Written Contribution
of the National Association of Statutory
Health Insurance Funds
of 16.11.2015

to the Public Consultation
of the European Commission on
Standards in the Digital Single Market:
setting priorities and ensuring delivery

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I. Introduction

The general objective of the European Commission's Digital Single Market Strategy adopted on 6 May 2015 is to accomplish a free market where individuals and businesses can seamlessly access and exercise online activities under conditions of fair competition, and a high level of consumer and personal data protection, irrespective of their nationality or place of residence. In its analysis document the Commission underlines the key role standards play in achieving this objective. Thus, the Commission intends to pave the way for standardisation in order to achieve greater interoperability and thereby boosting innovation and the competitiveness of the European economy. The European Commission particularly proposes to launch an integrated standardisation plan to identify and define key priorities for standardisation with a focus on the technologies and domains that are deemed to be critical to the Digital Single Market. This includes electronic health, telemedicine, and mobile health.

The National Association of Statutory Health Insurance Funds is observing standardisation initiatives with the aim in mind to focus on benefit for patients and contributors. The statutory health insurances consider standards to be useful in many areas. This applies particularly to areas where standards assist with the safety and quality of products and technologies that are used in healthcare and thus, serve patient safety.

Regarding healthcare, the focus of European and international standardisation organisations in recent years has not only been on products and technology but also on health services and social services. Generally speaking, European and international initiatives must not interfere with the core areas of the national health systems. Member States themselves and their respective institutions are the ones best suited to develop eHealth and telemedicine as part of their national health systems. The procedures and the provision of healthcare services and thus the embedment and use of eHealth and telemedicine depend on the characteristics and traditions of each of the health systems. These differ between the individual Member States. Any initiative needs to respect the responsibility of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care as stipulated in Article 168(7) TFEU and specified in Recital 12 of the Regulation (EU) No 1025/2012 regarding European standardisation.

Hence, an integrated standardisation plan touching the health system should be strictly limited to the field of health products, electronic health and telemedicine technology, and mobile health applications in a cross-border context. Healthcare services, social services, and the provision of curative or preventive treatment should be explicitly excluded from standardisation agendas.

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Finally, it should be noted that the aim to promote the competitiveness of companies and to simplify the trade in digital services cannot fully apply to the health sector. Unlike the trade in products and other services, health services provided as part of a social insurance system are only partially subject to free market conditions. The provision and utilisation of such services can be limited by national rules within the Member States. This applies even more so when a social insurance system provides benefits in kind, as is the case in Germany.

The National Association of Statutory Health Insurance Funds represents all 123 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. Moreover, the representation of interests of the statutory health insurance funds towards supranational and international organisations and institutions is the statutory task of the Association. It is a member of the European Social Insurance Platform (ESIP).

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II. Contribution towards the consultation

1. Questions on general framework and problem statement

1.1. Do you share the Commission's analysis in Part 2 of this document?

The National Association of Statutory Health Insurance Funds partly shares the Commission's analysis as illustrated in the introduction.

1.2. ICT is assuming a greater role in sectors of the economy which were not previously significant users of ICT. How do you see the role of ICT standards for the economy, in particular beyond the ICT sector?

From the National Association of Statutory Health Insurance Funds' point of view ICT standards play an important role. See answer to Q1.1.

1.3. Do you agree that setting priorities for ICT standards at EU level, accompanied by clear time-tables, could help standard-setting organisations in better organising their work and support the Digital Single Market

No opinion.

1.4. What other steps should be considered to ensure that any such prioritisation would enjoy broad support of key stakeholders?

The National Association of Statutory Health Insurance Funds considers cooperation with key stakeholders in the Member States and their active involvement crucial for developing any priorities. Thus, the involvement of stakeholders needs to adequately reflect their role in this sector, e. g. in potentially financing the application of the technologies in question. Any standard-setting activity needs to respect the competence of the Member States and their respective institutions to organise and finance their healthcare systems.

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1.5. What would be the most effective instrument at EU level to ensure that any such prioritisation is taken up by relevant standard-setting organisations? (please select and rank up to 3 instruments)

"Standardisation requests issued to EU standard-setting organisations and included in the Annual Union Work Programme for European standardisation" and a "Commission Communication" are considered effective and transparent instruments to ensure that prioritisation is taken up.

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2. **Questions on priority domains for standardisation in the Digital Single Market**

   In this section, the Commission invites survey participants to express opinions and ideas on setting priorities for ICT standardisation. The Commission has identified 10 domains, as well as a set of sub-domains within each domain.

   2.1. **Please identify and rank the domains (up to 5) and subsequently subdomains (up to 3 per domain) within each domain that you consider a priority. If specific domains or subdomains are missing please add them.**

   The National Association of Statutory Health Insurance Funds considers "Domain 3: Cybersecurity" as well as "Domain: 6 eHealth and aging" a priority.

   Under the domain "Cybersecurity" the National Association of Statutory Health Insurance Funds identifies the following subdomains as especially relevant:

   - Technical standards for encryption

   - Technical standards for public key infrastructure

   - Technical standard for security and privacy by design

   Under the domain "eHealth and aging" the National Association of Statutory Health Insurance Funds identifies the following subdomains as especially relevant:

   - Drug identifiers for medical prescriptions

   - Quality criteria for health and wellness apps

   - Security and Safety of mHealth apps

   - Semantic interoperability of Electronic Health Records

   - Telemedicine technology

   - Others: The National Association of Statutory Health Insurance Funds would welcome standardisation for an internationally readable patient-emergency health card.

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Domain 3: Cybersecurity

2.2. For the Domain 3: Cybersecurity and the subdomains which you have selected, please explain briefly how the criteria indicated in Box I apply to them.

The Digital Single Market Strategy aims at modernising public administration (e-government) in order to make it easier and more efficient to communicate with citizens and businesses and to reach cross-border interoperability. In very different intensities public services in Europe are making use of new technologies and create digital access to services for citizens.

The National Association of Statutory Health Insurance Funds strongly shares this view expressed in the Digital Single Market Strategy. To date, German statutory health insurance funds offer digital services to the insured, to the employers and to the healthcare providers. Setting up a comprehensive infrastructure for the exchange of healthcare related data (telematics infrastructure) and the implementation of concrete applications in Germany is a clear priority for the German statutory health insurances. This is a major challenge as regards data security, data protection, and efficient communication between healthcare providers and statutory health insurance funds with a proven added value for patients and the healthcare system.

The National Association of Statutory Health Insurance Funds plays a major role in the telematics infrastructure 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 data flows, 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.

For the statutory health insurance funds, it is a top priority that in the future the secure telematics infrastructure is the exclusive network for the exchange of medical data in Germany. The telematics infrastructure is able to demonstrate that it meets the highest safety requirements by the German Federal Office for Information Security (BSI).

Advancing the administration of cross-border healthcare is a common goal of the German statutory health insurers and the European Commission. Making the best use of digital communication in this field is in the interest of patients and the healthcare system. Data security and data protection, fast and effortless handling of administrative processes as well as economic aspects need to be taken into account when discussing cross-border exchange of data.

Interoperability is a prerequisite for effective communication between different components of a system and between different systems. Standardisation plays an essential role for the in-

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teroperability of new technologies. Technical standards for encryption, technical standards for public key infrastructure, and technical standard for security and privacy by design can contribute to a secure cross border exchange of personal data and health data. In this realm the German statutory health insurance funds identify major gaps (see answer to Q2.3 for details).

One example of cooperation at European level between the European Commission and the social insurances is the EESSI project (Electronic Exchange of Social Security Information). German statutory health insurance funds and the National Association of Statutory Health Insurance Funds play an active role in this project. Via this IT system, the social security institutions in the EU shall in future exchange information faster and more secure. It is being implemented in accordance with the Regulations (EC) Nos 883/2004 and 987/2009 on the coordination of social security systems. However, the EESSI project illustrates that cooperation at European level in such complex issues can only be successful if the European Commission seriously integrates the expertise from the Member States.

National telematics infrastructures are a Member State competence. When shaping cyber security and interoperability, the compatibility with national telematics infrastructures generally need to be respected and economic aspects need to be taken into account.

2.3. **The Priority ICT standards plan should lead to the production of technical specifications, standards or architectures where there is a need/gap, but could also propose any other type of standardisation action such as landscape analysis, gap finding, roadmaps or, ecosystem building that could contribute to ensure that standardisation plays its role in achieving a Digital Single Market. Please explain if a standardisation need/gap exists in the Domain 3: Cybersecurity and the subdomains which you have selected. Please also indicate within which time-frame such need could be addressed. Please limit to a maximum of five needs/gaps per domain or sub-domain:**

"Technical standards for encryption", "technical standards for public key infrastructure", and "technical standard for security and privacy by design" can contribute to a secure cross-border exchange of personal data and health data. In this realm the German statutory health insurance funds identify major gaps. The high data protection and data security standards were an essential factor, why Germany did not actively participate in the testing in the framework of epSOS (Smart Open Services for European Patients), since the so-called National Contact Points did not meet the stringent requirements for privacy and security. For a cross-border exchange of sensitive personal and health data that is transferred by the German

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telematics infrastructure, continuity of the highest level of data protection must be ensured by an end-to-end encryption.

Technical standards for security and privacy by design in the view of the National Association of Statutory Health Insurance Funds are an important point because the focus on security in software development process and the lifecycle of secure software minimises risks and thus, inter alia, represents a building block for confidence in relation to IT systems.

2.4. Among those below, which action could be a priority in the Domain 3: Cybersecurity and the subdomains which you have selected? Please rank the list below and explain your choice.

"Support research and innovation projects to contribute to standardisation", "Community building" as well as "Increase strategic coordination of ICT standardisation at EU level" could be priorities in "Domain 3: Cybersecurity".

Due to the very different national requirements for cybersecurity it will be necessary, first of all, to coordinate the ICT standardisation at EU level. This also includes an equal definition of objectives for cybersecurity.

2.5. Please indicate any other standardisation initiatives which would help achieving the Digital Single Market in the Domain 3: Cybersecurity and the subdomains which you have selected, and who in the standardisation landscape would be best placed to lead on these initiatives:

From the National Association of Statutory Health Insurance Funds' point of view, cooperation with key stakeholders in the Member States should be fostered and they should be actively further involved in developing any priorities.

2.6. Would your organisation be prepared to invest resources in standard-setting to achieve the priority standards within the proposed time-frames?

The National Association of Statutory Health Insurance Funds would be prepared to invest resources in standard-setting to achieve the priority standards, provided some conditions are met. The National Association of Statutory Health Insurance Funds considers cooperation with key stakeholders in the Member States and their active involvement crucial for developing any priorities. Thus, they would be prepared to invest resources, given the workload is proportionate to the envisaged outcomes and benefits for the insured and the involvement of stakeholders adequately reflects their role in this sector, e. g. in potentially financing the applica-

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tion of the technologies in question. Any standard-setting activity needs to respect the competence of the Member States and their respective institutions to organise and finance their healthcare systems.

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Domain 6: eHealth and aging

2.2. For the Domain 6: eHealth and aging and the subdomains which you have selected, please explain briefly how the criteria indicated in Box I apply to them.

German statutory health insurance funds have recognised the massive potential deriving from electronic health, telemedicine and mobile health, and wish to make greater use of them. 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. They are already offering their affiliates a large number of electronic services and mobile applications for advice, education and information. The statutory health insurance funds are also key players in establishing a comprehensive telematics infrastructure in Germany.

eHealth is a fast-growing and innovative sector the European Commission intends to support through its Digital Single Market Agenda. One key element of a successful strategy could be to make the possible solutions easily linkable to the health systems' digital infrastructures and reimbursable within public health systems. A crucial prerequisite for this is that the eHealth industry complies with the highest standards that are demanded by healthcare systems. When it comes to eHealth, telemedicine and mHealth security is a key aspect for the National Association of Statutory Health Insurance Funds – both the security of the data and the security of the respective 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.

2.3. The Priority ICT standards plan should lead to the production of technical specifications, standards or architectures where there is a need/gap, but could also propose any other type of standardisation action such as landscape analysis, gap finding, roadmaps or, ecosystem building that could contribute to ensure that standardisation plays its role in achieving a Digital Single Market. Please explain if a standardisation need/gap exists in the Domain 6: eHealth and aging and the subdomains which you have selected. Please also indicate within which time-frame such need could be addressed. Please limit to a maximum of five needs/gaps per domain or sub-domain:

The National Association of Statutory Health Insurance Funds identifies major possible standardisation needs when it comes to reliable and safe eHealth solutions, especially when it comes to telemedicine, electronic health records, security, safety, and quality of mHealth

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apps, drug identifiers for medical prescriptions and internationally readable patient-emergency health cards.

Security and Safety of mHealth apps/Quality criteria for health and wellness apps:

End-user license agreements need standardisation to ensure that their contents are clear, legible and comprehensible for the user.

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. Additional (uniform) rules are needed to do justice to the cross-border nature of the processing and use of health data.

It is important to make an unambiguous distinction between medical devices and lifestyle applications. 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. 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 health applications if they serve a purpose in the sense mentioned above for therapy, diagnosis, screening or prevention.

Telemedicine

The National Association of Statutory Health Insurance Funds sees a need for standardisation in the area of telemedicine to allow for interoperability of the various applications and devices.

The integration of the data collected in public healthcare systems using mHealth apps is subject to legal restrictions in Germany. It is as yet not intended to connect mobile services from

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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 a statutory health insurance fund 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 appropriate 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.

Semantic interoperability of Electronic Health Records

Standardisation is needed, so that data between different systems of files and data sources are interoperable. Yet, the conditions and restrictions described above as regards telemedicine apply in Germany to including mHealth data in an electronic health record (EHR) as well.

Drug identifiers for medical prescriptions

Standardisation of drug name and dose and dosage information for various purposes is considered to be useful for example for patients' medication plans.

Others

The National Association of Statutory Health Insurance Funds would welcome standardisation for an internationally readable patient-emergency health card.

2.4. Among those below, which action could be a priority in the Domain 6: eHealth and aging and the subdomains which you have selected? Please rank the list below and explain your choice.

"Support research and innovation projects to contribute to standardisation" as well as "Community building" could be priorities in "Domain 6: eHealth and aging".

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2.5. Please indicate any other standardisation initiatives which would help achieving the Digital Single Market in the Domain 6: eHealth and aging and the subdomains which you have selected, and who in the standardisation landscape would be best placed to lead on these initiatives:

From the National Association of Statutory Health Insurance Funds' point of view cooperation with key stakeholders in the Member States should be fostered and they should be actively further involved in developing any priorities.

2.6. Would your organisation be prepared to invest resources in standard-setting to achieve the priority standards within the proposed time-frames?

The National Association of Statutory Health Insurance Funds would be prepared to invest resources in standard-setting to achieve the priority standards, provided some conditions are met. The National Association of Statutory Health Insurance Funds considers cooperation with key stakeholders in the Member States and their active involvement crucial for developing any priorities. Thus, they would be prepared to invest resources, given the workload is proportionate to the envisaged outcomes and benefits for the insured and the involvement of stakeholders adequately reflects their role in this sector, e. g. in potentially financing the application of the technologies in question. Any standard-setting activity needs to respect the competence of the Member States and their respective institutions to organise and finance their healthcare systems.