**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: ESTONIA |
| Name: Mihhail Muzõtšin and Eve Pilt |
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| Organisation: Estonian Health Board |

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

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

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

* **Medical devices x**
* **e-medicine x**
* **M(obile)Health2 (for example medical apps) x (as concerns medical prescriptions)**
* **Telemedicine3 (consultations via internet etc) x**
* **Prevention/promotion via e-health –we supervise advertising health services in media**
* **others**

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| We marked positive answers with x.  Recently an e-vaccination passport was introduced via E-Health information database. This database also sends information about communicable diseases to NAKIS database (collects information on communicable diseases and is maintained by Health Board). |

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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| Our main areas of supervision are:  1) issuing medical e-prescriptions (either by computer or m-phone) by doctors (and starting from the Oct 01, 2015 by nurses)  2) making sure that medical service providers send medical epicrisis to E-health information system .  The subjects of our supervision are licensed health care providers in hospitals and outpatient care and in social care homes. We are not entitled to supervise the substantial quality of e-health services. As telemedicine services from doctor to a patient are marginal by quantity we have supervised accessibility of these services once. As concerns transmission of medical data through sound, images or other forms it is still under development, so it has not been subjected to supervision yet.  As concerns medical devices we check that producers insert their products into an electronic database and that medical devices, distributed in Estonian market, meet the demands of regulation as set forth in the Law on Medical Devices. |

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 do not have a special department or position dedicated only to supervising e-health services. Mostly supervision of e-health is part of our supervising routine and every inspector does it in the case of necessity. One of our colleagues (who has a qualification of a social worker) is trained to send direct enquiries to e-prescriptions database. |

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

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| We practice supervision on e-health based on section 60 of Health Services Organization Act that provides: state supervision over compliance with the requirements established for health care providers shall be exercised by the Health Board (<https://www.riigiteataja.ee/en/eli/505032015002/consolide>)  Provisions on health information system are part of the same act (chapter 51).  Subsection 2 of section 2 of the Personal Data protection Act provides that: an administrative authority shall process personal data only in the course of performance of public duties in order to perform obligations prescribed by law, an international agreement or directly applicable legislation of the Council of the European Union or the European Commission. (<https://www.riigiteataja.ee/en/eli/529012015008/consolide>) |

**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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| We use all the methods mentioned in the question above. |

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

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| The main risks are:  - the quality of data is low (either too much or too little, the data is not structured and machine readable);  -Service providers use different types of software programs that sometimes do not align with software used by E-health Information System that causes delays in sending information or the information is not sent at all, i.e. the data is not available;  - Service providers make use of the fact that they can access the data base in any place (for example prescribe using mobile telephone and not show up in their practice during the reception hours, allowing to use their ID cards by colleagues who are not qualified to write prescriptions);  - failure of technics (and sometimes development of IT programs) or disability to make proper use thereof;  - high costs and rapid development of new knowledge which brings to rapid deterioration of older programs;  - when too many organizations have direct access to the E-health information system then many patients may close their information.  Benefits are:   * Patients who live in remote places (like small islands) can still access medical care via telemedicine; * All data on a single patient is theoretically contained in one database * Number of procedures and medical images can be reduced * Health care service providers, Ambulance and Social Insurance Board can use patients information on-line |

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

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| Based on information that we received from the Estonian Road Administration we made an inquiry to e-prescriptions data based on the usage of psychotropic drugs by professional drivers. The result was that 17,6 % of professional drivers aged between 40-65 have been prescribed psychotropic drugs. As according to Estonian law (contrary to the EU legislation) using of psychotropic drugs is an absolute contraindication for having a valid driver`s health certificate. Based on this information we made a proposal to the Ministry of Social Affairs to consider to change the law and consider using of psychotropic drugs as a relative contraindication where the doctors have a say about their patient. |

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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| Some doctors seem not to be aware that prescriptions on paper are digitalized and can still be followed in the e-prescriptions data base. In some cases it has become apparent that prescriptions to psychiatric drugs were given to the wrong patient or for too big amounts.  Please see also our answer to question no 2. |

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

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| Our main challenge is that we do not have a direct access to E-Health Information System as the Ministry of Social affairs considers the privacy of delicate personal data the topmost value over other possible benefits pursued by supervision. In every case we have to ask for an extra permission from Ministry of Social Affairs based on what the E-Health Foundation is allowed to deliver us the needed information (or sometimes not). |

**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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| Yes. We are interested what is the practice in supervising e-health services in other EPSO member states. |

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

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| Relevant trainings are organized by E-Health Foundation. |

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

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| It is very important that supervisory organizations have access to the databases they are supposed to supervise.  Supervisory organizations have up to date devices and technological solutions to process electronic data.  We support developing specialized software that helps to track violations. |

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

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| To share ideas how to develop a specialized software for health care/social care supervisory body that has a capacity to draw information from other databases, analyze it and helps to detect risk areas. |

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. The contact person is Eve Pilt; [eve.pilt@terviseamet.ee](mailto:eve.pilt@terviseamet.ee); skype: eve.pilt  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)