MOBILE HEALTH – "mHEALTH" –

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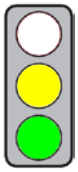
Centrum für Europäische Politik

KEY ISSUES

Objective of the Green Paper: The Commission wants to leverage the potential of mobile health.

Parties affected: mHealth companies, health systems and patients.



Pro: Mobile health may result in gains in efficiency and cost savings in the health sector as doctors can treat more patients whilst maintaining the same level of quality.

Contra: EU funding for innovative mobile health technologies and the "digital skills" of medical staff and patients is not justified because the benefit does not arise at EU level but in national health systems.

CONTENT

Title

Green Paper COM(2014) 219 of 10 April 2014 on **mobile Health** ("mHealth")

Brief Summary

- **Context and objectives**
  - The Commission wants to hold an open debate on the possibilities of mobile health and, in particular, to establish whether and what problems exist in relation to extending the sector. It calls on the public to answer a list of 23 questions (see attachment).
  - Mobile health ("mHealth") refers to "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants(PDAs), and other wireless devices" (Definition of the World Health Organization; WHO).
  - The Commission sees in the market for mobile health significant potential for growth which could lead to a restructuring of health systems.
  - The Commission's assumptions are based on third-party surveys – Groupe Spéciale Mobile Association, PricewaterhouseCoopers, IDC, IHS, Research2Guidance, Deloitte und Juniper.
- **Problems and potential for health care**
  - The Commission sees, in particular, two challenges for healthcare systems: the ageing population and dwindling financial resources.
  - Member States will be better able to meet these challenges if mobile health is used to make healthcare more patient-focussed and to encourage prevention.
    - Individualised healthcare results in a more efficient use of resources.
    - Active prevention extends health and avoids treatment costs.
  - By using mobile devices, medical staff will be able to save up to 30% of their time because deployment will be better planned, unnecessary visiting time will be avoided and medical interventions and care can be carried out remotely or by the patients themselves under instruction.
  - The Commission sees particular potential for savings in the monitoring and advising of the chronically ill.
  - The personal data generated can be analysed by way of mass data processing ("big data") and used to improve disease prevention and healthcare. This reduces treatment costs. The Commission sees particular potential for using data in the field of research for three reasons:
    - Epidemiological research will be able
      - to look for patterns of disease on a larger scale and
      - recognise links between the development of diseases and environmental factors.
    - Trial periods for new drugs can be reduced.
    - Mechanisms for early detection and prevention of diseases can be improved.
  - The Commission believes that people will take greater interest in their health if they are easily able to obtain information about their vital signs - e.g. pulse, blood pressure and body temperature. As a result, they may also be motivated towards greater prevention.
  - The "healthcare infrastructure" will have to be re-designed so that
    - patients have "ubiquitous access" to healthcare professionals via the internet,
    - patient data can be called up at any time so that it can be monitored remotely and
    - electronic communication is possible between medical staff and patients.

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- **Mobile health market**
  - In future everyone will have permanent and comprehensive connectivity to mobile networks facilitating mobile health by way of smartphones, tablets and wearable, portable, or implantable devices.
  - In 2017, mobile health in the EU will
    - achieve a turnover US$ 6.9 billion and
    - save a total of € 105 billion in healthcare costs divided between
      - € 69 billion as a result of preventative measures and
      - € 36 billion due to more efficient healthcare services.
- **Development and use of mobile health**
  - The development of health apps (applications for mobile devices) is driven by individuals (30%) and small companies (34.4%) with fewer than 10 employees.
  - In 2013, the top 20 of the 97,000 free sports, fitness and health apps were installed by 231 million people worldwide.
  - Approximately 70% of health apps target the consumer and about 30% target health professionals.
  - By 2016, 3 million patients worldwide will be monitored via mobile networks.
- **Data protection and processing**
  - The Commission regards health data as particularly sensitive and believes that mobile health will only be accepted if data protection is guaranteed.
  - The applicable data protection Directive (95/46/EC) no longer satisfies the requirements of new technologies. Remedial action will be provided by the – yet to be passed – General Data Protection Regulation [COM(2012) 11; see cep**PolicyBrief**].
  - The Commission calls for security measures such as the encryption of patient data and the authentication of users.
  - The Commission sees as particularly critical the automatic transmission of healthcare data by apps to companies such as Google or Apple. According to the Commission, citing the Financial Times, this already happens in the case of 9 of the top 20 health apps.
  - The proposed General Data Protection Regulation does not contain any concrete provisions on encryption, authentication or automatic transmission.
  - In addition, care must be taken to ensure that patient data is not used for "data mining" without the express consent of patients. "Data mining" refers to the systematic analysis of large amounts of anonymous data in order to identify patterns.
- **Confidence in health apps**
  - People's confidence in health apps is still limited particularly because there is no indication of who developed them, whether they comply with medical standards or whether they have undergone clinical tests.
  - Confidence in health apps can be increased by
    - uniform standards,
    - quality labels,
    - certification schemes and
    - certification and sale via specialised on-line portals.
- **Legal questions on delimitation and liability**
  - There are no criteria for the delimitation of medical products (Directive 93/42/EC) and in-vitro diagnostic devices (Directive 98/79/EC) from either lifestyle or well-being apps. The Commission is currently providing the industry with "guidance" on this issue. Nor do the proposals for a medical product Regulation [COM(2012) 542; see cep**Standpoint**] and an in-vitro diagnostic devices Regulation contain any criteria for delimitation [COM(2012) 541].
  - The Commission specifies two particular problems in dealing with questions of liability (without identifying any possible solutions):
    - Many people are involved in the use of a health app, in particular the manufacturer, user, doctor and network operator.
    - There is a wide variety of possible causes of harm to patients including defective devices, faulty data transmission and misdiagnosis due to incorrect data.
- **Interoperability and internationality**
  - The absence of standards for the interoperability of mobile health "impedes innovation and economies of scale" (p. 14).
  - The development of such standards is very complicated. The description and coding of health data alone requires millions of terminologies and vocabularies. Added to this are the diverse and often incompatible health information systems of the 28 Member States in 24 languages.
  - Since November 2013 there have at least been Commission guidelines on a patient summary dataset for cross-border use.
  - The EU is to take part in various global initiatives including
    - the scheme for using mobile health to combat non-communicable diseases and
    - regulatory convergence on medical products within the International Medical Device Regulators Forum (IMRDF).

- **Reimbursement of costs**
  - The Commission believes that one obstacle to the spread of mobile health is the fact that there is no guarantee that costs will be refunded.
  - The Commission suggests that health insurance companies
    - bear the cost of health apps or provide smartphones and
    - remunerate doctors for work outside their surgery hours - e.g. for emails and telephone calls.
- **Additional problems with the use of mobile health**
  - The Commission suggests that another reason why mobile health is not used to its full potential is that
    - healthcare service providers and insurance companies require additional evidence of the benefits and
    - there are still too few people in the EU with internet access via a smartphone.
  - The Commission wants
    - to fund the development of innovative mobile health technologies and the "digital skills" of medical staff and patients,
    - to promote cooperation and the exchange of information between Member States through a voluntary network of national experts on health technology assessment (cf. Art. 15 Directive 2011/24/EU) and
    - to speed up the expansion of faster and higher quality networks for which purpose it has submitted the proposal for a Regulation on the Single Telecommunications Market [COM(2013) 627; see cep**PolicyBrief**].

Policy Context

The Commission already announced the Green Paper in its Communication on the Action Plan for electronic health services 2012–2020 [COM(2012) 736]. In its Resolution of 14 January 2014 (T7-0010/2014) the European Parliament sees great potential in mobile health and calls for a binding EU Regulation on this.

Options for Influencing the Political Process

Directorates General:	DG Employment and Social Affairs (leading)
Committees of the European Parliament:	Employment and Social Affairs (leading), Rapporteur: TBA
Federal Ministries:	Health (leading); Economy
Committees of the German Bundestag:	Employment (leading); Economy
Consultation Procedure:	Every citizen can give an opinion. The process ends on 3 July 2014; https://ec.europa.eu/digital-agenda/en/public-consultation-green-paper-mobile-health

ASSESSMENT

Economic Impact Assessment

Ordoliberal Assessment

Mobile health has a lot of potential. Full use can only be made of this potential, firstly if protection of health-related data is guaranteed, as this is the requirement for acceptance of mobile health on the part of the patients; and secondly if questions of liability are settled, as this is essential for legal certainty – particularly for patients, manufacturers and doctors. In addition, there must be clear definition of which mobile health apps constitute medical products and in-vitro diagnostic devices pursuant to the applicable regulations. This distinction is important because medical products and in-vitro diagnostic devices are subject to extensive certification procedures. In this respect, the fact needs to be borne in mind that, due to the costs involved, high regulatory requirements may become barriers to market entry, particularly for small providers who predominate in the market.

Impact on Efficiency and Individual Freedom of Choice

Mobile health may – as some studies show – **lead to increased efficiency and cost savings in the health sector. In particular**, by using mobile health, **doctors** and other medical staff **can treat more patients whilst maintaining the same level of quality.** Such increased efficiency is necessary for sustainable healthcare in the Member States as the workload per doctor will grow in the coming years – firstly due to demographic changes and secondly because in many Member States the number of doctors is actually going to fall starkly.

There must be some doubt as to whether the Commission's expectation of an annual gross potential saving in the EU of € 105 billion is realistic because more than two thirds of the savings (€ 69 billion) will be achieved as a result of preventative measures – such as healthier diet, sport or giving up smoking. For this to happen, however, a change in people's attitude to health is required which cannot be brought about simply by way of health apps. On the other hand, the predicted savings of € 36 billion due to more efficient healthcare – such as improved treatment compliance and easier access to medical care – are more realistic because faster and better treatment can avoid often high follow-up costs.

Increased use of mobile health, however, requires adequate remuneration otherwise doctors – as well as other medical staff – will have little incentive to use such services. The Commission can help, by way of an EU-wide comparison of the applicable rules, to publicise effective cost refund models EU-wide.

EU funding for innovative health technologies and the "digital skills" of medical staff and patients is not justified however; **since the benefits of mobile health arise in the national health systems** and economies, **all the costs should also be borne by the respective heath system.**

The patient's freedom to choose – at least where use of mobile health is optional rather than obligatory – is increased. Provision of the necessary infrastructure by the health insurance companies, free of charge, will also increase the patients' willingness to use mobile health. This should be voluntary, however, rather than mandatory for the insurance companies.

Impact on Growth and Employment

More efficient healthcare strengthens growth and employment because either the same number of patients are treated using fewer resources, leading to a drop in health expenditure which relieves the strain on employers and employees and thus has a favourable effect on growth an employment; or more patients can be treated using the same level of resources which helps to improve the health of the population as a whole. Costs resulting from lost working time fall and people can remain in gainful employment for longer.

Impact on Europe as a Business Location

To the extent that mobile health can contribute to the health of the population, Europe is strengthened as a business location because this depends, not least, on the availability of qualified and healthy employees.

Legal Assessment

Legislative Competence

The EU has the power both to issue rules to protect people in relation to the processing of personal data (Art. 16 (2) TFEU) and to issue standard definitions within the existing legal framework for medical products and in-vitro diagnostic devices (Art. 168 (4) (c) TFEU).

The EU has no power to introduce incentive models via national payers because the responsibility for organising health services and medical care lies with the Member States (Art. 168 (7) TFEU).

Subsidiarity

EU action – particularly in the case of data protection – is appropriate because mobile health makes use of the internet which is available across borders. National rules threaten to fragment the market.

Proportionality with Respect to Member States

Unproblematic.

Compatibility with EU Law in other Respects

The Green Paper itself complies with EU law. The proposal, made by the Commission, for a General Data Protection Regulation is an unacceptable violation of the principle of the separation of powers (see cep**PolicyBrief**).

Impact on German Law

The Green Paper does not give rise to any changes to German law.

Alternative Approach

The proposed General Data Protection Regulation does not contain any concrete provisions on encryption, authentication or automatic transmission. It should be amended accordingly.

Possible Future Follow-up Measures by the EU

The Commission will decide on follow-up measures after the pubic consultation has been evaluated.

Conclusion

Mobile health may result in gains in efficiency and cost savings in the health sector. In particular, doctors can treat more patients whilst maintaining the same level of quality. EU funding for innovative mobile health technologies and the "digital skills" of medical staff and patients is not justified: since the benefits of mobile health do not arise at EU level but in national health systems and economies, all the costs should also be borne by the respective heath system.