



Spitzenverband

**Written Contribution
of the National Association of Statutory
Health Insurance Funds
of 27.06.2014**

**to the Public Consultation
of the European Commission
on the Green Paper on mobile Health (mHealth)
(SWD (2014) 135 final)**

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I. Introduction

The European Commission launched a public consultation on the Green Paper on mobile Health on 10 April 2014. The Commission understands mobile health ("mHealth") to cover "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices" (Green Paper SWD (2014) 135 final, p. 3). It also includes applications (hereafter "apps") such as lifestyle and wellbeing apps that may connect to medical devices or sensors (e.g. bracelets or watches) as well as personal guidance systems, health information and medication reminders provided by sms and telemedicine provided wirelessly.

The Green Paper as submitted forms a component of the European eHealth Action Plan 2012-2020. The Green Paper rightly points out that many of the questions to be discussed are not within the competence of the EU. The subsidiarity principle must be adhered to.

The National Association of Statutory Health Insurance Funds however supports the Commission's goal of analysing both the potential and the problems in the spread of mobile health services and of learning from one another. The primary concern of the statutory health and long-term care insurance funds in Germany is to provide a very high level of care to insured parties and patients. The health insurance funds have recognised the massive potential deriving from mobile healthcare applications, and wish to make greater use of them. Statutory health insurance funds are already offering their affiliates a large number of possibilities for advice, education and information via mobile services.

A key aspect for the National Association of Statutory Health Insurance Funds when it comes to mHealth applications is security – both the security of the data and the security of the applications themselves. It is important for mHealth applications which go beyond education, advice and information and initiate or manage medical therapies to operate in a reliable and secure manner. Such applications should fall under Medical Device Directive 93/42/EEC in future.

Equal importance attaches to the security of the data that are provided. Secure processing of health data by mobile health services is contingent on end-to-end encryption, unambiguous access rights, secure authentication of those with an access entitlement, as well as the use of

secure end devices. The European Data Protection Directive currently does not comprehensively regulate on these problem areas.

All in all, the conditions should be improved EU-wide to enable mHealth applications to achieve their potential over and above the present extent, whilst not neglecting to make high demands of the security of data and applications.

The National Association of Statutory Health Insurance Funds represents all 132 statutory health and long-term care insurance funds in Germany, and hence the interests of the 70 million affiliates and contributors, vis-à-vis policy-makers and service-providers. It advises parliaments and ministries within ongoing legislative procedures, and is a voting member of the Federal Joint Committee. The representation of interests of the health insurance funds towards supranational and international organisations and institutions is the statutory task of the National Association of Statutory Health Insurance Funds. It is a member of the European Social Insurance Platform (ESIP).

I. Contribution towards the consultation

1 Data protection including security of health data

1.1 Which specific security safeguards in mHealth solutions could help to prevent unnecessary and unauthorised processing of health data in an mHealth context?

When mobile health services are operated by third parties for health insurance funds, it should be ensured that the providers are subjected to adequate checks (as regulated for instance by section 80 of Book X of the German Social Code [*SGB X*], amongst other provisions). Contracts between third-party providers and funds should be worded accordingly. The processing and storage of health data in unprotected "cloud" systems are highly problematic.

The National Association of Statutory Health Insurance Funds plays a major role in the tele-matics infrastructure (TI) which is being established in Germany, and is implementing the basic prerequisites for the secure processing of health data there. These are uninterrupted, secure end-to-end encryption of the data and dataflows, unambiguous access rights, secure authentication of those with access rights, as well as the use of secure end devices. These prerequisites equally apply to the secure processing of health data by mobile health services.

2 Big Data

2.1 What measures are needed to fully realise the potential of mHealth generated "Big Data" in the EU whilst complying with legal and ethical requirements?

The principles of minimising data and ring-fencing of data are applied in Germany. As a matter of principle, only data which are indispensable are to be collected, used and processed for a specific purpose. Additional information which appears worth collecting in the interest of user friendliness, for statistical evaluations or for other reasons, but which is counter to the principle of minimisation, may not be collected, stored, processed or transmitted.

It is relevant when it comes to the application of "Big Data" what types of data are created where, and where they are stored. Bringing together and combining several data sources is subject to strict data protection regulation in Germany. Furthermore, it is rightly regulated

who has rights of access and processing subject to what conditions and to whom the results of such processing are made available. It must be ensured that data are effectively anonymised before datasets belonging to several individuals are merged. It must be ensured here that the different areas and parties concerned are clearly distinguished from one another.

3 State of play on the applicable EU legal framework

3.1 Are safety and performance requirements of lifestyle and wellbeing apps adequately covered by the current EU legal framework?

Data protection:

Additional (uniform) regulations are needed to do justice to the cross-border nature of the processing and use of health data. It must be transparent for what purposes data are collected and used, when and whether they are deleted if the app is uninstalled, and where the data are stored. The European Data Protection Directive currently does not comprehensively regulate on these problem areas.

Where health apps are offered in Germany by health insurance funds or other social insurance facilities, the national legislation contained in section 35 of Book I of the Social Code (*SGB I*), sections 67 et seqq. of Book X of the Social Code, and for instance section 284 of Book V of the Social Code, are adequate. These provisions strictly regulate for what purposes social data may be used and how consent is to be arranged. If an app which requests social data were to be created and operated on a sub-contract basis for a health insurance fund, the contract could only be awarded subject to the strict preconditions set out in section 80 of Book X of the Social Code. Should there be a need for regulation, it would be sufficient to expand national law.

Approval:

It is important to make an unambiguous distinction between medical devices and lifestyle applications. Mobile applications to record measurements such as heart frequency in case of performance sport are very broadly part of the sphere "life and nutritional advice" (training planners, nutrient calorie calculators, etc.). An mHealth application becomes a medical device

when its purpose serves to initiate or manage medical therapies by means of which a medical diagnosis is given or its application according to its purpose is equivalent to screening or prevention. The term “medical therapy” covers both prescribing and adjusting therapies where medical products come into use, as well as concrete diet plans. Screening or prevention in this sense would be for instance a smartphone app using photographs to estimate the risk of degeneration of skin lesions (cf. Wolf JA et al. Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection. JAMA DERMATOL 2013, 149: 422–426).

There is a need for action in this sphere. It should be clarified by means of rules applicable throughout Europe that apps serving such a purpose fall under Medical Device Directive 93/42/EEC. The National Association of Statutory Health Insurance Funds is therefore calling for an independent examination of the features of the software products to be carried out by a designated body in order to ensure the effectiveness and functionality of the products and the provision of transparent information on their performance and risks. A “voluntary declaration” pure and simple on the part of the manufacturers, as with medical devices of risk class I, is not adequate for mobile healthcare applications if they serve a purpose in the sense mentioned above for therapy, diagnosis, screening or prevention.

3.2 Is there a need to strengthen the enforcement of EU legislation applicable to mHealth by competent authorities and courts; if yes, why and how?

see answer 3.1.

4 Patient safety and transparency of information

4.1 What good practices exist to better inform end-users about the quality and safety of mHealth solutions (e.g. certification schemes)?

The certification schemes used for mHealth applications which are on the market, which currently operate on a voluntary basis only, are at best suited for general lifestyle and life advice apps in order to illustrate the quality of the products in a transparent fashion. When it comes to mHealth applications used for a purpose as described in Chapter 3.1, an appropriate conformity assessment procedure must be checked by a designated body. The tests performed

by this body must include a clinical evaluation of the products. It must be guaranteed at the time of market launch that users can obtain information in the public domain on the tested performance of the mobile application.

4.2 Which policy action should be taken, if any, to ensure/verify the efficacy of mHealth solutions?

It must be unambiguously established via rules which apply Europe-wide that apps with a purpose as designated in Chapter 3.1 fall under Medical Device Directive 93/42/EEC. The National Association of Statutory Health Insurance Funds is therefore calling for an independent examination of the features of the software products to be carried out by a designated body in order to ensure the effectiveness and functionality of the products and the provision of transparent information on the performance and risks of the applications.

4.3 How to ensure the safe use of mHealth solutions for citizens assessing their health and wellbeing?

see answer 4.1.

5 The role of mHealth in healthcare systems and equal access

5.1 What good practices exist in the organisation of healthcare to maximise the use of mHealth for higher quality care (e.g. clinical guidelines for use of mHealth)?

As yet no procedures have been established in Germany in the organisation of healthcare with regard to mHealth.

5.2 Do you have evidence of the contribution that mHealth could make to constrain or curb healthcare costs in the EU?

There is no systematic evaluation of studies on mHealth or eHealth applications by the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) or the Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG). Similar advantages are presumed to exist and are propagated for the neighbouring field of telemedicine (eHealth), in particular for the telemonitoring of patients, as for many mHealth applications. These appear to be suited to improve the healthcare of chronically-ill patients in regions with scarce infrastructure, to reduce in-patient treatment and also to save costs. A number of studies have been carried out in the field of telemonitoring, and more are underway. Major, randomised, controlled studies comparing the healthcare of heart failure patients with and without telemonitoring did not however observe any differences in mortality and in the frequency of hospital stays (Koehler F et al. *Circulation* 2011; 123(17):1873–1880. Chaudhry SI. et al. 2010; 363 (24), 2301–2309).

In order for mHealth applications to be funded by statutory health insurance, it is imperative for a benefit that is relevant to the patient to be proven in comparative, prospective studies. It is more important than saving costs for the benefit ensuing from the use of mHealth applications to be at least equivalent to standard medical care when it comes to patient care.

6 Interoperability

6.1 What, if anything, do you think should be done, in addition to the proposed actions of the eHealth Action Plan 2012–2020, in order to increase interoperability of mHealth solutions?

The integration of the data collected in public healthcare systems using mHealth apps, as proposed in the Green Paper, is subject to legal restrictions in Germany.

It is as yet not intended to connect mobile services from the Internet and from the EU's health telematics network to the German telematics infrastructure, which is under construction. Access to the German telematics infrastructure is granted exclusively via the personal electronic

health insurance card of the member of statutory health insurance concerned. The connection of external systems to this closed network is subject to strict conditions in terms of data protection and security. The particular need for protection of the platform, of its services and specialist applications, as well as the principles of data minimisation and ring-fencing, must always be taken into account when making adjustments and expansions. It is not acceptable to reduce the security level in order to facilitate improved networking.

It is therefore only expedient to improve interoperability when the concrete intention exists to integrate a specific mHealth sub-system into public structures and the accompanying framework conditions have been defined and agreed on.

6.2 Do you think there is a need to work on ensuring interoperability of mHealth applications with Electronic Health Records? And if yes by whom and how?

The same conditions and restrictions apply in Germany to including mHealth data in an electronic health record (EHR) as to the public healthcare systems described in 6.1.

7 Reimbursement models

7.1 Which mHealth services are reimbursed in the EU Member States you operate in and to what extent?

Health insurance funds or their associations in Germany are currently offering free downloads of apps with which, on the basis of section 13 of Book I of the Social Code (*SGB I*) (education) and section 14 of Book I of the Social Code (advice), information is provided on a variety of health-related topics (comparable to information via affiliates' magazines or on the website of the health insurance fund), such as regarding early diagnosis studies, dental care, vaccinations, prenatal care, paediatric check-ups, GPs and specialist physicians, as well as clinics in the surrounding area, tips on First Aid and what to do in an emergency, as well as worthwhile knowledge on patient-financed benefits.

In the field of prevention (section 20 of Book V of the Social Code), evaluated self-learning programmes (e.g. with personal guidance via telecommunication, the Internet or e-mail) may

be financially supported by the health insurance funds if the other preconditions for promotion are also met (see *Leitfaden Prävention* p. 37). The amount of the support is determined by each health insurance fund in its statutes. As a rule, the health insurance fund reimburses a proportion of the costs incurred by the affiliates.

For out-patient medical services, on the basis of an arrangement made in an individual contract (section 73c of Book V of the Social Code) between a health insurance fund and a quality association of ophthalmologists for amblyopic children whose vision is stagnant, a web-based stimulation therapy can be carried out at home on a PC or - via an app - on a tablet PC and smartphone as a supplementary therapy in addition to occlusion. The health insurance fund pays the service-provider directly, so that the insured parties do not have to pay the costs.

The provision of out-patient services by mobile health services (referred to in this context as out-patient telemedicine services in accordance with section 87 subsection (2a) sentence 8 of Book V of the Social Code) can as a matter of principle also be paid for by statutory health insurance in the framework of the standard treatment. When we are speaking of telemedical services, and what preconditions need to be satisfied for the costs to be met by statutory health insurance, can be ascertained from the details of the framework agreement enclosed (Annex 1). In the event of the out-patient telemedical service consisting in a new examination or treatment method, furthermore, the Federal Joint Committee must first of all have given recommendations on

1. the recognition of the diagnostic and therapeutic benefit of the new method, as well as its medical necessity and economic viability - including in comparison to methods already being provided at the expense of the health insurance funds - according to the current scientific state-of-the-art in the respective therapeutic discipline,
2. the necessary qualification of the physicians, the equipment needed, as well as requirements as regards quality assurance, in order to ensure that the new method is applied properly, and
3. the necessary records of the medical treatment (section 135 subsection (1) of Book V of the Social Code).

There are no out-patient telemedical services in this sense at present paid for by statutory health insurance in the standard treatment.

7.2 What good practice do you know of that supports refund of mHealth services (e.g. pay-er-reimbursement model, fee-for-a service model, other)? Please give evidence.

see answer 7.1.

8 Liability

8.1 What recommendations should be made to mHealth manufacturers and healthcare professionals to help them mitigate the risks posed by the use and prescription of mHealth solutions?

It is extremely important to statutory health insurance for the existing liability arrangements not to be watered down. Should damage occur, the valid product liability regulations must be applied on the part of the manufacturers, particularly of medical devices, in order to meet existing damage claims of insured parties and patients.

9 Research and innovation in mHealth

9.1 Could you provide specific topics for EU level research & innovation and deployment priorities for mHealth?

9.2 How do you think satellite applications based on EU navigation systems (EGNOS and Galileo) can help the deployment of innovative mHealth solutions?

no answer

10 International cooperation

10.1 Which good practice in other major markets (e.g. US and Asia) could be implemented in the EU to boost mHealth deployment?

no answer