**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**

|  |  |
| --- | --- |
| Country (or region) to which the answers correspond:  | The Netherlands |
| Name:  | Stefan Visscher |
| E-mail: | S.Visscher@igz.nl |
| Telephone (landline/mobile): | +31611585294 |
| Organisation: | Dutch Health Care Inspectorate |

**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**

|  |
| --- |
| Regulatory oversight of (mobile) applications that qualify as medical device (i.e. apps that fall under the definition of medical device as described in the European Medical Device Directive 93/42 EEC and the MEDDEV 2.1/6) started in 2013. Since then, manufacturers of the products are regularly visited by the inspectorate.In 2016, supervision of eHealth in health care institutions will start as a pilot project to see how these organizations incorporate new techniques and products in delivering health care and how possible risks are being dealt with.  |

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.)?**

|  |
| --- |
| Manufacturers of medical devices as well as in health care institutions.  |

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?**

|  |
| --- |
| Four (4) inspectors employed at the medical device department are responsible for supervision of eHealth/ IT in healthcare/ Home care technology. One of them studied Medical Informatics. |

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

|  |
| --- |
| * 93/42 EEC Medical Device Directive/ [MEDDEV 2.1/6](http://ec.europa.eu/health/medical-devices/files/meddev/2_1_6_ol_en.pdf)
* (Dutch version of the) ISO 27001 on information security
* ISO 13131 on telehealth
* Dutch law on Delivering good quality of care: one specific subsection/ guideline on putting new techniques into service in a safe way
 |

**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**

|  |
| --- |
| * Performing risk-based visits to manufacturers and health care insitutions
* Based on incident reports from manufactures and health care institutions.
 |

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

|  |
| --- |
| See the answer to question number 4.In addition , ECRI yearly produces a top 10 hazards of health technology in hospitals (<https://www.ecri.org/Pages/2015-Hazards.aspx> ) |

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

|  |
| --- |
| Manufacturers as well as health care institutions that experienced problems when developing/ implementing eHealth were visited by the inspectorate in order to identify the root causes. [We have some examples that can be elaborated more on during the conference of being discussed within the EPSO eHealth working group. ] |

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

|  |
| --- |
| Yes, due to:* Not having performed a proper prospective risk analysis;
* Incorrect interfaces between software products (i.e. interoperability);
* Not having performed a proper validation;
* Employees not having followed educative sessions to allow for the new products to be used / new ways of delivering health care in a safe way.
 |

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

|  |
| --- |
| * WHAT are the risks? What to focus on?
* WHERE can these risks be expected?
* WHO is participating? (resource planning)
* What laws/ guidelines/ standards can we base supervision of eHealth on?
 |

**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)?**

|  |
| --- |
| Yes; telehealth, i.e. monitoring patients from a distance. |

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

|  |
| --- |
| Before starting supervising eHealth, two conferences were organized by the inspectorate to inform the field about the topic ‘Software as a medical device’. One conference was meant for manufacturers ; the other for health care institutions. |

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

|  |
| --- |
| * [FDA’s guidance](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/ucm255978.htm) on medical apps and their approach to supervising these products.
* [The International Medical Device Regulators Forum](http://www.imdrf.org) is developing guidance for manufacturers/ developers of eHealth products on how to develop good quality of products.
* More and more, medical associations are developing guidance on how health care providers can use eHealth in a safe way.
 |

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

|  |
| --- |
| Other approaches to supervising eHealth within Europe are most welcome.  |

1. **Do you have any further comments and/or feedback (about all sections of this questionnaire)?** No

**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.

|  |  |
| --- | --- |
| **Are you or/and one of your colleagues available/interested to co-operate and/ join the EPSO e-Health working group?** | Yes If yes please give contact informationS.Visscher@igz.nl  |

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)