**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: **PORTUGAL** |
| Name: **CÉSAR CARNEIRO** |
| E-mail: **ccarneiro@ers.pt** |
| Telephone (landline/mobile): **00351913098402 (mobile)** |
| Organisation: **ENTIDADE REGULADORA DA SAÚDE (HEALTH REGULATION AUTHORITY)** |

**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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| **No, ERS does not regulate de market nor the utilization of e-Health devices or any other Medical Devices. This is under the scope of another institution, INFARMED – National Authority of Medicines and Health Products, which is a Government agency that regulates activities relating to human medicines and health products.** |

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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| **See answer to question 1 of section B.** |

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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| **See answer to question 1 of section B.** |

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

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| **See answer to question 1 of section B.** |

1. **What are your plans to implement supervision on e-Health in the future?**

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| **See answer to question 1 of section B.** |

**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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| **See answer to question 1 of section B.** |

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

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| **See answer to question 1 of section B.** |

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

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| **See answer to question 1 of section B.** |

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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| **See answer to question 1 of section B.** |

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

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| **See answer to question 1 of section B.** |

**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, but strictly from an academic point of view.** |

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

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| **No.** | No. |

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

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| **No opinion on this.** |

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

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| **No.** |

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

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| **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.

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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?** | **No, since it’s not relevant to my institution.**  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)