

Brussels, 10 July 2019 Case No: 83590

Document No: 1067613 Decision No 057/19/COL

Ministry of Trade, Industry and Fisheries Postboks 8090 Dep 0032 Oslo Norway

Subject: eHealth

# 1 Summary

- (1) The EFTA Surveillance Authority ("the Authority") wishes to inform the Norwegian authorities that, having assessed the public financing of eHealth and digital health infrastructure in the Norwegian healthcare system, as well as the provision of certain support services and registers ("the measures"), it considers them not to constitute state aid within the meaning of Article 61(1) of the EEA Agreement.<sup>1</sup>
- (2) The Authority has based its decision on the following considerations.

#### 2 Procedure

(3) The Norwegian authorities submitted a notification by letter of 3 May 2019.<sup>2</sup> The notification was submitted for legal certainty, as the Norwegian authorities do not consider the measures to constitute state aid. Since the notification concerns measures that have already been implemented the two-month deadline set out in Article 4(5) of Part II of Protocol 3 to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice does not apply.<sup>3</sup>

# 3 Description of the measures

## 3.1 Background

(4) The term "eHealth" stands for the use of information and communication technologies ("ICT") in the health sector. According to the World Health Organization, it is recognised as one of the most rapidly growing areas in health today.<sup>4</sup>

<sup>&</sup>lt;sup>1</sup> Reference is made to Article 4(2) of the Part II of Protocol 3 to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice.

<sup>&</sup>lt;sup>2</sup> Document Nos 1067437, 1067441 and 1067439.

<sup>&</sup>lt;sup>3</sup> Reference is made to Article 13(2) of Part II of Protocol 3 to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice.

<sup>4</sup> https://www.who.int/goe/en/.

- (5) In line with many other countries, Norway has recognised eHealth's potential and invested substantial resources into its development. Today, public entities already provide a number of publicly financed eHealth solutions all across Norway, which can be used by all health service providers and patients. However, according to the Norwegian authorities, significant challenges still remain, in particular given the fact that individuals receive services from a multitude of different health service providers that record health related information differently and separately.
- (6) The notification submitted by Norway encompasses the public financing of the activities of Norsk Helsenett SF ("NHN"), a public corporation charged with the provision of nationwide eHealth solutions in Norway. It also covers the public financing of a number of activities that today are performed by the Norwegian Directorate of eHealth ("NDE"), but which will be transferred to NHN going forward. These activities will be described in further detail in sections 3.4 to 3.8 below.

## 3.2 The Norwegian healthcare system

#### 3.2.1 Introduction

- (7) Norway is often placed high on different rankings as regards health care performance worldwide, and it spends a comparatively high amount on healthcare, both in absolute and relative terms. In 2017, for instance, 10.4% of Norway's GDP went into health care. Norway is also one of the countries in the world where the share of private spending on health care is amongst the lowest of the total spending (approximately 15%), reflecting the solidarity-based nature of the system.
- (8) The Norwegian health care system can be characterised as semi-decentralised, with responsibilities separated for specialist and primary health care. The State is responsible for specialist care and owns the four Regional Health Authorities ("RHAs"). The municipalities are responsible for primary care. The counties are responsible for statutory dental care.
- (9) The Ministry of Health ("the Ministry") is in charge of regulation and supervision of the system, but many of these tasks are delegated to its various agencies, such as the Directorate of Health and NDE. The Ministry controls the activities of its agencies through direct steering (in the case of national agencies), ownership arrangements, such as budgets and letters of instructions (RHAs), and legislation and financial instruments (counties and municipalities). It ensures that health and social services are provided in accordance with national acts and regulations.

# 3.2.2 Organisation and legal framework

- (10) The organisational structure of the Norwegian health care system is built on the principle of equal access to services for all inhabitants, regardless of their social or economic status and geographic location. This overarching goal is laid down in the national health care legislation and strategic documents.
- (11) The activity of the RHAs is regulated in the Specialized Health Services Act,<sup>5</sup> the Health Authorities and Health Trusts Act,<sup>6</sup> and through the general meeting (foretaksmøte)<sup>7</sup> between the Ministry and representatives of the RHAs.

<sup>6</sup> Lov om helseforetak, <u>LOV-2001-06-15-93</u>.

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<sup>&</sup>lt;sup>5</sup> Lov om spesialisthelsetjenesten, <u>LOV-1999-07-02-61</u>.

- (12) Pursuant to Section 2-1 of the Specialized Health Services Act, the State has the overall responsibility for the provision of necessary specialized health services to the population. This entails determining the overall health policy objectives, securing sufficient financing for the RHAs, and supervising that they fulfil their duties. The RHAs are responsible for implementing the national health policy in the regions. The RHAs may not provide services themselves. They must either order their fully owned Public Health Trusts (independent legal entities owning hospitals, clinics, etc.) to provide the services, or enter into agreements with private providers, which provide the services on behalf of the RHAs. In 2016, the Public Health Trusts provided roughly 90% of the services that the RHAs are responsible for, and private providers around 10%.
- (13) The 422 Norwegian municipalities have a great deal of freedom in organising health services. There is no direct command and control line from central authorities to the municipalities. The municipalities may either provide the services themselves or enter into agreements with private providers, which provide the services on behalf of the municipality. It follows from the Municipal Health and Care Act,<sup>8</sup> that the role of the central Government is to assure the high quality of services across the municipalities through funding arrangements and legislation. Limited health care responsibilities, relating to dentistry, are held by the counties.
- (14) The decentralised organisation of the health care sector in Norway entails a relatively high degree of fragmentation. There are several hundred legal entities with legal obligations to provide health care to the public, and several thousand health service providers. The sector employs approximately 330 000 health professionals. The fragmented landscape of health and care service providers and hierarchies presents a challenge when it comes to introducing eHealth solutions that are interoperable and alike across all of Norway.

## 3.2.3 Financing and the principle of solidarity

- (15) Public financing, including, in particular, block grants from the state budget, account for more than 85% of total health expenditure, and comprise financing from the central and local Governments and the National Insurance Scheme ("NIS"). The majority of private health financing comes from households' out-of-pocket payments. Outpatient pharmaceuticals and dental care attract the highest share of private financing. The role of (private) voluntary health insurance in health care financing is negligible, according to the Norwegian authorities.
- (16) Pursuant to the Patients' and Users' Rights Act, patients residing in Norway are entitled to publicly funded emergency medical care and other necessary specialist and primary health care, adapted to the individual patient's needs. Patients are entitled to receive these services for free, or subject to a very limited degree of cost-sharing. For example, inpatient care in public hospitals or private hospitals contracted by the RHAs, including day-care and same-day surgery in hospitals (and pharmaceuticals), is free of charge, whereas general practitioner ("GP") and outpatient specialist visits require flat fee co-payments (approx. NOK 200–350 per visit, respectively). However, there are cost-sharing ceilings (approx. NOK 2 500

<sup>&</sup>lt;sup>7</sup> https://www.regjeringen.no/no/tema/helse-og-omsorg/sykehus/styringsdokumenter1/protokoller-for-foretakene/foretaksmoter/id443318/.

<sup>&</sup>lt;sup>8</sup> Lov om kommunale helse- og omsorgstjenester, <u>LOV-2011-06-24-30</u>.

<sup>&</sup>lt;sup>9</sup> Lov om pasient- og brukerrettigheter, LOV-1999-07-02-63.

per person per annum), meaning that services become entirely free once the costsharing ceiling has been reached.

- (17) The responsibility for the provision and financing of health care is regulated by the Municipal Health and Care Act, the Specialized Health Services Act and the National Insurance Act.<sup>10</sup> For example, each resident in Norway is entitled to approved prescription drugs, preventive services, primary care, in particular by GPs, specialist ambulatory and hospital care, emergency care and nursing care.
- (18) The Norwegian health system is thus founded upon the principle of solidarity, entailing that the individual patient's use of public health care services has only a negligible bearing on that patient's contribution to the system's financing, which is ensured through general tax revenue.

## 3.3 ICT use in the Norwegian health system

#### 3.3.1 Introduction

- (19) The Norwegian health care system has made use of ICT for decades, primarily for recording electronic medical records ("EMR").
- (20) However, the early introduction of ICT in a system as fragmented as in Norway has had its challenges. Initially, it made the health system comparatively efficient when IT was increasingly used for efficient storage of health-related information. Health service providers purchased or developed their own systems. At that time, it was not foreseen or foreseeable that in the future it might be possible to also exchange health related information between different health service providers digitally in an efficient manner. That led to a situation where in individual hospitals, dozens of different ICT and EMR systems were used which, when exchange of health-related information became possible, were not interoperable. Therefore, even today, it is necessary to request such information to be sent from previous places of treatment to the current treatment location, for it then to be entered again in yet another EMR.

## 3.3.2 The need for a national eHealth solution to overcome fragmentation

- (21) Attempts to overcome this digital fragmentation by means of standardisation, guidance or granting financial support for corresponding ICT-initiatives have not yielded satisfactory results. In addition, (patient) data protection legislation subjects the exchange of health-related information to stringent legal obligations. The Norwegian health sector's code of conduct for information security, described below in section 3.4.2, testifies to this development.
- (22) In 2012, the Norwegian health administration started to introduce a unified electronic record solution per citizen that could be used and accessed by all Norwegian health service providers (*one patient one record*).
- (23) The Norwegian authorities have explained that the health sector faces significant obstacles and market failures with regard to the introduction of eHealth solutions: At the level of single health service providers, there is a lack of knowledge and of necessary resources to develop or procure sophisticated eHealth solutions (barriers to entry). Single health service providers cannot reap all the benefits stemming from the development of common eHealth solutions (positive

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<sup>&</sup>lt;sup>10</sup> Lov om folketrygd, <u>LOV-1997-02-28-19</u>.



- externalities). Nationwide eHealth solutions can also, at least to some extent, be regarded as natural monopolies, in that it might be without purpose, or wasteful and counterproductive, to establish parallel structures. This is even more so in a system where the State is obliged to offer a uniform health service to all citizens.
- (24) Furthermore, health data is a valuable common good, decisive for governance and modern research, in addition to being particularly sensitive from a data protection point of view.
- (25) For those reasons, Norway's central health administration decided that it needs to step in and take stronger control of the development and roll-out of nationwide eHealth in Norway.
  - 3.3.3 The current Norwegian providers of eHealth
- (26) Currently, there are two entities active in delivering eHealth to Norway nationwide: NHN and NDE.
  - (i) NDE is a sub-ordinate institution of the Ministry, and hence part of the central Government administration. It was founded in 2016. NDE's task is to implement the national policy on eHealth, establish the requisite standards, and administrate the use of eHealth. It is also responsible for three of the notified eHealth solutions, namely the summary care record, e-prescription and the national patient portal (Helsenorge.no). NDE's responsibilities for those solutions will most likely be transferred in the near future to NHN, which today is already responsible for the operation of these eHealth solutions.
  - (ii) NHN is a public corporation, owned by the Ministry, founded in 2009 for the purpose of establishing a nationwide communication network (the Health Network or Helsenett) that would connect all actors in the Norwegian health system and enable safe and efficient sharing of health-related information. NHN is subject to control by the State, which can steer it through its ownership and through conditions attached to the financing it provides. The NHN by-laws also provide that it has a non-economic objective and shall not generate profits.
- (27) NDE and NHN implement policies and instructions from the central health administration, in particular from the Ministry. They do not have commercial freedom such that they could simply launch the development of a new product or a new service. In some instances, their activities follow directly from legal obligations embedded in law.
- (28) NHN and NDE make use of the market wherever possible and a large part of the eHealth solutions in use today has been purchased following public tenders, and their operation and further development is to a large degree provided by private suppliers. Therefore, the NHN and NDE can also be described as primarily national eHealth coordinators or buyers. According to the Norwegian authorities, it is complex to determine for each and every eHealth solution and feature to what exact degree they have been purchased on the market, since NHN and NDE have not introduced separate accounting for each feature and sub-feature. However, the following table attempts to give an estimate of the eHealth solution's current annual external expenditure as a share of their total annual expenditure:

eHealth feature	Total annual expenditure in	Share of external

	2018 (in NOK million)	expenditure
Health Network digital	103	82.5%
infrastructures		
Helsenorge.no (NDE's	215	48%
cost)		
E-prescription	118	56%
Summary care record	65	59%
(NDE's cost)		

#### 3.4 The Health Network

## 3.4.1 General

- (29) The Health Network (Helsenett) enables an efficient and secure electronic exchange of patient information via a network between all relevant parties within the health sector in compliance with relevant Norwegian and EEA legislation. Practically all health service providers (including public and private hospitals, municipalities, pharmacies, GPs and other health service providers) form part of this network.
- (30) Increasing amounts of messages containing health related information are sent via the Health Network. In 2017, approximately 218 million messages were sent, while the estimated figure for 2018 is 300 million (approx. 50–60 messages per inhabitant).
- (31) The Health Network is based on voluntary membership. NHN's role is that of a facilitator, enabling the communication between the Network's members.
  - 3.4.2 Objective ensuring effective interaction in the health care system and compliance with the rules on personal health data
- (32) The Health Network's principal purpose is to ensure that there is an appropriate and secure infrastructure for effective digital interaction between all parts of the Norwegian health care system.
- (33) Increasing amounts of work in the health sector are based on the electronic processing of patient information. Likewise, an increasingly large portion of interorganisational communication is carried out electronically. The increasing amount of electronic processing of information provides opportunities, but it also poses challenges to information security in the organisations. Electronic processing entails, amongst other things, that information can more easily and more quickly be made available both internally in an organisation and externally outside the organisation. This is an advantage, assuming the information is only made available to the right persons at the right time. However, unintended consequences may arise regarding the confidentiality of the information, and special measures must be implemented in order to prevent unauthorised access to electronically processed information. Mechanisms are required to ensure that all aspects of information security are satisfactorily handled in the relevant organisations.
- (34) Against this background, two important developments have taken place in Norway: First, the health sector has put in place a code of conduct for information security ("code of conduct"). The code of conduct has been prepared by representatives of the health sector, including the Norwegian Medical Association, representatives from the RHAs, the Norwegian Nurses' Organization, the Norwegian Pharmacy Association, and the Norwegian Association of Local and

Regional Authorities. In addition, the Data Protection Authority, the Norwegian Board of Health Supervision, the National Insurance Administration, and the Directorate for Health and Social Affairs have participated in the work. The code of conduct contains rules for the sector's actors that operationalise the legal obligations stemming from various laws and regulations, pertaining to patient information security. Of particular importance in this context are the General Data Protection Regulation ("GDPR"), and in particular Article 32 thereof (on security of processing), as well as Article 22 of the Patients' Medical Records Act and Article 21 of the Health Register Act. The code of conduct precedes the establishment of the Health Network.

- (35) Second, the Norwegian Government decided in 2008 that electronic means should be used instead of paper solutions, in order to store, process and communicate patient information. The establishment of the nationwide Health Network through NHN in 2009 is a result of those two developments.
- (36) Upon becoming a member of the Health Network, the (new) member must agree by means of an affiliation agreement to comply with the code of conduct.

## 3.4.3 The Health Network's functions

- (37) The Health Network's objective to deliver an appropriate and secure communications infrastructure for effective interaction between all parts of the Norwegian health care system entails that it must always be possible to exchange health-critical information at sufficient speed and with high data security. The Health Network must thus be able to withstand adverse events, such as power shortages, natural disasters, or significant maintenance works.
- (38) The Health Network comprises a "core net" (*stamnettet*) consisting of separate optical channels that it has leased from Broadnet following a public tender. Broadnet owns the fibres, but the Health Network has through the lease agreement obtained the right to exclusive use for some of the channels, making that part of the Health Network particularly stable and safe. The national core net connects the main Norwegian cities (Oslo, Bergen, Trondheim, Tromsø), while the regional net connects all hospitals and major health institutions. The Network's (other) members have to access the Network through "ordinary" broadband, either directly (interconnect) through their own existing internet provider, through a third-party Application Service Provider ("ASP"), or through an internet provider procured and made available by NHN. NHN has agreements with various internet providers. If a Health Network member wants to access the Network through one of those, NHN charges the price it pays to the internet provider plus an administrative fee of 3%.
- (39) In order for the Health Network's members to communicate, it is not sufficient that they have secure, reliable high-speed internet connections at their disposal. In

<sup>&</sup>lt;sup>11</sup> See <a href="https://ehelse.no/normen/documents-in-english">https://ehelse.no/normen/documents-in-english</a>.

<sup>&</sup>lt;sup>12</sup> EU Regulation 2016/679, OJ L 119, 4.5.2016 p. 23; cor. OJ L 127, 23.5.2018, p. 2, incorporated into the EEA Agreement by Joint Committee Decision No 154/2018, 6.7.2018, EEA Supplement No 46, 19.7.2018, p.1.

<sup>&</sup>lt;sup>13</sup> Lov om behandling av helseopplysninger ved ytelse av helsehjelp, <u>LOV-2014-06-20-42</u>.

<sup>&</sup>lt;sup>14</sup> Lov om helseregistre og behandling av helseopplysninger, <u>LOV-2014-06-20-43</u>.

Broadnet, now GlobalConnect, is a Northern European provider of fiber-based data communications and data centre services. It operates a 42 000 km fiber network. See <a href="https://www.globalconnect.no/om-oss">https://www.globalconnect.no/om-oss</a>.



addition, communication of health-related information requires easy to use solutions, which also provide the requisite degree of data security. There are a number of possibilities to communicate in the Health Network, and a number of additional features in the Health Network that enable and safeguard this communication.

- (40) The main feature is message exchange. In order to facilitate the application of and ensure compliance with the code of conduct, there are standardised messages for example relating to referrals, laboratory or examination results, refund requests, prescriptions, etc.
- (41) The address register (Adresseregisteret) is a prerequisite for message exchange and the functioning of the Health Network overall. It assigns a unique electronic ID to each of the services of the Health Network's members and is necessary to correctly encrypt/decrypt and deliver messages within the Health Network.
- (42) Further, NHN operates and makes available to its members the company register (Bedriftsregisteret) and citizen register (Personregisteret). Those registers are copies of registers owned and operated by the State. The availability of those registers for members of the Health Network facilitates the health service providers' interaction with citizens and companies.
- (43) In addition, the Health Network's members can exchange information via a specific, secure email-service, and NHN can provide sub-domains to its members, or link existing domains to a Health Network e-mail account.
- (44) A very important feature of the Health Network is its data security activities, implemented through HelseCERT. 16 HelseCERT is the health and care sector's national centre for information security. It is a section of the Health Network and is located in Trondheim, Norway. HelseCERT is intended to ensure future compliance with Article 9 of the NIS Directive. 17 It monitors traffic between the Network members (and the member's internet traffic if it has obtained internet access via NHN) for threats, and prevents unauthorised access. This is ensured through active monitoring of patterns of the network traffic between the members. HelseCERT's activities also go beyond guarding the Network against digital threats. As a Computer Security Emergency Response Team responsible for the health sector, it also advises the sector's members on ICT security more generally and provides vulnerability assessments, as well as ICT security training.
- (45) In addition, NHN has developed an authentication module for access to the network (and other eHealth services), HelseID. This module enables authentication and grants access to different authentication modules and systems, thus ensuring that users can use different solutions on a single log-on basis.
- (46) Another important prerequisite for the functioning of the Health Network is its test centre. Testing is vital for preventing data invalidity and breaches in communication. For example, before new types of messages can be sent by a member, they must first be tested and approved through the test centre's message validator. There are also test applications aimed at verifying for example

<sup>&</sup>lt;sup>16</sup> See https<u>://www.nhn.no/helsecert/</u>.

<sup>&</sup>lt;sup>17</sup> EU Directive 2016/1148, OJ L 194, 19.7.2016, p.1, not yet incorporated into the EEA Agreement.



the interoperability of EMRs with the Health Network. Finally, there is a test infrastructure for other software used in the health sector that reduces or eliminates the need for the Health Network's members to have their own testing environment.

(47) In addition to enabling written exchange of health-related information, members of the Health Network can also – against payment of a monthly fee – avail themselves of a video conferencing service that NHN provides. The hardware must be purchased by each member individually on the private market. The video conferencing solution has been purchased by NHN from the private provider Atea, following a tender. NHN in essence acted as a buyer of that service for the sector, resulting in the availability of an optional, but economically and data-safety wise advantageous video conferencing solution for the health sector. The operation of the service via the Health Network ensures that all video conference centres of the Network's members are linked, and interoperable, and that the health-related information exchanged is securely encrypted. Health service providers exchanging patient information in video conferences also must comply with the aforementioned data protection obligations, which the video conferencing solution enables them to do.

#### 3.4.4 The users of the Health Network

- (48) As previously noted, practically all of Norway's health service providers are members (and thereby users) of the Health Network, including in particular all hospitals, GP's and pharmacies. Around 90% of the Network's use relates to public health service providers (the public hospitals alone account for 75%).
- (49) The Health Network also counts private operators such as dentists amongst its members. While they do not, or not as regards all of their activities, form part of the solidarity-based Norwegian public healthcare system, it is nevertheless considered essential that also those providers can exchange patient information securely with other (public) health service providers.
- (50) In total, there are currently 129 members (of a total of around 6 000), which avail themselves of the video conferencing solution. The health service providers that use the video conferencing solution are predominately Public Health Trusts providing specialist health care service. These users account for approximately two thirds of all video studios. The remainder can mostly be attributed to municipalities. There are only around 20 private actors that use the video conferencing solution, most of which deliver non-economic health care services on behalf of the RHAs. In total, they have 29 video studios at their disposal. Health service providers not forming part of the solidarity-based health care system, thus account for less than 10% of the video conferencing solutions' use.
- (51) NHN does not provide ICT solutions that cover the entire range of the sectors' needs for digital solutions. Therefore, the Health Network is open to authorised third-party providers which provide services that the Health Network's members depend on in providing health care to Norway's inhabitants.
- (52) Third party providers offer services to the Health Network's members via the Health Network. The fact that they have access to the Health Network thereby ensures that the services and devices they provide are less likely to be affected by adverse events or data security threats. This, in turn, makes the digitally driven and digitally dependent health care sector less vulnerable.



- (53) Third-party providers requesting access to the Health Network must comply with the code of conduct and must undergo a data security vetting procedure by NHN.
- (54) The Norwegian authorities consider that third-party providers offer services that are complementary to those provided by NHN. Those services connect health service providers, and are essential to every member, whereas services provided by third-party providers encompass a large range of different digital services that some, but not all, health care service providers use or need. Moreover, third-party providers do not link members of the Health Network, but the data traffic between a specific provider and the providers' customer (a Health Network member) travels through the Health Network.

## 3.4.5 The Financing of the Health Network

- (55) There are two main sources of financing for the Health Network. First, there are direct transfers from the state budget. Those are generally earmarked for certain purposes. For example, HelseCERT is mainly financed by earmarked funds from the State budget.
- (56) The second main source of income are the membership fees, comprising a monthly fee and a one-time access fee. They are determined by the Health Network's board and intended to cover the Network's operating costs.
- (57) There is a separate fee for those members that use the video conferencing solution (a monthly fee of NOK 1 020 per video studio). This fee is determined, like the membership fee, with a view to covering NHN's costs (approx. NOK 13 million per year) related to the video conferencing solution.

# 3.5 The National patient portal (Helsenorge.no)

## 3.5.1 General

- (58) The national patient portal *Helsenorge.no* (Health Norway), launched in late 2011, contains information on statutory benefits and serves as a guide to the public healthcare services. Users have access to several self-service options. For example, they can access information on their user-fees, electronic prescriptions and vaccinations, and can change their GP. This Internet portal also contains information on prevention, health, wellness, illness, treatment and patients' rights, with the aims of helping people take better care of their own health and encouraging more active involvement in the health system. It also contains information on quality indicators to support patients in choosing hospitals.
- (59) Helsenorge.no forms part of the public digital communication infrastructure enabling interaction between the health sector (including the health administration) and Norway's population. While the Health Network connects health service providers, Helsenorge.no connects citizens to those health service providers and the public health administration.

## 3.5.2 Objectives and legal framework

(60) Helsenorge.no's objective is to make citizens' interaction with the Norwegian health sector simple and safe. Helsenorge.no is meant to offer the same functionalities regardless of which IT/EMR system each health service provider uses.

- (61) Helsenorge.no furthermore enables patients to exercise their rights pursuant to the Patients' and Users' Rights Act, including in particular the right to participate in their treatment and have access to their medical records. The solution also facilitates the exercise of other patient rights, such as, for example, the right to request reimbursement for patient transports.
- (62) Further, in terms of interaction with citizens, Helsenorge.no provides a solution for them to interact with community health services, GPs and hospitals. GPs can for instance receive electronic bookings for appointments. This is not only useful for citizens, but also enables the GPs to comply with their legal obligation to offer electronic booking of appointments.
- (63) Through offering citizens a number of "self-service" features, Helsenorge.no increases the quality of the health services whilst at the same time decreasing the (administrative) costs and burden of health service providers.
- (64) NDE makes Helsenorge.no's services available to every patient, health personnel and service provider complying with the terms for gaining access to the solution. There is no requirement of payment for access.
  - 3.5.3 Helsenorge.no's functions
- (65) As described above, Helsenorge.no is an information and interaction platform.
- (66) Regarding the latter, Helsenorge.no enables citizens to communicate with health service providers ("communication features"), to access their medical records and the summary care record, to obtain an overview over their prescriptions (information provided by e-prescription), to update information in their summary care record, to change GPs, to apply for reimbursements, and to access/adjust data protection settings.
- (67) The aforementioned communication features comprise the so-called Digital GP Dialogue (*Digital Dialog Fastlege*). This is a feature that lets the patients book appointments, apply for prescription renewals, consult GPs digitally and contact GPs in practical matters. Approximately 26% of all GPs are participating today. Participation is so far voluntary. The use of this feature is free for patients and GPs alike. GPs, through their EMR providers, have to enable the integration between Helsenorge.no's Digital GP Dialogue and their own EMR systems.
- (68) Finally, there are services that allow citizens to address questions, manage appointments and receive communications from hospitals and municipal care providers, thus reducing the need for consultations in person or by telephone. Such services are currently used by approximately a quarter of health service providers.
- (69) Further, the underlying IT platform for the website can also be used by public specialist health service providers for their own websites. This reduces development and maintenance costs in the specialist health care system, and also makes it easier for patients to navigate similarly looking websites in the Norwegian health care system. Helsenorge.no also provides a website where the specialist health care providers can share content that is relevant for all.<sup>18</sup>

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<sup>&</sup>lt;sup>18</sup> https://fellesinnhold.hn.nhn.no.

# 3.5.4 The users of Helsenorge.no

- (70) The principal users of Helsenorge.no are Norway's inhabitants. In addition, as it enables communication and interaction between inhabitants and health sector actors, the latter can also be regarded as users. However, private health service providers are not users of Helsenorge.no.
- (71) Helsenorge.no provides information to patients and citizens, giving access to public, general information about health, as well as information regarding their personal health (subscriptions, summary care records, etc.). This aspect is described above as Helsenorge.no being an "information" platform.
- (72) Furthermore, Helsenorge.no has a listing of available health service providers, which includes both public and private providers. The private providers listed deliver public health services on behalf of and based on contracts with public health service providers. The listing includes for example rehabilitation, mental health and drugs/alcohol treatment providers.
- (73) Helsenorge.no's communications features the Digital GP dialogue solution and the possibility to interact with health service providers are available to citizens intending to communicate with public health service providers. All communications features, as well as some information features, are log-on services, requiring authentication of the user. These log-on services, where patients can book appointments, have a conversation with their healthcare provider or view journal documents, test results, etc., are only available to: (i) the GPs, (ii) public secondary healthcare providers, and (iii) primary healthcare providers.

## 3.5.5 The financing of Helsenorge.no

- (74) The development and operating costs of Helsenorge.no were initially financed by the Government through the State budget. Since 2014, Helsenorge.no has been financed by municipalities, RHAs and the State. Financing is agreed when one of the cooperating organisations establishes a new service, and in annual agreements between NDE and the health care organisations.
- (75) While there is no mandatory user payment, the aforementioned public health sector organisations have decided to contribute to the development and operating costs of Helsenorge.no. The Norwegian authorities are considering whether they should make the RHAs' and municipalities' financial contributions to the management and operations of Helsenorge.no mandatory. There are no plans to introduce payments for the public.

## 3.6 Electronic prescription (e-resept)

## 3.6.1 General

- (76) Electronic prescription ("e-prescription" or e-resept in Norwegian) is a system that ensures that any prescription can be sent to a central prescription database. Then the patient can pick up the prescribed medicine at any pharmacy of her/his choice throughout Norway.
- (77) The correct prescription, use and handling of medicines is an essential part of the health system. Incorrect use of medicines is among the two most frequent causes of damage to patients' health. Therefore, the Norwegian authorities consider a

<sup>&</sup>lt;sup>19</sup> https://helsenorge.no/velg-behandlingssted/private-behandlingssteder.



- complete, correct overview of medicines prescribed to a patient to be of decisive importance for both patients and health service providers.
- (78) The prescription database is accessible to patients via Helsenorge.no, and its contents are transmitted to the Summary Care Record. The database is accessible through the Health Network, and prescribers must be members of the Health Network. E-prescription is completely financed by the State.

## 3.6.2 Legal framework

- (79) E-prescription has been established on the basis of Section 12 of the Patients' Medical Records Act and is further regulated in the Prescription Agent Regulation.<sup>20</sup>
- (80) Pursuant to the Patients' Medical Records Act there is a statutory monopoly for e-prescription. The handling of e-prescriptions requires a central register of patient care data, which, according to Section 6 of the Patients' Medical Records Act, must be explicitly regulated by law and secondary law. The e-prescription patient care data register is regulated in Section 12 of the Patients' Medical Records Act and in the Prescription Agent Regulation.
- (81) NDE is obliged to make the service available to all health personnel and service providers complying with the Regulation's provisions on conditions for gaining access to the solution. There is no requirement of payment for access.
- (82) The use of the system is obligatory unless the prescriber does not have access to an IT-system that allows for the use of e-prescription. Over 90% of prescriptions are prescribed electronically today. All pharmacies in Norway use the solution.

#### 3.6.3 E-prescription functions

- (83) E-prescription is an electronic communications chain communicated via the Health Network for secure transmission of prescription information. It also facilitates reimbursement between pharmacies and the Norwegian Health Economics Administration (Helseøkonomiforvaltningen or "Helfo").
- (84) The communications chain includes prescribers (e.g. GPs or hospitals) and pharmacies, in addition to the Norwegian Medicines Agency and Helfo. The prescription agent (*reseptformidleren*) is the central and state-owned solution, connecting all the remaining actors and enabling the practical use of electronic prescriptions in the Norwegian health system.
- (85) In practical terms, a prescriber must send an e-prescription to the prescription agent, in general through his own EMR system. Once the prescription is sent, all pharmacies have access to it via the prescription agent, and can dispense the prescribed medicine to the patient that merely has to show his ID.
- (86) In order for prescribers to use e-prescription, a digital link must be established from the user's own EMR system. There are many different EMR solutions to be found today across the health sector in Norway. In order to facilitate the integration of these two systems, a prescription module is provided to EMR providers free of charge, enabling them to integrate prescription functionality in

<sup>&</sup>lt;sup>20</sup> Forskrift om behandling av helseopplysninger i nasjonal database for elektroniske resepter, FOR-2007-21-21-1610.



their EMR solutions at lesser cost, while also reducing integration efforts and costs on NDE's side.

(87) NDE is responsible for the prescription agent today. That responsibility includes ownership, overarching steer and further development. The prescription agent was bought on the market following a public tender, and the winning bidder operates the solution today, with NHN overseeing the operation by the private operator (Evry) on behalf of NDE. The prescription module and the maintenance and further development of the module have also been purchased on the market, following public tenders.

## 3.7 Electronic Patient Summary Care Record

#### 3.7.1 General

- (88) The summary care record ("SCR") is the first national system for direct sharing of patient information among the various levels and institutions of health care throughout Norway. As of 2017, all Norwegian citizens, who have not actively opted out, have a personalised SCR. The SCR is financed through the state budget.
- (89) The SCR contains selected and important information about each citizen's health and gives health care professionals immediate access to this information, regardless of the (previous) place(s) of treatment.
- (90) The information stored in the SCR is largely obtained automatically from registers such as e-prescriptions. In addition, the doctor, in consultation with the patient, can record critical information, such as on allergies, manually. Citizens can also enter information in SCR, via the portal Helsenorge.no.

#### 3.7.2 Objectives and legal framework

- (91) The SCR has been established on the basis of Section 13 of the Patients' Medical Records Act and is further regulated in the SCR Regulation.<sup>21</sup>
- (92) There is a statutory monopoly for the SCR. The handling of these records requires a central register of patient care data, which according to Section 6 of the Patients' Medical Records Act must be explicitly regulated by law and secondary law. The SCR is regulated in Section 13 of the Patients' Medical Records Act and in the SCR Regulation. The legal framework does not provide for other electronic patient summary care records. Thus, there is only one such service available.
- (93) The main purpose of the SCR is to increase patient safety by contributing to rapid and secure access to structured information about the patient. NDE is also obliged to make the service available to every health personnel and service provider complying with the Regulation's provisions on conditions for gaining access to the solution. There is no requirement of payment for access.

## 3.7.3 SCR's functions

(94) The SCR comprises the following types of information:

 Personal data such as name, contact data, family relationship, GP, sickness record and donor card. The sources of this information are the population register, the GP register and the patient's own entries in the SCR;

<sup>&</sup>lt;sup>21</sup> Forskrift om nasjonal kjernejournal, FOR-2013-05-31-563.



- ii. Prescriptions. SCR obtains this information directly from e-prescriptions.
- iii. Serious allergies and specific critical information that health care professionals need to know. This information is provided by the treating physicians.
- iv. Treatment history, showing when and where patients have been treated. This information is uploaded from the Norwegian Patient Register.
- (95) Citizens can enter and amend the information saved on their SCR via Helsenorge.no, and control third party access.
- (96) Health care professionals enter data through their own EMR systems. The SCR includes a web-based module through which health care professionals can enter this data, but the module must be integrated into the various EMR systems. It is for the EMR providers to enable this integration.
- (97) In addition to enabling the amendment of information, the SCR also provides an application programming interface (API) that enables the SCR to export data to EMR systems. Again, this requires that the EMR provider develop an integration solution.
- (98) NDE is today responsible for the SCR. That responsibility includes ownership, oversight, user support and further development. The solution was bought on the market following a public tender. NHN is responsible for SCR's operation and a private operator operates a "read-only" copy as a back-up.
- (99) Aside from patients who can access their SCR, health care professionals working as GPs, in emergency care centres or in hospitals have access to the SCR. In the future, the Norwegian authorities will likely expand the SCR user base to municipal care services.

# 3.8 The provision of various support services and operation of registers

## 3.8.1 General

- (100)NHN has been given the task to operate certain digital solutions and registers as well as providing ICT, procurement or archiving support to Government agencies and RHAs (support services). The recipients of these services are exclusively state or state owned entities charged with health administration (such as for example Government agencies for healthcare reporting to the ministry). According to the Norwegian authorities, the services to which NHN provides an input are not in competition with services provided by the market.
- (101)NHN's costs stemming from the performance of those activities are covered by the State from the state budget, including by various state agencies (such as Government agencies for healthcare that report to the Ministry) or the RHAs.

# 3.8.2 NHN's operation of different health registers

(102)NHN operates three different types of registers (administrative health registers, quality registers and national health registers) for Government agencies and RHAs. The responsibility for those registers rests with different public bodies. The State has decided to pool the operation of those registries in NHN, in order to avoid costly duplications or multiplications of identical or at least largely similar operational expenditure and expertise across various public bodies charged with health administration.



(103) The technical operation of the registers entails the provision of server services, back-ups, security, application operation and customer support. The centralising of the operation of the registers at one provider allows for harmonisation of the routines and technical tasks mentioned.

# 3.8.3 Administrative health registers

- (104) This first category of health registers, which NHN operates in particular for the Norwegian Health Directorate, NDE and RHAs, can be described as administrative health registers. In contrast to the other health registers that NHN operates, these registers serve health administrative purposes:
  - i. The Register of entities in specialist healthcare charts the entities in specialist healthcare and the health services they offer. This register is of particular importance for the (other) health registers, in that it enables assigning data reported to the health registers by the various specialist health service providers to a specific entity.
  - ii. The Health Personnel Register contains all authorized health personnel. Access to this register is necessary to issue certificates for sick leave and prescriptions.
  - iii. The Doctor's Staffing Register lists doctors in employment and posts in both primary and special health care. Its main purpose is to monitor, analyse and predict developments in the employment market for doctors.
  - iv. The General Practitioner's Register shows which patients are assigned to which GPs (each Norwegian patient has an assigned GP). This register can be accessed also through Helsenorge.no, and patients can use it to switch GPs.
  - v. Medusa is a national database of all medical equipment owned by the specialist health sector. The database encompasses information about the equipment's nature, its location, age, status, etc. Medusa is owned and paid for by the four RHAs.
  - vi. Two ICT solutions for patient transport, 22 owned indirectly by the RHAs, that allow the organization and refunding of costs regarding patient transport.

# 3.8.4 Quality registers

- (105) Secondly, there is an obligation for the RHAs to operate quality registers, which are given a national status from the Directorate of Health, according to a set of defined criteria. Clinical quality registers and national quality registries record the results of patients' treatment for specific diseases or treatments given in the healthcare services.
- (106) The main objective of the quality registers is to increase the quality of diagnosis and treatment for patients, while reducing disparities in treatment or diagnosis across Norway. The content of the registers is an important factual basis for medical research and for the improvement of the quality and safety of the treatment of patients. For instance, the data allows for the comparison of different

<sup>&</sup>lt;sup>22</sup> See https://pasientreiser.no/om-pasientreiser/pasientreiser-hf.



treatment methods, and thus complements clinical research as to the efficacy of individual treatment methods. Based on the data from the quality registers, quality indicators are developed. The data also enables the public health administration to verify if national treatment guidelines have been followed in the treatment of patients. NHN is responsible for the technical operation of the national quality registers. The responsibility for the input of data, and for ensuring the data's quality as well as information security, remains with the RHAs.

## 3.8.5 National health registers

- (107) Finally, the Norwegian Institute for Public Health (NIPH) and the Directorate of Health are responsible for maintaining so-called national health registers, based on the Health Register Act. Those registers record statistical data related to specific issues, such as cause of death or vaccinations.
- (108) The objective of the health registers is to enable statistics and research to promote health and prevent disease, and to support the provision of better health services in Norway. NHN is responsible for the operation of the following health registers:
  - i. Birth register.
  - ii. Abortion register.
  - iii. National heart and cardiac illnesses register.
  - iv. Cause of death register.
  - v. Prescription based pharmaceuticals register.
  - vi. National vaccination register.
  - vii. Notification system for contagious diseases.
  - viii. Surveillance system for use of antibiotics and health service related infections.
  - ix. Surveillance system for antibiotics resistance in microbes.
  - x. Surveillance system for virus resistance.
  - xi. Norwegian patient register.
  - xii. Municipal patient and user register.
- (109) The Norwegian authorities note that the entrustment of NHN with the operation of the registers has freed the NIPH and the Directorate of Health of the costs operating these registers themselves and led to greater efficiency.
  - 3.8.6 Support services related to procurement, ICT and archiving
- (110)With effect from 1 January 2017, a number of Government agencies entrusted NHN with the provision of support services in the areas of procurement, ICT and archiving. In doing so, the concerned bodies also transferred their employees that were previously charged with these tasks in those bodies to NHN. The objective was for the Government agencies to benefit from economies of scale and NHN's know-how.
- (111)Regarding public procurement, NHN provides advice and quality assurance, handles procurements, manages a record of agreements, makes available data for target management and reporting, and facilitates coordination with other public procurement bodies. The purpose of pooling those services in NHN is in particular



- to enable efficient and coordinated procurement processes, robust good agreements and procurement deals.
- (112)Regarding ICT, NHN manages and develops common operational architecture, solutions, strategy, processes and procedures for the central health administration's administrative processes. This includes development of infrastructure, necessary technical expertise, product selection and follow-up of service content. It also includes support, supplier follow-up and procurement of ICT.
- (113)Regarding archives and document management, NHN is charged with handling, archiving, digitalisation and storage of documents that must be archived pursuant to legal archiving obligations in a cost-efficient way.
- (114)NHN cannot and does not offer these services on the market, in competition with private companies that may be active in similar fields. The services are only offered internally within the Norwegian health care system.

# 4 Comments by the Norwegian authorities

- (115)In the Norwegian authorities' view, the notified financing is not state aid, within the meaning of Article 61(1) of the EEA Agreement, in particular because the publicly financed activities do not constitute 'economic activities'.
- (116)According to the Norwegian authorities, it is appropriate to assess all the eHealth solutions and services described in Sections 3.4 to 3.8 above as one interconnected service, namely national eHealth. The national eHealth activities of NHN and NDE fall into two categories:
  - i. First, there are eHealth solutions that these public bodies provide themselves in their entirety (including by relying on private suppliers). These are eHealth solution(s) in a narrower sense, in that they all aim at enabling communication, interaction and exchange of health-related information within the health sector, and between health service providers and citizens.
  - ii. Second, with regard to health registers and support services, NHN merely provides inputs, consisting of the operation of the registers on behalf of the responsible Government agencies and RHAs and the provision of support services. As regards the input that NHN provides, the Norwegian authorities consider that the sole issue that the Authority would need to address is the Norwegian authorities' understanding that those activities are non-economic, because they are performed in genuine self-supply within the public sector, or alternatively so closely connected to the exercise of a non-economic activity that they themselves must be considered non-economic.
- (117) The Norwegian authorities note that there are no genuine market alternatives to the notified publicly provided eHealth solutions. According to the Norwegian authorities, the State provides eHealth solutions itself, because market forces cannot provide satisfactory outcomes. The national eHealth solutions resemble natural monopolies. Given that the national eHealth solutions enable the entire health sector to exchange health-related information in an efficient, secure manner in line with data protection obligations, it is no longer meaningful, let alone profitable to establish a rival system. For this reason, the Norwegian authorities have not identified (genuine) market alternatives to any of the eHealth solutions



they provide, and therefore do not consider that they are provided in competition with others.

- (118)The Norwegian authorities have identified a small number of instances where commercial providers offer services that at first sight appear to be competing in part because they carry some similar features. However, these similarities always relate to a sub-feature of the national eHealth solutions. For instance, the public eHealth solution *Helsenorge.no* enables the booking of appointments with GPs, whereas commercial providers offer standardised SMS services to book appointments. On a general level, it can nevertheless be stated that no actual substitutes for the services have been found. Where a limited degree of competitive friction may exist, it is mainly due to the fact that the public eHealth service has been deployed in an area where previously there was no public offer, and there may have been some unsatisfactory attempts by the market to fill an existing or perceived vacuum.
- (119) Furthermore, the Norwegian authorities consider that the eHealth solutions described above do not confer an advantage upon private users or private thirdparty providers in the Health Network. In any case, any potential advantage would not be selective, as the solutions are available to all undertakings that are in a comparable factual or legal situation. The same considerations are applicable as regards third-party providers offering their services to members of the Health Network via the Health Network.
- (120)With regard to the support services, described in Section 3.8 above, the Norwegian authorities note that it seems clear that the Government agencies and the RHAs to which NHN provides input and support services are not undertakings within the meaning of Article 61(1) of the EEA Agreement. Nor is the establishment or operation of public health registers an economic activity. The support services NHN performs are solely provided to support non-economic public tasks of the Norwegian state and its public health administration, and are also to be qualified as non-economic.

## 5 Presence of state aid

#### 5.1 Introduction

(121)Article 61(1) of the EEA Agreement reads as follows:

- "[...] any aid granted by EC Member States, EFTA States 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 shall, in so far as it affects trade between Contracting Parties, be incompatible with the functioning of this Agreement."
- (122) The qualification of a measure as aid within the meaning of this provision therefore requires the following cumulative conditions to be met: (i) the measure must be granted by the state or through State resources; (ii) it must confer an advantage on an undertaking; (iii) favour certain undertakings (selectivity); and (iv) be liable to distort competition and affect trade.

# 5.2 Do NHN and NDE carry out economic activities?

- (123)In the present case, the Norwegian authorities argue that NHN and NDE are not undertakings within the meaning of Article 61(1) of the EEA Agreement, as the eHealth and support services they provide, do not constitute economic activities.
- (124)In accordance with Article 61(1) of the EEA Agreement, the state aid rules apply to 'undertakings'. Undertakings are entities engaged in economic activities, regardless of their legal status, the way in which they are financed or whether they make a profit or not.<sup>23</sup> Any activity consisting in offering goods and/or services on a given market is an economic activity.<sup>24</sup> The classification of an entity as an undertaking therefore depends on the nature of the activities it carries out. An entity that carries out both economic and non-economic activities is thus to be regarded as an undertaking only with regard to the former.<sup>25</sup>
- (125)In the following the Authority will assess whether NHN when operating the Health Network, various registers and providing support services, as well as the NDE when operating Helsenorge.no, e-prescription and the summary care record system, carry out economic activities.
- (126)Article 61(1) of the EEA Agreement does not apply when public entities exercise public powers or where public entities act in their capacity as public authorities. An entity may be deemed to exercise public powers where the activity in question forms part of the essential functions of the State or is connected with those functions by its nature, its aim and the rules to which it is subject. Where states fulfil legal obligations and facilitate the fulfilment of such obligations, the activities to comply with those obligations are an exercise of public powers, or so closely connected to them, that they are not considered to be economic.
- (127)In so far as a public entity exercises an economic activity which can be separated from the exercise of public powers, that entity acts as an undertaking in relation to this activity. In contrast, if the economic activity cannot be separated from the exercise of public powers, the activities exercised by that entity as a whole remain connected to the exercise of those public powers and therefore fall outside the notion of undertaking.<sup>29</sup>
- (128)When the nature of an activity carried out by a public entity is assessed with regard to the state aid rules, it cannot matter whether the activity might, in principle, be pursued by a private operator. Such an interpretation would in practice bring any activity of the State not consisting in an exercise of public authority under the notion of economic activity.<sup>30</sup>

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<sup>&</sup>lt;sup>23</sup> Judgment in *Pavlov and Others*, C-180/98, EU:C:2000:428, paragraph 74. Judgment in *MOTOE*, C-49/07, EU:C:2008:376, paragraphs 27 and 28.

<sup>&</sup>lt;sup>24</sup> Judgment in Commission v Italy, 118/85, EU:C:1987:283, paragraph 7.

<sup>&</sup>lt;sup>25</sup> The Authority's Guidelines on the notion of state aid ("NoA"), OJ L 342, 21.12.2017, p. 35 and EEA Supplement No 82, 21.12.2017, p. 1, paragraph 10.

<sup>&</sup>lt;sup>26</sup> Judgment in *Commission* v *Italy*, C-118/85, EU:C:1987:283, paragraphs 7 and 8, and judgment in *Bodson*, C-30/87, EU:C:1988:225, paragraph 18.

<sup>&</sup>lt;sup>27</sup> Judgment in SAT/Eurocontrol, C-364/92, EU:C:1994:7, paragraph 30, and judgment in Calì & Figli, C-343/95, EU:C:1997:160, paragraphs 22 and 23.

<sup>&</sup>lt;sup>28</sup> Judgment in *TenderNed*, T-138/15, EU:T:1987:283, paragraphs 59 and 60.

<sup>&</sup>lt;sup>29</sup> NoA, paragraph 18.

<sup>&</sup>lt;sup>30</sup> Judgment in Case E-5/07 *Private Barnehagers Landsforbund* v *ESA* [2008] EFTA Ct. Rep. 62, paragraph 80.

- (129)As described in Section 3.2.3 above, the Norwegian public health care system itself is founded upon the principle of solidarity and public financing accounts for more than 85% of total health care expenditure. The majority of health care services are provided to patients for free, on the basis of universal coverage, or subject to a very limited degree of cost-sharing (subject to cost-sharing ceilings). The EU Courts have confirmed that, where such a structure exists, the relevant organisations do not act as undertakings.<sup>31</sup>
- (130)The Health Network, Helsenorge.no, e-prescription and the SCR form part of a national eHealth solution that is provided nationwide by public entities (NHN and NDE) to enable exchange of and interaction pertaining to health-related information within the solidarity-based Norwegian health care system. In fact, the Norwegian authorities have confirmed that the eHealth solutions are necessary to fulfil public duties towards the population.
- (131)The aforementioned eHealth solutions all help ensure compliance with relevant Norwegian and EEA legislation. In particular:
  - i. The Health Network enables an efficient and secure electronic exchange of patient information, through various technical solutions, in compliance with the code of conduct for information security, which sets out rules relating to patient information security that derive from the GDPR, the Patients' Medical Records Act and the Health Register Act.
  - ii. Helsenorge.no ensures that citizens' interaction with the Norwegian health sector is simple and safe and enables patients to exercise their rights pursuant to the Patients' and Users' Rights Act.
  - iii. E-prescription was established on the basis of Section 12 of the Patient Medical Record Act and is further regulated in the Prescription Agent Regulation. There is a statutory monopoly for e-prescription in Norway as the handling of e-prescriptions requires a central register of patient care data, which, according to Section 6 of the Patients' Medical Records Act, must be explicitly regulated by law and secondary law. Pursuant to the Prescription Agent Regulation, the use of e-prescription is also quasi-obligatory for prescribers.
  - iv. The SCR was established on the basis of Section 13 of the Patients' Medical Records Act and is further regulated in the SCR Regulation. There is a statutory monopoly for the SCR as the handling of these records requires a central register of patient care data, which, according to Section 6 of the Patients' Medical Records Act, must be explicitly regulated by law and secondary law.
- (132)It follows from the above that Norway has established these eHealth solutions to both fulfil certain legal obligations and facilitate the fulfilment of such obligations. The activities to comply with such legal obligations are an exercise of public powers and as a consequence do not constitute economic activities. When it comes to designing tools to ensure compliance with such legal obligations, EEA States must have some margin of discretion and can even go somewhat beyond

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<sup>&</sup>lt;sup>31</sup> Judgment in *FENIN*, T-319/99, EU:T:2003:50, paragraphs 38 and 39; and Judgment in *FENIN*, C-205/03 P, EU:C:2006:453, paragraphs 25 to 28.

what is strictly required by the legal provision if that is considered necessary to fulfil the state's public duties. It is therefore not necessary to assess whether the State is obligated by law to provide each particular feature of the eHealth solutions and how those features correspond to specific legal obligations. What is important is the general objectives pursued through providing these eHealth solutions, 32 i.e. ensuring and facilitating the fulfilment of legal obligations.

- (133)To the extent that competition exists, it appears to be more of a complimentary nature, or a remnant from a time predating the roll-out of the respective eHealth solution. Furthermore, the Norwegian authorities have confirmed that Norway does not intend to promote competition with its backbone eHealth solutions. Norway has not created a market for parallel backbone national eHealth solutions, but is taking and maintaining control of these solutions. There is, however, competition for the sub-contracts necessary for building this national infrastructure and, as previously noted, many of the technical solution or services relating to eHealth have been purchased from private providers following a public open tender procedure.
- (134)As concerns the operations of the various registers, described in Section 3.8. above, it follows from case law that the collection of data to be used for public purposes on the basis of a statutory obligation imposed on the undertakings concerned to disclose such data fall within the exercise of public powers and as a result such activity does not constitute economic activity.<sup>33</sup> The administrative health registers and the national health registers all contain sensitive personal and patient related data, the collection of which is used for public purposes and is regulated by law, for example by the Act on Health Registers and Treatment of Health Data. Consequently, the Authority considers that the operations of those registers do not constitute an economic activity.
- (135)Finally, with regard to the support services described in Section 3.8.3 above, it follows from case law that even activities that by themselves could be considered to be of economic nature, but are carried out merely for the purposes of providing another non-economic service, are not of an economic nature. The Authority has also previously found that genuine self-supply within the public sector does not constitute an economic activity. The public procurement, ICT and archive/document management services that have been entrusted to NHN are exclusively provided to state or state owned entities charged with health administration. These support services cannot be offered on the market in competition with private companies and are only provided to enable and support the provision of public health administration tasks. The services were simply consolidated within NHN as a result of an efficiency-oriented reorganisation of tasks within the public health administration. Therefore, the Authority concludes that these support services constitute a genuine self-supply within the public sector and that, as a consequence, they are of a non-economic nature. This

<sup>32</sup> Judgment in *TenderNed*, T-138/15, EU:T:1987:283, paragraph 96 (appeal pending before the Court of Justice, *Aanbestedingskalender and Others* v *Commission*, C-687/17 P).

40. <sup>34</sup> Judgment in *FENIN*, T-319/99, EU:T:2003:50, paragraph 40 as confirmed by judgment in *FENIN*, C-205/03, EU:C:2006:453, paragraphs 26 and 27.

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Judgment in *SELEX Sistemi Integrati* v *Commission*, Case C-113/07 P, EU:C:2009:191, paragraph 72, and judgment in *Compass-Datenbank GmbH*, C-138/11, EU:C:2012:449, paragraph 40.

<sup>&</sup>lt;sup>35</sup> <u>Decision No 144/13/COL</u> on alleged aid to services provided by Bergen Kirkelige Fellesråd and Akasia (OJ C 220, 8.8.2013, p. 16 and EEA Supplement No 44, 8.8.2013, p. 4), paragraph 31.



- conclusion is not affected by whether, in theory, the aforementioned services could be provided by or purchased from private operators on the market.
- (136)In view of the above, the Authority considers that NHN and NDE, insofar as they provide the eHealth solutions in accordance with the current organisation of the solidarity-based Norwegian health sector, and provide various support services and operate registers on behalf of the State (as described in sections 3.4 to 3.8 above), are not carrying out economic activities.

#### 5.3 Conclusion

(137)The Authority concludes that NHN and NDE, when providing the aforementioned eHealth solutions, support services and operating registers, do not carry out economic activities and are thus not considered 'undertakings' within the meaning of Article 61(1) of the EEA Agreement.

#### 6 Conclusion

(138)On the basis of the foregoing assessment, the Authority considers that the measures do not constitute state aid within the meaning of Article 61(1) of the EEA Agreement.



For the EFTA Surveillance Authority, acting under <u>Delegation Decision No 068/17/COL</u>,

Yours faithfully,

Bente Angell-Hansen President Responsible College Member

> Carsten Zatschler Countersigning as Director, Legal and Executive Affairs

This document has been electronically authenticated by Bente Angell-Hansen, Carsten Zatschler.