



A digital single market for Europe:

Uniform provisions also impact social security



Dear Reader,

The European Commission is increasingly concerning itself with the challenges and opportunities afforded by the digitalisation of work and private life. This affects nearly all areas of work and administration, including social security.

In line with the principle of subsidiarity, structuring and organising social security falls within the competence of the Member States. As such, the European Commission is endeavouring to work across borders, most noticeably by providing digital infrastructures and supporting the coordination of national initiatives for digitalisation. This is way of driving forward effective cross-border cooperation, which EU citizens perceive more as “hidden”.

Of concrete relevance to social insurance are digital health and the “containment” of health apps. After all, medical devices and medicinal products are subject to a raft of European legislation. This is applicable today and even more so tomorrow for any new forms of treatment with digital apps or software.

In the future, this will go much further: digitalisation is one of the European Commission’s ten priorities for ensuring Europe’s competitiveness. As part of the strategy for a digital single market, the EU Commission has presented activities and strategic plans for research, businesses and public bodies.

What does this mean for German social insurance? We’ll look at three examples to help give an overview: cross-border data exchange, a binding regulation on health apps, and establishing infrastructures for cross-border electronic health services in the Member States.

We hope you enjoy reading this edition of ed!



Ilka Wölflé

EESSI – Faster communication between social security bodies

The EESSI project should finally gain momentum in the middle of 2017 as soon as the European Commission makes the most important parts of this IT system available. Thanks to EESSI, social security bodies in the European Member States will be able to communicate with one another electronically in the future.

The status quo

Although there is often electronic communication in the Member States, most of the information on social security that is exchanged between the Member States has been paper-based. This has been done using 50 “E-forms”. The “E” does not stand for “electronic” but rather is a reference to Europe.

This has resulted in a mountain of paperwork. An example of this in health insurance are documents related to proof of entitlement. Millions of invoices for health benefits provided in other EU countries are sent back and forth for processing. In pension insurance, it must be ensured that people who have worked in several Member States over the course of their career receive their pension from all participating countries. This requires claim application data and other information to be exchanged between the pension insurance systems. In accident insurance, the institutions send written confirmations for cross-border entitlements following workplace accidents and occupational diseases.

The way of the future: EESSI

EESSI stands for “Electronic Exchange of Social Security Information”. This assists with the compulsory, cross-border electronic exchange of messages and information as required by the EU regulations on social security coordination.

This regulation also requires the German social insurance institutions to connect to the European infrastructure. Following several delays in the project, the Administrative Commission should declare EESSI to be fit for purpose in June 2017.

Electronic data exchange between social security bodies expected to start in 2019



Sectors directly related to a branch of social security:



Electronic data exchange between social security institutions expected from 2019

The principle behind EESSI

The aim of the EESSI project is to replace the paper-based exchange of European social service documentation and administration with electronic processes. EESSI provides a central platform via which the national social security bodies can exchange all information using structured electronic documents (SEDs) based on business use cases (BUCs). Each BUC is assigned to a specific sector (see diagram above).

The information to be exchanged is entered into the relevant SED and must meet the various requirements

set by the Member States in order to ensure the smooth exchange of data.

Social security experts from the Member States played a vital role in the development phase of EESSI.

What happens now?

As part of the technical implementation, national access points will be set up in the Member States and the social security bodies in each country will be linked to the EESSI system. Starting in summer 2019, the exchange of social security data between the European social security institutions should happen electronically.

This change represents a major challenge to the German health insurance system. More than 100 health insurance funds must make extensive modifications to their existing procedures in order to participate in the new system of European data exchange. This means that every paper-based document must be put into electronic format and reimbursement processes must be converted to electronic data exchange.

For German pension insurance, the number of pension applications from people who have worked across multiple EU countries has been steadily increasing for years. Thus, linking the programme system to the EESSI system also aims to transfer personal data and insurance periods from an electronic message directly into a person's pension insurance account.

The various German social accident insurance institutions need to be linked to the access points and a decision needs to be made quickly with regards to which technical options seem reasonable and proportionate for the cases to be processed.

Implementation requires an enormous effort on the part of the German social security institutions. Nevertheless, this means the optimisation potential of digitalisation is being utilised. The quality of the information being transferred increases significantly and data can be transferred directly into the institutions' processing systems after standardised electronic validation. The added value of standardisation as the result of a well-thought-out digitalisation strategy also benefits EU citizens because applications can be processed faster and benefits can be paid out sooner.

Digital health products fall under EU legislation

If an app is a medical device it is subject to the Directive on medical devices



There are currently discussions in Germany and the EU on how to regulate the testing of quality and safety standards for new digital health products such as apps. There are many similarities to the market access rules for medical devices and medicinal products, which have clear EU regulations. The EU has now created provisions for digital applications.

Social insurance bodies offer apps

The range of mobile apps offered by the statutory insurance bodies is growing. The statutory health care funds offer their members numerous information apps related to stress, nutrition and general services. There are an increasing number of apps for prevention (e.g. vaccination manager), diagnosis (e.g. detecting changes in skin moles) and therapy (e.g. medication reminder apps). In statutory pension insurance, “tele aftercare” plays an important role. This can be used to

help patients suffering from depression by providing aftercare with a smartphone app following inpatient rehabilitation. The social accident insurance institutions offer prevention apps for hazard assessments in the workplace.

It is important to have a clear distinction between an app which is a medical device and one which is not. This is because a diabetes app which calculates the wrong insulin dosage can have a severe adverse effect on health, but this is not the case for an app with a step counter.

New EU classification rules for apps

The new EU Directive on medical devices, which came into force in May 2017, not only places stricter conditions on market access and competition for analogue medical devices such as hip prostheses but also for digital health products. According to the Directive, an app or software is a medical device when it exhibits a medical purpose.

There are new risk classification rules to help with delineation and differentiation (see graphic on Page 6)

There are new risk classification rules to help with delineation and differentiation:

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person's state of health, in which case it is in class III
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb

All other software is classified as class I

Directive (EU) 2017/745 on medical devices,
Annex VIII, Rule 11

Safer apps through CE certification?

The new EU directives are likely to result in a higher classification for apps. In practice, most apps tend to meet the requirements set out in risk class IIa at the very least. These apps can influence decisions on therapy or diagnosis.

As a result, notified bodies are increasingly involved in assessing the conformity of apps. This ensures that the quality management systems and clinical evaluations of app manufacturers are examined by a notified body. This should improve safety.

The new directive states that products in class I, such as prevention apps for cardio sports which primarily give

training recommendations, do not require a notified body to be involved. A manufacturer declaration is enough.

(No) European quality standards for health apps

Health apps related to lifestyle and wellbeing, which are not medical devices, are still not subjected to any sector-specific EU regulations. The European Commission's attempt to draw up quality criteria guidelines for apps as part of its Green Paper on mobile health has stalled for the time being.

The aim was to draw up a list of criteria for transparency and uniform quality standards such as effectiveness, trust and data secu-

rity. The working group set up to do this, which included German social insurance representatives, failed to reach an agreement on a positive list of quality standards. The various stakeholders were at odds regarding the conditions which a health app must fulfil in order to be given an "EU mark of quality".

The EU and the Member States

The EU should make use of its right to adopt European minimum standards on safety and health for digital health products. The situation is different in terms of access to healthcare. The funding of apps by social insurance bodies and the required benefit assessment are the sole responsibility of the Member States.

Building a European eHealth infrastructure

As a result of the growing mobility of insured persons, the European Commission wants infrastructures for electronic cross-border healthcare in the Member States to have been built by 2020. eHealth infrastructure is the keyword.

Cross-border exchange of health data

As per the Directive on patients' rights, the European Commission wants to use electronic services for health and long-term care across borders. The promise is of high-quality care at affordable prices and more innovation. The Commission sees the advantage of having interoperable electronic patient records and prescription systems, for example, when staying or living abroad.

Electronic medical records

Basic medical information is transferred electronically in the event a patient is treated in another Member State.

Electronic prescriptions

Electronic prescriptions make it easier to dispense medicines based on a prescription issued by a physician in another Member State.

Better networking of specialised health services and data is also provided for by the European Reference Networks (ERN) for rare diseases.

The level of maturity in the use of digital health services varies between countries depending on the legal framework, national data processing and the actual level of care.



Vytenis Andriukaitis
European Commissioner for
Health and Food Safety

“Digital technology has become part of the fabric of modern society, and the EU must be at the forefront in creating the right conditions for allowing digital developments to flourish. 52% of citizens wish to have electronic access to their health records. We must work harder to make this happen. The development of digital health services has enormous potential for better healthcare at an affordable cost. I’m counting on all stakeholders, particularly the health insurance institutions, to contribute to the transformation of the European healthcare systems.”

EU funding project: Connecting Europe Facility eHealth (CEF eHealth)

The European Commission actively supports the networking of national infrastructures. The Connecting Europe Facility (CEF) is a funding instrument which is used to establish sustainable trans-European networks. In the area of health, a stand-alone Digital Service Infrastructure (DSI) is being established to exchange health data. Member States can apply to receive funding for their projects.

In addition to the promising idea of it being easier to use health services in other EU countries, it is crucial that national systems are not to be harmonised. Instead, “defined interoperability” between foreign structures will be created. Each Member State will set up a National Contact Point for eHealth (NCPeH) to do this.

Germany’s contribution to promote digital progress

It is very important to take into consideration the specificities of German healthcare when introducing and permanently establishing the cross-border exchange of health data. This is because it is important to set up a German contact point for eHealth in such a way that is compatible with the German telematics infrastructure and is future-proof. The organisation responsible for the project in Germany is gematik.

Germany’s first contribution to the initiative is to introduce an ePatient Record. This will benefit insured persons from other countries as German service providers will be able to

access electronic patient records from abroad. Following this, it is planned that insured persons from Germany will have access to their electronic health records (e.g. emergency medical data) by 2020.

Outlook

Ultimately, building any cross-border network or interoperable system in national organisations leads to major adjustments. The way forward is progress with prudence and “healthy proportionality”, because only 5% of Europeans have medical treatment in another EU country.¹ The low uptake of health benefits in other countries is even more pronounced when looking at German health insurance where the costs for medical services taken abroad represent only a relatively small proportion of the total expenditure of 200 billion euros. This might be due to the lack of foreign language-skills or distance of the family.

This is why the social insurance institutions are actively involved in the change process at European level in order to take advantage of the opportunities for even better care for insured persons and patients.

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¹ http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_425_sum_en.pdf