licensing of private health/welfare-care providers in needed.  A data transmission and archiving service that ensures interoperability of regional HER-services is on the way. It makes the supervision easier by simplifying the access and collection of data. |

**Section D – New developments in the field of e-Health**

1. **Are you interested in certain topics in the field of e-Health (to learn more/ share knowledge)?**

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| Telemedicin, patient safety and information security. |

1. **Do you organize (among staff, care facilities) e-Health related training?**

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1. **What do you consider important developments for supervisory organisations in Europa concerning e-Health?**

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| Common rules, regulations, guidelines. |

1. **Is there anything you would like to learn about/ share experience concerning e-Health?**

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1. **Do you have any further comments and/or feedback (about all sections of this questionnaire)?**

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**3. Follow-up**

Results of this survey will be used as a basis of the e-Health working group and will be presented and discussed at the Helsinki conference.

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| **Are you or/and one of your colleagues available/interested to co-operate and/ join the EPSO e-Health working group?** | (Yes or No)  If yes please give contact information |

Work group is co-ordinated by EPSO secretary, contact :Mari Murel

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1. In this context we are defining e-Health as follows: “*eHealth is the term for delivering healthcare supported by electronic products”* (Stefan Visscher, Dutch Health Care Inspectorate) [↑](#footnote-ref-1)
2. **mHealth** is defined as “*medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices”(*WHO “mHealth – New horizons for health through mobile technologies, Global Observatory for eHealth series – Volume 3”, page 6*)* [↑](#footnote-ref-2)
3. **Telemedicine** is defined as *"the provision of healthcare services, through the use of ICT, in situations where the health professional1 and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients"* ( European Commission Working Document on telemedicine services) [↑](#footnote-ref-3)