



EUROPEAN COMMISSION

Brussels, 04.12.2013
C(2013) 8441 final

<p>In the published version of this decision, some information has been omitted, pursuant to articles 24 and 25 of Council Regulation (EC) No 659/1999 of 22 March 1999 laying down detailed rules for the application of Article 93 of the EC Treaty, concerning non-disclosure of information covered by professional secrecy. The omissions are shown thus [...].</p>		<p>PUBLIC VERSION This document is made available for information purposes only.</p>
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Subject: State aid n° SA.35679 (2012/N) – Germany
Telemedicine Infrastructure in Saxony

Sir,

1. PROCEDURE

- (1) By electronic notification of 7 November 2012 (SANI 7641), the German authorities, in accordance with Article 108(3) of the Treaty on the Functioning of the European Union ("TFEU"), notified the ad hoc aid measure "Telemedicine Infrastructure in Saxony".
- (2) The Commission requested additional information by letters of 19 December 2012, 1 March 2013, 14 June 2013 and 13 September 2013. The German authorities submitted the additional information by letters of 21 January 2013, 29 April 2013, 15 May 2013, 18 July 2013, 14 October 2013 and 23 October 2013. The German authorities accept that the decision be adopted in the English language as stated in their letter of 7 November 2012.

Seiner Exzellenz Herrn Dr Guido WESTERWELLE
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2. DESCRIPTION OF THE MEASURE

2.1. Objective

- (3) The Free State of Saxony intends to make eastern Saxony a pilot region, in which telemedicine services will be generally available. The objective therefore is the sustainable development of an efficient infrastructure, which ensures and improves the medical care for several thousand people in this region.
- (4) The objective of this pilot project is to create a market for telemedicine services through the development of a telemedicine infrastructure and in this manner ensure security of supply of healthcare services in rural areas. In addition, important knowledge about the functioning of a telemedicine market under the prevailing framework conditions in the Federal Republic of Germany will be acquired through the project, so that similar projects may be carried out in other rural regions, based on the experience gained in this project.
- (5) The German authorities explain that to their knowledge there is currently no comparable project in place in Germany: other German telemedicine projects do not have the same scale and scope as this pilot project. In particular, most past initiatives in Germany were small scale, standalone projects that were not integrated into the wider healthcare system¹. According to the German authorities, the project to establish telemedicine infrastructure in Saxony differs in several ways from other German telemedicine projects because:
 - it is a large scale telemedicine project that intends to improve the medical care for several tens of thousands people in the region of eastern Saxony by ensuring a comprehensive availability of and recourse to telemedicine services;
 - the project is designed to exist in the long-term and to enable the long-term assurance of health service provision in the region and is therefore much more sustainable than pilot projects of the past;
 - the specific objective of the project is to set up an open infrastructure which allows different providers of electronic health services to provide all patients with secure access to their products and services while the existing systems are usually not compatible with applications from other providers;
 - the project supports a telemedicine infrastructure for a whole region by including all the relevant players of the healthcare system (e.g. doctors, hospitals, other care providers, patients, etc.) and as such it will drive cross-sectoral medical care.
- (6) Under Article 168(1) TFEU, a high level of human health protection shall be ensured in the implementation of all European Union policies. In this process, the Member States are responsible for the organisation and provision of healthcare.

¹ This integrated approach, novel to the project in Saxony, is necessary to build confidence in and acceptance of telemedicine services. It can be achieved by closely cooperating with all the relevant players of the healthcare system (e.g. doctors, hospitals, other care providers, patients, etc.).

- (7) The Free State of Saxony is suffering from an under-provision of healthcare in rural areas, especially in the structurally weak eastern Saxony. Telemedicine is a suitable instrument for ensuring medical care sustainably in rural areas in the long-term.
- (8) The German authorities refer in this context also to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society², which refers to the concerns linked to the ageing population. The German authorities also refer to the possible problems linked to the availability of medical care as regards certain specialties in remote areas. According to the Commission, telemedicine can improve access to specialised care in areas suffering from a shortage of expertise, or in areas where access to healthcare is difficult. The Commission continues that "despite the potential of telemedicine, its benefits and the technical maturity of the applications, the use of telemedicine services is still limited. In addition, the market remains highly fragmented. Although Member States have expressed their commitment to wider deployment of telemedicine, most telemedicine initiatives are no more than one-off, small-scale projects that are not integrated into healthcare systems." It is especially these limitations that the current project aims to overcome by integrating telemedicine services into the healthcare system (i.e. by involving all relevant players) of a region in eastern Saxony.

2.2. National legal basis, granting authority, financing

- (9) The national legal bases for the notified measure are:
- the Directive of the Saxon State Ministry for Social Affairs and Consumer Protection;
 - the ERDF³ operational programme for Saxony under the "Convergence" objective covering the period 2007-2013;
 - Articles 23 and 44 of the Budgetary Act (SäHO) in the version published on 10 April 2001 (SächsGVBl. S.153) last time modified by Article 1 of the Act from 13 December 2012 (SächsGVBl. S. 725) in consolidated version from January 2013;
 - Administrative Regulations of the Saxon State Ministry of Finance to the Budgetary Act of Saxony (VwV-SäHO) from 27 June 2005 (SächsABl. SDR. S.226), last time modified by the Administrative Regulation from 2 May 2013 (SächsABl. SDR. S. 520).
- (10) Based on the national legal framework (a broadly defined scheme, which was approved by the Cabinet of Ministers of the Free State of Saxony), Saxony offered to grant aid with an aid intensity of up to 80% for innovative health projects. The proposed aid intensity of up to 80% was first and foremost based on the considerable interest of Saxony to implement telemedicine projects which the market so far does not provide. Indeed, besides the notified project there was no other comparable infrastructure project proposed by other market participants.

² Brussels, 4.11.2008, COM(2008)689 final.

³ The European Regional Development Fund.

- (11) The Sächsische Aufbaubank acts as the granting authority. The role of the Sächsisches Staatsministerium für Soziales und Verbraucherschutz (Saxon State Ministry of Social Affairs and Consumer Protection) is to decide whether the project would in principle be eligible for support.
- (12) The financing of the project involves resources from the ERDF.

2.3. The project

- (13) The project consists of the development of a telemedicine⁴ service platform including software and hardware components, as well as the provision of a secure computer centre (certified according to ISO 27001, based on coordinated data protection guidelines and operated by correspondingly trained staff).
- (14) The platform is designed with open infrastructure architecture. While the platform itself will be owned by the recipient of the aid, for the inclusion of further services, the platform's interface architecture will be made available to interested parties by means of separate interface documentation (which is based on the most important medical data exchange standards). Providers of telemedicine services are granted open access (for an access fee, see point 61) to these interfaces. Portal providers, providers of diagnoses and/or knowledge databases as well as providers of medical-technical services can make their services available to doctors, hospitals and where applicable also to health insurance funds or their insured persons through the platform.
- (15) The openness of the platform is ensured through its technological neutrality: the architecture of the platform is based on open international ICT standards for the format and communication protocols of data (e.g. JAVA, HTML, HL7, IHE, DICOM). Any technology suppliers that base their products on these open standards can be connected to the platform if they are compliant with its safety requirements as well as with the relevant legal framework, e.g. Bundesdatenschutzgesetz⁵ (German Federal Data Protection Act), Medizinproduktegesetz (German Medical Products Act).

⁴ Telemedicine can be defined as the delivery of healthcare services through the use of Information and Communication Technologies (ICT) in a situation where the actors are not at the same location. The actors can either be two healthcare professionals (e.g. teleradiology, telepathology) or a healthcare professional and a patient (e.g. telemonitoring of chronically ill persons such as those with diabetes and heart conditions, telepsychiatry, etc). Telemedicine includes all areas where medical or social data are being sent/exchanged between at least two remote locations, including both Caregiver-Patient/Citizen as well as Doctor-to-Doctor communication. Telehealth solutions comprise systems and components (patient interfaces in hardware and software; sensors / peripherals; operating software & applications intended for care provider usage; clinical content & intelligence; data transmission, storage and intelligent routing) as well as supporting services (system operation; logistics; financial services; etc.). Accordingly a telemedicine service provider is in principle a doctor no matter whether he or she is an independent physician, employed at a hospital or employed at a healthcare management company. The provider will set up and operate a telemedicine centre to serve end users. The end user is then typically a patient or another doctor.

⁵ The purpose of the German Federal Data Protection Act (Bundesdatenschutzgesetz -BDSG, Bundesgesetzblatt (Federal law gazette) 2003 I p. 66) is to protect individuals against infringement of their right to privacy as the result of the handling of their personal data.

- (16) The services, interfaces and data formats used by the platform are based on open standards. Applications and services from third parties can be implemented based on this platform. They are required to be certified by the beneficiaries of the aid measure for the sake of stability, sustainability and safety of the platform and its telemedicine applications. The platform also defines the safety architecture. All applications and services using the platform have to be compliant with this architecture.
- (17) Four telemedicine applications are to be developed by the beneficiaries⁶ of the aid measure themselves and made available to users as sample applications. These four applications were chosen specifically to demonstrate the spectrum of operability of the infrastructure. Applications were selected that have different technical features, the technical functionality of which has yet to be proven. The medical conditions covered are those that are of particular public interest for Saxony (e.g. because a condition is more prevalent with older persons and Saxony has an ageing population).
- **Telecoaching:** This application is destined for patients with cardiac insufficiency with the goal of reducing the mortality rate as well as improving the patients' wellbeing, motivation as well as participation in the healing process and (if necessary) for early rehospitalisation. Planned users of this application are first of all patients and the Dresden Cardiac Center. An expansion to family doctors and medical specialists, rehabilitation institutions and nursing services is conceivable. The main focus is the regular consultation between medical attendant or physician and the patient with heart failure. Technically, this is realized via a tablet application with video telephony and specific patient questionnaires.
 - **Telestroke-SOS Care:** In the framework of this application specially trained staff (case managers) will support the compiling of the information from stroke patients and from the institutions participating in the treatment/cure. Users will be hospitals and the above mentioned case managers as well as rehabilitation institutions, nursing services and family doctors. The purpose is mainly to standardize the case management process and to assure its quality. The application will therefore enable telemedical mapping of an integrated care path.
 - **Telepathology:** Through providing telepathological second opinions on the basis of this application, transport times and costs can be saved while maintaining the diagnostic quality. In addition, this kind of diagnostic testing is a meaningful and effective tool in the primary diagnostics, when a pathologist with special expertise of rare diseases is not available in peripheral regions (shortage of specialist doctors). Possible users are for example the Institute for Pathology of the Leipzig University Clinic as well as other hospitals in the region. In addition, cooperation with reference centres outside of Saxony is also

⁶ The beneficiaries of the aid measure will offer their services primarily to telemedical application providers or medical technology producers and to telemedicine service providers. The exceptions from this approach are the four sample applications. Through the provision of the four telemedicine applications the members of the civil law partnership will act directly as provider of telemedicine services. The aim here is primarily to demonstrate the reliability of the applications on a telemedicine network.

conceivable. The application will enable specialists in different locations to assess tissue sections by means of virtualization.

- **Teletumorboard:** With the teletumorboard (which already exists in another structure), the Carl-Gustav-Carus University Clinic in Dresden and the Freiberg District Hospital have been ensuring interdisciplinary, individual treatments of cancer patients since June 1, 2010. Doctors of both hospitals sit down together once a week by videoconference to discuss the diagnoses and therapies. Thanks to a telemedicine infrastructure, a live link between both locations is established, in which the participants cannot only hear and see, but also show each other X rays, MRI pictures and electronic patient files. Possible user groups for such an (expanded) application are doctors, specialist doctors, medical healthcare centres, hospitals and clinics as well as radiotherapy practices and centres.
- (18) It is expected that the number of telemedicine applications based on this platform will increase in time. The services, data formats and interfaces that are provided by the platform are designed to be used by various telemedicine applications to be provided by third parties. In further development phases, the underlying platform will be gradually developed towards the participation of additional sectors in healthcare (e.g. acute-care hospitals, out-patient and in-patient care facilities, rehabilitation clinics) as well as the use for further relevant illness and treatment types (e.g. diabetes, radiology) to ensure a broadly effective positive and sustainable influence on the healthcare of the future in Saxony. The beneficiaries do not intend to increase the number of applications provided and operated by them as a sample, which should just test the functionalities and reliability of the platform⁷.
- (19) According to the German authorities (based on the assessment of the Free State of Saxony), the beneficiaries not only guarantee the technically and professionally reliable implementation of the project, but also the compliance with the strict data protection law requirements. Besides the encryption of the data flows and the separation of information, the development of a computer centre, which conforms to the strictest data protection provisions, is also required.

⁷ For details concerning the structure and functioning of telemedicine services in the context of the notified measure see footnotes No 4 and 6.

2.4. The beneficiaries

- (20) The project will be carried out by a civil law partnership (*Gesellschaft bürgerlichen Rechts* - GbR)⁸, which is composed by two entities:
- a medical networking specialist / project organiser Carus Consilium Sachsen GmbH (hereinafter CCS); and
 - T-Systems International GmbH, a subsidiary of Deutsche Telekom AG (hereinafter TSI).
- (21) CCS as project coordinator mainly contributes in the form of medical expertise and process knowledge as well as its contact to primary users and communicates between the specialist users on the one hand and TSI on the other, which is responsible for the technical implementation.
- (22) TSI carries out all services that are connected with the development and implementation of the technical systems.
- (23) The civil law partnership will retain the ownership and rights of use of the infrastructure to be constructed.
- (24) Under the German legal order, the beneficiaries of the aid will however be the individual members of the partnership, i.e. CCS and TSI. The aid will be used within the jointly founded private law partnership.
- (25) The total maximum aid amount of EUR 10 097 850⁹ for the use by the civil law partnership is divided among the beneficiaries in the following way:
- TSI: EUR [...]*
 - CCS: EUR [...]*

2.5. The eligible costs

- (26) The following costs are considered eligible during the 5-year aid period:
- *Personnel expenses*: costs for project management, new software development and associated medical know-how necessary for the modelling of the software, costs for establishing and commissioning a data centre;
 - *Costs for external/contracted services*: if inexistent internally, competences and additional know how will be purchased from external sources;
 - *Initial investment costs*: procurement of hardware and software.

⁸ An association of individuals or enterprises united in the achievement of a joint contractual purpose without a legal personality.

⁹ The aid amount of EUR 10.1 million (rounded up) will be split as follows: EUR 4.3 million will be used to set up the infrastructure while EUR 5.8 million will be used to develop the four sample applications.

* Business secret.

- (27) Personnel costs (for the development of the software) can in principle only be taken into account up to the amount based on the applicable collective agreement for the public service of the Federal States (Tarifvertrag für den öffentlichen Dienst der Länder).
- (28) For the activity of the civil law partnership, an independent, project-related bookkeeping will be carried out.
- (29) The total projected eligible costs of EUR 12 622 312¹⁰ are calculated as follows:

Table 1: Total eligible costs during the 5-year aid period

[...]*

2.6. The aid: form, amount, and intensity

- (30) The aid will be granted in the form of direct grants.
- (31) As mentioned in point 10 above, the maximum aid intensity is 80% of eligible costs.
- (32) The aid amount corresponds to:
- 80% of the sum of CAPEX (capital expenditure, i.e. the yearly depreciation amounts) during 5 years (eligibility period)¹¹; plus
 - 80% of OPEX (operating expenditures¹²) for the timeframe from the start of the project to the end of the ERDF grant period¹³, i.e. at the time of notification in principle for a maximum of 3 years.

The maximum aid amount is capped at EUR 10 097 850. A precondition for following this approach would be to have previously incurred and demonstrated capital and operating expenditure during the ERDF grant period. The aid amount will only cover eligible costs incurred during the 5-year aid period (see Table 1).

- (33) To sum up, the maximum aid amount of EUR 10.1 million (rounded up) is calculated as follows:
- Total projected eligible costs: EUR 12 622 312;
 - 80% state aid: EUR 10 097 850;

¹⁰ The eligible costs of EUR 12.6 million (rounded down) will be divided as follows: EUR 5.4 million will be incurred for the setup of the infrastructure while EUR 7.2 million will be incurred for the development of the sample applications.

¹¹ The eligibility period represents the time period in which the project is bound to follow the granting conditions.

¹² Linked to the investment as described in Section 2.5. Eligible costs (above).

¹³ The grant period covers the time period in which the aid will be paid out – according to the current ERDF procedures.

* Business secret.

- 20% own contribution of the beneficiaries: EUR 2 524 462.
- (34) The aid amount of EUR 10.1 million will be paid out as follows:
- CAPEX: these costs (depreciation) shall be paid out in the form of one or more “up-front” payments during the ERDF grant period and then adjusted downwards if necessary. The payments will only be authorised if the civil law partnership can demonstrate the capital expenses actually incurred, of which only 80% may be supported.
 - OPEX: 80% of these costs will be paid out on a yearly basis (ex post).
- (35) The depreciation will start at the point in time when the software is ready for use (implemented). In case the software is implemented step-by-step, the depreciation will start when the first software module is prepared for use. It is expected that the depreciation will not start before January 2014. The depreciation will be based on an expected useful life of 5 years for the software and 3 years for the hardware.

2.7. Absence of overcompensation, reasonable profit

- (36) The verification of absence of overcompensation will take place at least twice, i.e. at the end of the ERDF grant period and at the end of the 5-year eligibility period. It shall, however, take place on a yearly basis, should the annual turnover of the civil law partnership exceed EUR 1 million p.a..
- (37) To verify the absence of overcompensation, the notified project foresees the following calculation method based on cumulated figures¹⁴:
- Revenues: State aid for the project + turnover of the project;
 - [minus] Expenses: Costs of the project (CAPEX + OPEX).

If the revenues exceed the costs of the project, the surplus shall be recovered by the granting authority as far as it exceeds the reasonable profit level (expressed as share of turnover) of 9.7%¹⁵. The aim of this mechanism is to ensure that there is no overcompensation.

- (38) An exit clause shall additionally safeguard the absence of overcompensation in the situation (which cannot be completely excluded) that the project is already supporting itself before the end of the 5-year eligibility period in the event of success and a rapid overcoming of the currently existing market barriers. This clause applies when the cumulated turnover exceeds the cumulated eligible costs. In this case, the pro rata infrastructure costs attributable to the remaining time are to be completely recovered.

¹⁴ This means that in year 1 the calculation is based on the revenues and expenses of year 1, in year 2 this will be on the basis of the cumulated revenues and expenses for year 1 and year 2, and so on.

¹⁵ For detailed explanation see section 2.8 below.

- (39) A final check takes place, normally, at the end of the 5-year eligibility period¹⁶, which foresees that if the total amount of State aid received exceeds 80% of the cumulated net cost of the project including a reasonable profit¹⁷, the surplus shall be recovered. The German authorities submitted to the Commission a theoretical calculation demonstrating the practical application of the principles of the no-overcompensation test described above in points 36-39.

2.8. Benchmark information concerning reasonable profit

- (40) A profit margin of 9.7% is regarded by the German authorities as reasonable. The profit margin is calculated as follows: $EBIT / \text{Turnover} * 100$ ¹⁸.
- (41) As regards the benchmark information¹⁹ for the determination of the reasonable profit, the German authorities submitted the following data:

Table 2: 2012 Health care/ telehealth providers EBIT/EBIT margin data

		2012 FY	Revenue	EBITDA	EBITDA margin	EBIT	EBIT margin
millions of €	1	DT Group	58.183	17.978	30.9%	6.984	12.0%
millions of €	2	Philips Healthcare	9.983	1.322	13.2%	1.122	11.2%
millions of €	3	CompuGroup	450.569	105.284	23.4%	66.788	14.8%
millions of \$	4	GE Healthcare	18.300	2.900	15.8%	n.a.	n.a.
millions of \$	5	Athena Healthcare	422.271	90.863	21.5%	34.627	8.2%
					20,97%		11,57% average

Table 3: 2011 Health care/ telehealth EBIT/EBIT margin data

		2011 FY	Revenue	EBITDA	EBITDA margin	EBIT	EBIT margin
millions of €	1	DT Group	58.715	18.685	31.8%	7.606	13.0%
millions of €	2	Philips Healthcare	8.852	1.145	12.9%	93	1.1%
millions of €	3	CompuGroup	396.564	73.065	18.4%	36.655	9.2%
millions of \$	4	GE Healthcare	18.083	2.803	15.5%	n.a.	n.a.
millions of \$	5	Athena Healthcare	324.067	70.574	21.8%	32.733	10.1%
					20,09%		8,34% average

¹⁶ However, in case the exit clause applies, the calculation is performed based on the figures of the year before the project becomes self-sustaining.

¹⁷ Total eligible expenses minus total turnover plus 9.7% of the total turnover.

¹⁸ Also called EBIT margin; in this case EBIT (earnings before interest and taxes) does not include extraordinary items, e.g. restructuring costs.

¹⁹ Benchmark information is based on financial reports of companies operating in the healthcare and telehealth sector from Germany, other EU Member States and from outside the EU.

(42) Finally, the German authorities explain that they do not expect that the civil law partnership will make any profit during the first 5 years. Accordingly, the predefined reasonable profit is, considering all that is known at this point in time, only a theoretical calculation element.

2.9. Control and monitoring mechanisms

(43) Considering the involvement of the ERDF financing, detailed rules for the project implementation are laid down in the description of the managing and control systems (pursuant to Art. 21 of Commission Regulation (EC) Nr. 1828/2006²⁰).

(44) The mechanisms at hand should ensure *inter alia*:

- that the implementation of the management and inspection systems is effective and their operation is sound;
- that the accounting and supporting documents correspond to the promoted expenditure;
- that the audit is adequate;
- that the nature and date of expenditure on an appropriate number of individual items comply with EU requirements;
- that the actual national and/or regional part-financing is provided.

(45) With regard to the specific project, the granting authority, i.e. the Sächsische Aufbaubank ("the Bank"), will verify that the co-financed products and services are delivered and that the expenditure declared by the beneficiaries has actually been incurred. Corresponding information has to be provided to the Bank with any application for State aid tranches. Payments will only be made by the Bank on the basis of expenditure actually incurred.

(46) Furthermore, the beneficiaries have to respect the public procurement law. As a precondition for any payment of State aid, the Bank will check the compliance of the acquisition of goods and services with the respective rules. This check will include the transactions between the beneficiaries and third parties.

(47) With any application for the payment of State aid tranches, the beneficiaries must also submit a list of the invoices for which co-financing is requested. According to the procedure laid down in the description of the managing and control system, the Bank will demand, and later on check, 20% of the invoices listed in the payment application.

(48) The Bank will also carry out on-the-spot verifications.

(49) After completion of the project, the beneficiaries will have to submit a report on expenditure of funds that will be controlled by the Bank.

²⁰ Commission Regulation (EC) Nr. 1828/2006 setting out rules for the implementation of Council Regulation (EC) No 1083/2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and of Regulation (EC) No 1080/2006 of the European Parliament and of the Council on the European Regional Development Fund; OJ L 371, 27.12.2006, p. 1.

- (50) The beneficiaries will have to maintain either a separate accounting system or an adequate accounting code for all transactions relating to the project.
- (51) If irregularities caused by the beneficiaries are detected, beneficiaries can be obliged to pay back a certain amount of the grant and may even be liable under criminal law.

2.10. Telemedicine market, market failure

- (52) As regards the situation in Germany, the national authorities mention that despite the potential of telemedicine in Germany, no market has developed so far. The potential market participants are not able to establish the required infrastructure under the current market conditions. The uncertainty regarding key elements (such as users' behaviour, user fees, reimbursement of fees by the health insurers; see also below) needed to calculate the possible return from investing into telemedicine appears to be a barrier for investors. This also explains why so far the sustainability of other telemedicine projects in Germany has not been assured.
- (53) Particularly problematic according to the German authorities is the uncertainty about what a user's (i.e. both users of the infrastructure such as application providers and end users of the applications such as doctors and patients) behaviour will look like and what income from the use can be expected. This high degree of uncertainty constitutes an additional discouragement for potential market participants, who would otherwise be able to develop an infrastructure. The novelty of the service and the not yet existing market form aspects which make any calculation of the risks associated with the investment impossible. The lack of calculability of the risk will be thus mitigated through the aid.
- (54) Telemedicine services are presently in principle not reimbursable by the health insurers within the framework of standard care in Germany (standardised accounting numbers in the catalogues of outpatient care, medical-fee schedules for inpatient care do not exist at this moment for telemedicine services) and it is still unclear, how such services will be integrated into these catalogues and how end user fees charged to the hospitals, doctors, and patients that use the applications will be calculated.
- (55) In certain cases the applicable German law enables health insurers to conclude selective contracts with healthcare providers. To date, any financing of telemedicine by health insurances has been the result of individual negotiations for particular projects (pilot projects, integrated provision contracts). None of the previous German telemedicine projects have been able to achieve that the reimbursement of telemedicine services is accepted on a wide scale, which explains why the project in Saxony still needs to negotiate with the health insurers.

- (56) The German healthcare market is highly regulated and is subject to a specific legal framework (“Sozialgesetzbuch V”). The execution of the law is administrated via a self-regulatory body comprised of associations of health insurers and healthcare service providers. This self-regulatory body determines the arrangements of the healthcare service catalogue and negotiates which healthcare services are billable and which administrative costs can be calculated and reflected in the catalogue.
- (57) As a requirement for the start of negotiations, the healthcare service first has to be implemented in order to test and evaluate its technical and economic feasibility. The companies thus have to develop a telemedicine service and have to offer it for a certain (self-defined) rate to customers, who will pay for the service without being reimbursed by the statutory health insurance. As a result of the State aid, the infrastructure operator can charge a lower fee to the users of the telemedicine platform/applications which in turn will lower the threshold for making use of telemedicine services. The integrated approach seeking to involve all players in the healthcare system (e.g. doctors, hospitals, other care providers, patients, etc.) aims to further increase the chances of success for the project. In order to achieve the objective of ensuring and improving the medical care for the citizens of the pilot region, the beneficiaries aim to obtain the approval for reimbursement by the health insurance by showing that telemedicine is a well-functioning system in Saxony.
- (58) This transitional period, before the telemedicine services are reimbursable, may according to the German authorities last several years. According to the German authorities, during this transitional period, users of the subsidised telemedicine platform/applications might have a relative advantage in so far as the costs of the infrastructure cannot be completely passed on to them. However, the German authorities explain in this context that the access fees (charged to the application providers) and the end user fees (charged to the hospitals, doctors, and patients that use the applications), if they were to reflect the full costs of the infrastructure and its operation, would be prohibitively expensive. The transitional period, i.e. until the inclusion of telemedicine services in the catalogues of reimbursable health service, will therefore be according to them marked by a lack of competition between operators.
- (59) In order to demonstrate the proportionality of the aid the German authorities submitted two business scenarios from the members of the civil law partnership for the notified project: one based on an optimistic assumption that the telemedicine services form part of the catalogues of reimbursable health services (through the creation of appropriate standardised billing code numbers) and another less optimistic scenario, which is based on the assumption that the reimbursement of the telemedicine services depends on individual contracts negotiated with health insurers²¹.

²¹ These contracts are named “IV-Verträge” (integrated contracts) in the German Book Five of the Social Law Code (SGB V).

2.11. Controls to mitigate the potential negative effect of the aid on competition

- (60) The supported infrastructure will be open to third parties interested in the development of their own telemedicine applications. However, to ensure that the market is not foreclosed by the owner of the infrastructure the German authorities have committed, by letter of 14 October 2013, to implement several additional control mechanisms.
- (61) During a period of ten years²² (i.e. the eligibility period and the subsequent five years), the access fees charged to the users of the infrastructure (such as application developers and providers) will be capped. In particular, during the eligibility period the costs charged to the users of the infrastructure will be limited to the full costs plus a reasonable profit (i.e. 9.7%, see above) minus the State aid. For the next five years, these users should not be charged more than the full costs plus a reasonable profit for the use of the infrastructure.²³
- (62) In addition, the German authorities will set up a contact point for complaints concerning the pricing of the access to the infrastructure and ensure that its existence is made publicly known. The beneficiaries of the aid will also have to provide relevant cost information concerning the infrastructure and the aided applications to the German authorities. This will enable monitoring of the limits described in point 61. Both mechanisms will be applicable for the control period of ten years (i.e. the eligibility period and the subsequent five years).
- (63) The beneficiaries operate four sample applications primarily in order to test the functionalities and reliability of the platform. The civil law partnership has no intention to introduce additional telemedicine applications which would be using the platform (see also point 18). Regardless of this, it is in theory possible for the beneficiaries to get involved in the development of new telemedicine applications as long as the civil law partnership is continued but only if third parties will be the majority owners of the applications (this condition applies during the control period of ten years). After the possible liquidation of the civil law partnership this restriction would remain applicable up to the end of the control period of ten years for TSI but not for CCS. In this way TSI, who is responsible for the infrastructure, cannot become a dominant player in the applications market. The German authorities have committed to monitor that these restrictions are respected during the control period of ten years (i.e. the eligibility period and the subsequent five years).
- (64) Finally, the German authorities also committed to require that after the eligibility period each of the four (i.e. unbundled) sample applications are offered for sale in an open, transparent and non-discriminatory procedure and that this procedure is repeated up to two times in case market participants show no interest in the first call for tender.

²² The period of ten years can be justified based on the fact that the infrastructure that was funded by the State aid will have no more residual value after at most five years (see also description of the useful life of the hardware and software in point 35). The beneficiaries will have to reinvest in hardware and software using their own funds to keep the infrastructure operational.

²³ The definition of the amount of reasonable profit might be reviewed by the German authorities after the end of the eligibility period to ensure that the reasonable profit level reflects the market situation after that period.

In case the three successive calls (with 18 months between each call) are unsuccessful²⁴ the beneficiaries may continue to operate the applications, unless they choose to abandon them. In case a sample application is sold, the beneficiaries are obliged to repay the State aid for the development of the respective application minus the pro rata net costs of the project partners and the reasonable profit of 9.7%.²⁵ Alternatively, if the beneficiaries choose not to organise a tender procedure for all or some of the applications (e.g. because the project was unsuccessful and they expect no market participants would be interested) the beneficiaries will be required to abandon that or those application(s). The German authorities will also check that the abandonment of the aided applications will not be reversed during the five years following the eligibility period.

3. ASSESSMENT OF THE MEASURE

3.1. Existence of aid within the meaning of Article 107(1) TFEU

- (65) State aid is defined in Article 107(1) TFEU as any aid granted by a Member State or through State resources in any form whatsoever, which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods, in so far as it affects trade between Member States.
- (66) The notified aid measure allows the beneficiaries to be relieved, by means of State resources (ERDF resources put at the disposal of the national authorities and co-financing from national sources²⁶), of a part of the costs which they would normally have to bear themselves.
- (67) Consequently, the financial aid from the State (granted by the Sächsische Aufbaubank – a public body) strengthens the position of the beneficiaries in relation to their competitors in the EU and therefore has potentially distorting effects on competition.
- (68) One of the beneficiaries, TSI, is a subsidiary of Deutsche Telekom AG, a company active in cross-border trade in a liberalised sector. The telemedicine services to be carried out under the notified measure by this beneficiary might possibly be subject to intra-EU trade, and the aid may thus affect trade between Member States considering *inter alia* that there are undertakings active in the telehealth sector elsewhere in the EU.
- (69) Accordingly, the Commission concludes that the notified measure constitutes State aid within the meaning of Article 107(1) TFEU.
- (70) As regards potential aid to the users of the platform (indirect beneficiaries), the Commission notes that the aid might enable these entities to provide telemedicine

²⁴ Unsuccessful means that there are no interested market participants or that the bids are below the minimum price. The minimum price will be equal to the costs of the project partners in developing the respective application minus State aid. A higher minimum price will not be allowed.

²⁵ The German authorities committed in their letter of 23 October 2013 to monitor that this repayment obligation is fulfilled during the ten year control period (i.e. the eligibility period and the subsequent five years).

²⁶ The national co-financing is provided at rate of 20%.

services at conditions that would not be available under normal market conditions without the aid. As explained in point 58 above, the full reflection of the infrastructure costs would make the use of the platform prohibitively expensive. As the German authorities emphasise, currently there is no market in Saxony for telemedicine services as the telemedicine service sector is separate from general medical services. Accordingly, the Commission cannot exclude the presence of an advantage at the level of the providers of telemedicine applications who use the platform nor at the level of the end users of these applications (insofar the latter qualify as undertakings). The Commission notes in this context that this potential advantage granted indirectly to the users of the telemedicine platform and to the end users of the applications would be necessary for achieving the objective of the measure (i.e. to introduce the telemedicine services in Saxony). Indeed, this potential advantage, which must be passed on to the users of the platform in the form of capped fees, would lower the threshold to make use of telemedicine services and thus increase the chance of success of the project. For the assessment of the compatibility of such potential aid the same methodology as for the direct aid granted to the civil law partnership would be applied.

3.2. Lawfulness of the aid

- (71) By notifying the aid measure before its implementation, the German authorities fulfilled their obligation according to Article 108(3) of the TFEU.

3.3 Compatibility of the aid

- (72) In its paragraphs (2) and (3), Article 107 TFEU provides for rules under which certain aid shall be compatible with the internal market, or certain aid may be considered to be compatible with the internal market.
- (73) The Commission considers that the compatibility of the measure at stake with the internal market can be assessed according to the derogation in Article 107(3)(c) TFEU which provides for the authorisation of "...aid to facilitate the development of certain economic activities or of certain economic areas, where such aid does not adversely affect trading conditions to an extent contrary to the common interest."
- (74) The Commission notes that the measure does not fall within the scope of existing guidelines for the application of Article 107(3)(c) of the TFEU. Thus it should be assessed directly under this Treaty provision. In order to be compatible under Article 107(3)(c) TFEU, an aid measure must pursue an objective of common interest in a necessary and proportionate way.
- (75) When assessing the compatibility, the Commission balances the positive impact of the measure in reaching an objective of common interest against its potentially negative side effects, such as distortion of trade and competition.

(76) The balancing test is structured as follows:

1. Is the aid measure aimed at a well-defined objective of common interest, i.e. does the proposed aid address a market failure or other objective?
2. Is the aid well designed to deliver the objective of common interest? In particular:
 - (a) Is the aid measure an appropriate instrument?
 - (b) Is there an incentive effect, i.e. does the aid change the behaviour of the potential beneficiaries?
 - (c) Is the aid measure proportionate, i.e. could the same change in behaviour be obtained with less aid?
3. Are the distortions of competition and the effect on trade limited, so that the overall balance is positive?

Ad 1) Objective of Common Interest

(77) The objective of the notified measure is to enable the sustainable provision of telemedicine services in Saxony. In that context, the German authorities refer to the limited availability of the medical care in rural areas of eastern Saxony as well as to the issue of an ageing population. The German authorities also mention the Commission Communication on telemedicine (for details see point 8 above), which clearly encourages the development of telemedicine services in the EU.

(78) For these reasons, the Commission considers that the notified measure serves a well-defined objective of common interest not delivered by the market as explained in point 2.10. The Commission notes in this context that the national authorities mention that despite the potential of telemedicine in Germany, no market has developed so far as the potential market participants are not able to establish and maintain the required infrastructure under the current conditions. In this context, the uncertainty regarding key elements which would allow a calculation of a possible return on investment is a barrier, which seems to be linked inter alia to the fact that currently telemedicine services are in principle not reimbursable by the health insurers within the framework of standard care.

Ad 2) Aid well designed to deliver the objective of common interest

(79) An aid measure is considered to be well designed to deliver the objective of common interest when it constitutes an appropriate instrument to achieve the identified objective of common interest, when it has an incentive effect on the beneficiaries in terms of changing their behaviour and when the aid is proportionate.

Appropriate instrument

(80) The beneficiaries of the aid aim to obtain the approval for reimbursement of telemedicine services by the health insurance by showing that telemedicine is a well-functioning system in the pilot region of eastern Saxony. Reimbursement will strongly contribute to the sustainability of offering telemedicine services to achieve the overall

objective of ensuring and improving the medical care for the citizens of eastern Saxony. As a particular telemedicine service has to be implemented and offered to customers even before the start of discussions on its inclusion in the list of reimbursable services, the proposed aid will mitigate the uncertainties concerning the return on investment and will increase the chances of success of the project by lowering the fees to a level at which it is more likely that the platform will be used by a sufficient number of patients to show that it is efficient and viable.

- (81) Furthermore in this context, the Commission refers to the innovative character of the notified project and in particular the integrated approach, involving all players in the healthcare system, necessary to build confidence in and acceptance of telemedicine services.
- (82) In view of these considerations, the Commission considers that the notified State aid in the form of grants is an appropriate instrument to attain the well-defined objective as described above.

Incentive Effect

- (83) The Commission considers that the aid measure is capable of modifying the behaviour of the beneficiaries since the aid in the form of direct grants constitutes an incentive for these entities to establish a platform for the provision of telemedicine services. This would not happen in the absence of the aid considering the current situation in Germany as described above²⁷. In fact, such a project would be significantly loss-making based on the information provided in the business plans provided (see point 86) to such an extent that the beneficiary would not pursue the project.
- (84) From a formal point of view, the Commission notes that the beneficiaries applied for the aid before the start of the works on the project.

Proportionality of the aid

- (85) Aid is considered to be proportionate only if the same change of behaviour could not be achieved with less aid. The amount of aid must be limited to the minimum needed for the aided activity to take place. In the present case, the Commission considers that the German authorities designed the measure in such a way as to minimise the possible amount of State aid involved and the distortions of competition arising from the measure.
- (86) Firstly, in this context the Commission refers to the business plan and the two scenarios submitted by the German authorities, which both show that without the aid over the period 2013-2017 the project would be significantly loss-making²⁸. Even in the optimistic scenario with the aid (at the level of 80% of eligible costs), the project is still not profit-making over the same period.

²⁷ For details see mainly section 2.10. above.

²⁸ Based on cash-flow data submitted by the German authorities (approximately between EUR 10.1 - 14 million of losses)

- (87) The Commission also notes in this context that the project of the beneficiaries was the only application for aid for this type of activity submitted under the pre-defined granting conditions, including the 80% aid intensity.
- (88) Furthermore, the Commission refers in the context of the proportionality of the notified measure to the different verification mechanisms in order to avoid overcompensation, which involve regular checks based on actual revenues and costs. The control mechanisms ensure that the revenues from operating the telemedicine platform/sample applications are taken into account in the overcompensation verifications.
- (89) As regards the level of reasonable profit (9.7% based on turnover) applied in the calculations, the Commission considers that the benchmarking information²⁹, submitted by the German authorities, despite the fact that due to market failure perfect telemedicine comparators cannot be found demonstrates that the level of profit applied under the notified measure is not excessive and can be thus considered as reasonable.
- (90) Finally, the Commission notes that the notified project must have a separate accounting for all transactions relating to the project and that compliance with the public procurement rules forms part of the granting conditions. This will help to ensure that the project's costs are kept as low as possible.
- (91) In view of the above, the Commission comes to the conclusion that the notified aid is limited to the minimum necessary to ensure that the objective of the aid, i.e. ensuring and improving medical care by means of the sustainable provision of telemedicine services in Saxony, is achieved.

Ad 3) Impact on competition and trade between Member States

- (92) As regards the impact of the notified measure on competition, the Commission notes the following aspects of the aid, which in its view mitigate the potential negative effect of the aid on competition:
- The subsidised infrastructure will be open to third parties interested in the development of their own telemedicine applications, the aid will thus not lead to the creation of a local monopolistic situation. The German authorities have committed, by letter of 14 October 2013, to implement several control mechanisms to ensure that the market is not foreclosed. In particular, during a period of ten years (i.e. the eligibility period and the subsequent five years) the fee that can be charged to the users of the infrastructure will be limited (see point 61), a contact point for complaints concerning the pricing of the access to the infrastructure will be set up (see point 62), and the beneficiaries of the aid will have to provide relevant cost information to the authorities (see point 62);
 - Except for four sample applications operated by the beneficiaries primarily in order to test the functionalities and reliability of the platform, the civil law partnership does not intend to develop further telemedicine applications and the German authorities have committed, by letter of 14 October 2013, to monitor this during a

²⁹ As described in section 2.8 above.

period of ten years (i.e. the eligibility period and the subsequent five years) (see point 63). In addition, the German authorities also committed to require that each of the four sample applications are offered for sale in an open, transparent and non-discriminatory procedure after the eligibility period and that this procedure is repeated up to two times in case market participants show no interest in the previous call for tender (see point 64). These measures would further limit the impact of the aid in the telemedicine application market since the owner of the infrastructure would have no or only a limited presence in the market for applications and this would strongly reduce the risk of foreclosure of the market by the owner of the infrastructure;

- The subsidised project is a pilot project and there is, according to the German authorities, no infrastructure in place (either at regional or at national level) that would be able to support the comprehensive availability of telemedicine services envisaged in the project. The aid will thus not lead to any unnecessary duplication of infrastructure.
- (93) As regards the potential negative impact on trade between Member States, the Commission notes that while the supported platform will be regionally limited in scope (i.e. primarily eastern Saxony), the German authorities indicate that similar projects may be implemented in other German regions and even the creation of a nation-wide system could be possible in the future. Moreover, the experience gained by the beneficiaries in the German market could subsequently also be used for the introduction/development of telemedicine services in other Member States.
- (94) Taking into account all of the foregoing considerations, the Commission comes to the conclusion that, despite the negative effects of the aid described above, the overall balance of the implementation of the measure is positive.
- (95) Accordingly, the aid granted for the establishment and operation of the telemedicine platform pursues an acknowledged public policy objective, is necessary and proportionate and does not affect trade and competition between Member States to an extent contrary to the common interest. The notified measure is thus compatible with the internal market pursuant to Article 107(3)(c) TFEU.

4. CONCLUSIONS

- (96) The Commission therefore finds that the notified measure is compatible with the internal market. Accordingly, pursuant to Article 4(3) Council Regulation (EC) No 659/1999³⁰ the Commission has decided not to raise objections to the notified measure.
- (97) The German authorities accept that the decision be adopted in the English language.
- (98) If this letter contains confidential information which should not be disclosed to third parties, please inform the Commission within fifteen working days of the date of receipt. If the Commission does not receive a reasoned request by that deadline, you will be deemed to agree to the disclosure to third parties and to the publication of the full text of the letter in the authentic language on the Internet site: <http://ec.europa.eu/competition/elojade/isef/index.cfm>

Your request should be sent by registered letter or fax to:

European Commission
Directorate-General for Competition
State Aid Greffe
B-1049 Brussels
Belgium
Fax No: +32 2 29 61242

Yours faithfully,
For the Commission

Joaquín ALMUNIA
Vice-president

³⁰ OJ L 83, 27.3.1999, p. 1.