



Joint Plenary Green Paper on mHealth: "Conclusions and Actions"

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1. Context: Green Paper on mHealth

The Green Paper asked stakeholders for their inputs on how to overcome the main challenges to mHealth deployment, e.g.:

- data protection
- the legal framework
- patient safety
- mHealth's role in healthcare systems
- interoperability
- web entrepreneurs' market access



mobile devices



Personal Digital Assistant (PDA)



smart watches & other body-worn devices or implants



2.1 Results - Privacy and security of data

- Importance to give citizens control over their data
- Strong privacy and security principles needed, e.g. data encryption and authentication mechanisms
- Importance of secured network settings to prevent data interception
- Data minimisation, data protection by design and default

2.2 Results - mHealth role in healthcare systems



- Importance of funding, education and awareness raising as well as ensuring quality of products to support equal access to healthcare via mHealth
- More evidence on economic benefits of mHealth
- Good practice examples and clinical guidelines needed to maximise the use of mHealth for high quality care

2.3 Results - Interoperability

- Need for an EU eHealth interoperability framework, incl an mHealth subset
- Importance of interoperability between mHealth apps and eHRs
- eHR vendors should publish open APIs for mHealth apps to access them





2.4 Results - Legal framework

- Safety and performance requirements of lifestyle and wellbeing apps should be clarified, through legislation, guidance or certification/quality labelling
- Need to clarify the borderline between apps that are medical devices and others, e.g. by guidelines
- Strengthened enforcement of medical device and data protection rules needed

3.1 Next steps

- mHealth stakeholder event, 13.30-15.30, discussion focussing especially on:
 - **Code of conduct, covering privacy and security**
 - **Possible action on safety and quality of mHealth apps**
- Revision of medical devices guidelines (finalization after adoption of medical devices regulations)
- Adaptation of consumer legislation to cover digital

3.2 Next steps

- Follow-up actions to support mHealth deployment under Horizon 2020 in future work programmes, notably on:
 - **digital health literacy**
 - **big data**
 - **digital security**
 - **evidence-gathering and exchange of best practices**
- Possible extension of the EU eHealth Interoperability Framework to cover mHealth



Thank you for your attention

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