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Short Report

Assessment Greek Health Public System

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THE PROJECT

The Covid-19 pandemic is undoubtedly an obvious threat to public health that requires a huge commitment by the Italian, Greek and international scientific community aimed at a deeper knowledge of both the molecular mechanisms that cause the pathological condition and the evolutionary characteristics of the virus genome pathogen SARS-CoV-2.

The COVID-19 outbreak has affected Member States in a sudden and dramatic manner and will have implications, specifically on the Greece Italy Programme territory. In Puglia, at the end of July 2020, there were over than 4,500 cases of COVID-19 (1,14‰ of the total population). According to the official data, 551 people have died for COVID-19 causes in Puglia. The profile of the sick people has an average age of 56 years out of which 51,2% are of male gender. In Greece, in the same period, there are 4,401 cases 20 died people for COVID-19 causes.

With these data, it is clear the involvement of all the eligible area. Until today we are living a great impact of the COVID-19 and it is necessary to have a common approach in order to try to solve or to mitigate the problem.

The COOFHEA project, indeed, will operate with three approaches:
A. supporting Puglia Region and the Hospitals in the Greek eligible area to purchase the personal protective equipment and/or medical equipment (ventilators, beds, monitors, etc.).
B supporting scientific research that will use a set of methods based on different types of approaches, to identify possible molecular mechanisms that can be exploited for the development of innovative and more efficient therapies.
C. sharing with the Greek hospitals the Puglia platform of telemedicine/clinical remote assistance. This is an innovative system with lets the monitoring of patients forced to quarantine for Covid-19 in their home, to avoid the hospitals costs, thanks to the "H-Casa" clinical remote assistance platform and to give a possibility of "normal life" to the population affected but not in a very serious way.

With this differentiated approach it will be possible to give organic answers to a complex problem like COVID-19.

INTRODUCTION

The present work is the result of a study of the existing and publicly available bibliography and of the information made available by the national competent authorities. Therefore, it probably has some gaps in the information provided.
Health care systems in the European Union (EU) are managed in very different ways.
The central theme of this report is to analyse and evaluate the peculiarities of the Greek Health Care System and to highlight the main connections with the Italian Health Care System, to transfer, both from an organisational and a technological point of view, the health information technology solutions adopted in the Italian Health Care System and specifically by the Apulia Region in the framework of the Covid-19 emergency management.

Chapter 1 - provides an overview of the two healthcare management systems, Italian and Greek (with the focus on the Greek system), outlining their structure, the way in which healthcare services are delivered, the financing mechanisms and the main types of expenditure. Although the aim of the study is to assess the transferability and applicability of information systems managed at the regional level in Apulia, the definition of the upstream institutional context (national level) together with a brief description of the downstream catchment area (beneficiaries of services and types of services) are necessary steps to understand the framework in which local and regional authorities operate.

Chapter 2 - uses the same model comparison methodology as in the previous chapter to analyse, assess and compare the respective privacy and data management models to highlight differences, criticalities, and opportunities.

1.

ORGANIZATIONAL FRAMEWORK **OF THE HEALTH SYSTEM**

The focus of this review will be on the Greek health system. This brief analysis intends to highlight the preminent aspects of its organisation and governance, and of the way in which it finances and provides healthcare services. The aim is to evaluate these aspects in comparison with the Italian system and in view of the transfer of the technological solution adopted in Italy, and in the Apulia Region, for the management of the Covid-19 emergency.

The present analysis, therefore, does not intend to be exhaustive of the specificities of the two systems at all. The main objective is to identify and outline the key elements and the consequent application modalities to allow the technological transfer of the solution. Many aspects, not considered essential for this purpose, will therefore be left out or briefly treated, favouring the analysis of all those factors that directly impact on the applicability of the technological solution.

1.1 Italian framework

The Italian National Health Service (SSN) is a decentralised system organised on a regional basis. The central government allocates part of the general tax revenues to health care, defines the health care package, and exercises a stewardship role. Each region is then responsible for the organisation and delivery of health services through local health agencies and accredited public and private hospitals.

1.1.1 Governance

The Italian SSN is therefore divided into three levels: national, regional, and local. At the national level, the Ministry of Health is responsible for guaranteeing all citizens the right to health, as enshrined in Article 32 of the Constitution. The Ministry of Health guarantees the equity, quality, and efficiency of the National Health Service and, in addition to this role, promotes actions for improvement, innovation and change. The central government is responsible for establishing the so-called essential levels of health care (*Livelli Essenziali di Assistenza* sanitaria - LEA), i.e., the services that the health system is obliged to provide to all citizens free of charge or upon payment of a contribution also called ''ticket"[1]. It also allocates resources to the regions for health care, as set out in the specific Health Agreements, concluded between the government, the regions and the two autonomous provinces of Trento and Bolzano.
The 20 regions and the two autonomous provinces of Trento and Bolzano are responsible for the governance and organisation of all activities aimed at ensuring the delivery of health care and the health service. The regional level has legislative, administrative, planning, financing and monitoring functions. Executive functions are set out in the regional health plans, which run for three years. The regions also have responsibilities for allocating resources to local health units (Aziende Sanitarie Locali - ASL), and public hospital units (Aziende Ospedaliere - AO), determining

[1] More than 5700 types of assistance and services for prevention, treatment and rehabilitation are defined.

accreditation criteria for public and private health care facilities, appointing general managers of ASLs and public hospitals, setting the regulatory framework for the operation of ASLs and public hospitals, and establishing technical and management guidelines for service delivery. As regions are free to develop their own health policy, their level of involvement in the direct management of health services varies considerably.

Health care is mainly financed by taxes levied at regional and national level. Direct taxes include IRAP, a regional tax on companies, levied at the national level but mostly (90 %) returned to the regions where it is applied, levied on the capital gains of companies and on civil servants' salaries, and an 'IRPEF surcharge', a regional tax levied on top of the national personal income tax.

Indirect taxation includes a percentage of VAT and excise duties on petrol. In addition, ASLs also receive revenue from the purchase of services and over-the-counter medicines and the co-payment paid by patients on medicines, diagnostic procedures, and specialist visits.

Public funding accounts for 70 % of total health expenditure and private insurance companies (non-public funding), direct payments and co-payments cover the remainder. Voluntary health insurance does not play a significant role in terms of financing[2].

1.1.2 Provision of services

The provision of services at territorial level is organised through a network of local health agencies. The ASLs are public bodies with entrepreneurial autonomy as regards to their organisation, administration, accounting, and management. Services are provided through public or accredited private facilities. Public facilities include hospitals directly managed by ASLs, the so-called "presidi ospedalieri", and public hospital enterprises (AO), which are independent facilities, generally with a regional or interregional catchment area, independently managed and with purchasing power, including research hospitals.

General practitioners act as a filter within the NHS. Primary care is provided by general practitioners, pediatricians, and freelance and independent doctors, who receive remuneration based on the number of patients (adults or children) who have chosen them.

Specialist care is provided through the ASLs or through public and private accredited facilities, with which the ASLs have agreements and contracts. Access to specialist care requires a general practitioner's prescription or, for some services such as dental care, direct access through a centralised booking system. Hospital care is provided through public facilities that provide outpatient and residential services, or through private hospitals that have an agreement with the ASL.

Pharmaceutical care is regulated by the Italian Medicines Agency (AIFA), which is responsible for the authorisation, monitoring, pricing, and reimbursement of pharmaceutical products.

[2] https://www.salute.gov.it/portale/home.html

Medicines can be dispensed directly by ASLs or by pharmacies throughout the territory. Pharmacies can be public or private, and revenues are collected by the pharmacy owner.

The Italian SSN therefore guarantees assistance to all citizens and foreigners legally resident in Italy. Coverage is automatic and universal, and assistance is generally free for hospital and medical services. The basic health care package covers a wide range of services and must be guaranteed uniformly throughout the country. At the national level, a compliance monitoring system is in place to identify regions that are not guaranteeing the basic healthcare package to the population. Regions are also allowed to offer services not included in the basic package, but these must be financed by funds from regional taxes. Compared to the EU average, Italy's share of public funding for health services is higher for hospital care and the purchase of medicines[3].

1.2 Hellenic framework

The Greek health system, historically characterised by a highly centralised organisational structure and a mixed financing system of taxation and social health insurance, has suffered over time from lasting operational and structural weaknesses, whose reform attempts have often failed or stopped at the implementation stages.

This has been compounded in the recent past by an economic and financial crisis that has had a major impact on Greek society and, consequently, on its health system. In 2010, more than a quarter of gross domestic product (GDP) was lost. The resulting sovereign debt crisis led to a bailout by international lending institutions and the adoption of three successive economic adjustment programmes (EAPs), the last of which ended in August 2018. Considering these circumstances, the country implemented large-scale austerity measures, which involved substantial reductions in public spending, including within the health sector.

However, the country's economic adjustment programme, following the crisis, also provided an opportunity to address many wide-ranging reforms that also affected the health sector, and that aimed not only to reduce public sector spending, but also to correct inequalities and inefficiencies in the system including the strengthening and expansion of public primary care services. Since 2010, these reforms have included the establishment of a single purchaser for the National Health System, unifying the benefits package, restoring universal coverage and access to health care, significant reductions in pharmaceutical spending, and major changes to the system of hospital services and reimbursements. There has also been an increased focus on prevention and combating factor risks through a new national public health plan. On the other hand, most of these reforms, which were implemented in the wake of and as a function of the economic crisis, have focused primarily and necessarily on reducing costs, leaving aside, inevitably, strategic reforms to improve the efficiency and overall quality of care. Challenges remain in ensuring

[3] [ibidem]

accessibility, especially affordability, to care, particularly considering high private outlays and the health and socio-economic impacts of the pandemic.

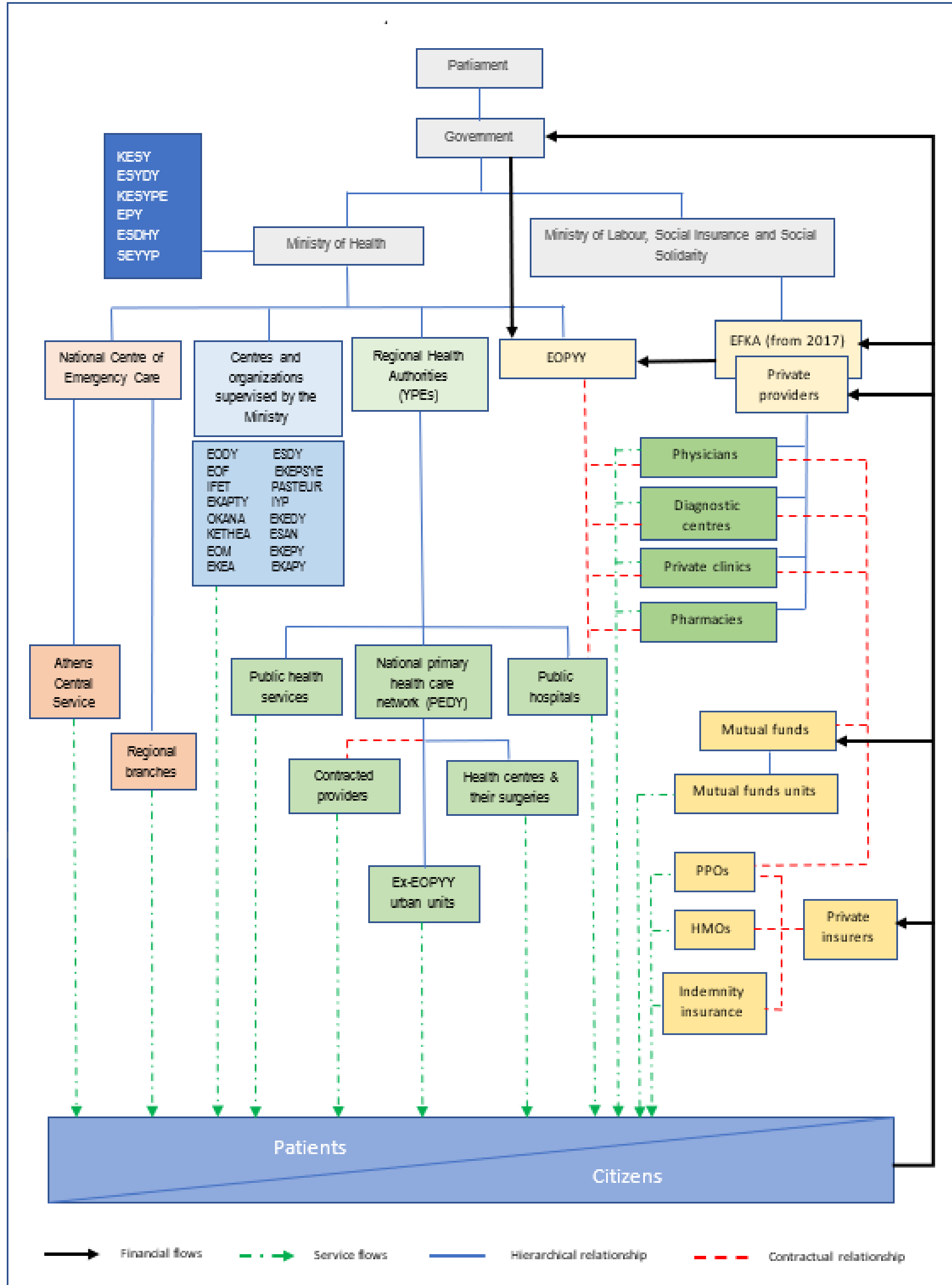
1.2.1 Governance

The provision of health services and their financing in Greece are both organised through a mixed system, with a national health service, health insurance based on professional membership and the presence of private providers. The financing, planning, administration, regulation, and delivery of health care thus involve many actors and different types of relationships between them.

Structure, actors, and roles of the Greek National Health System (ESY)

KESY - Central Health Council
ESYDY - National Public Health Council
KESYPE - Central Regional Health Council
EPY - Health Procurement Committee
ESDHY - National eHealth Governance Council
SEYYP - Body of Inspectors for Health and Welfare Services
EODY - National Organization for Public Health
EOF - National Organization for Medicines
IFET - Institute of Medicinal Research and Technology
EKAPTY - National Evaluation Centre of Quality and Technology in Health
OKANA - Organization Against Drugs
KETHEA - Therapy Centre for Dependent Individuals
EOM - National Transplant Organization
EKEA - National Blood Donation Centre
ESDY - National School of Public Health
EKEPSYE - Hellenic Centre for Mental Health and Research
PASTEUR - Hellenic Pasteur Institute
IYP - Institute of Child Health
EKEDY - National Centre for Diabetes Mellitus
ESAN - Greek DRG Institute
EKEPY - National Centre for Health Operations
EKAPY - National Central Procurement Authority for Health
EOPYY National Organization for the Provision of Health Services
EFKA Unified Social Security Fund
PPO - Preferred Provider Organization
HMO - Health Maintenance Organization

Overview of the Greek health care system[4]



[4] Adapted from Economou C, Kaitelidou D, Karanikolos M, Maresso A. Greece: Health system review. Health Systems in Transition, 2017; 19(5):1–192.

Ministry of Health

At the central level, the Ministry of Health is responsible for the regulation, planning and management of the national health service, including the allocation of resources and funds to achieve nationally set priorities and the regulation of the private sector. It is responsible for ensuring the general objectives and fundamental principles of ESY, such as free and equal access to quality health services for all citizens. The Ministry decides on health policy issues and the overall planning and implementation of national health strategies. It sets priorities at the national level, defines funding for proposed activities and allocates the necessary resources, proposes changes to the legislative framework and is responsible for implementing laws and reforms. It is also responsible for health workers and coordinates the recruitment of new health staff, subject to approval by the Council of Ministers.

Although there have been attempts to devolve some of the Ministry's responsibilities to regional health authorities, it still plays a dominant role in regulating, planning, and managing ESY and regulating the private sector. Other bodies involved in the management and regulation of the sector depend on the Ministry, including the Regional Health Authorities (EPYs), the National Centre of Emergency Care, the National Organization for the Provision of Health Services (EOPYY), and several centres, institutions and organisations directly supervised by the Ministry.

Centres and organizations supervised by the Ministry of Health

The Ministry of Health also supervises several organisations and institutions operating under its direction, including:

- The **National Organization for Public Health** (EODY), responsible for disease prevention services and epidemiological surveillance, as well as the control of all communicable diseases. It is a legal entity under private law established in 2019[5] to replace the pre-existing and abolished[6] Centre for Disease Control and Prevention (KEELPNO). The institutional mission of the organisation is to provide services that can effectively respond to threats to human health posed by communicable diseases, through early detection, monitoring, and risk assessment, reporting and the submission of evidence-based intervention proposals and measures. The organisation develops and promotes actions to promote health, prevent chronic diseases and reduce the burden of non-communicable diseases in general. Its main functions include activities such as epidemiological surveillance, risk assessment, scientific advice, preparation, and provision of epidemiological and statistical data to national, European and international authorities; education, training and promotion in the field of public health, aimed at both the

[5] Low 4633/2019.
[6] Low 4600/2019.

public and health professionals, on the risks of serious health threats. Its objectives are therefore[7]:

- monitoring and assessment of population health and of the biological, socio-economic, and environmental determinants that influence it.
- epidemiological surveillance and monitoring of the impact of communicable diseases on public health.
- developing and taking preventive measures and informing the target population on how to protect their health and safeguard their well-being.
- developing and adopting measures to protect the population from all kinds of threats from communicable diseases.
- promote actions to improve health, prevent chronic and non-communicable diseases and address adverse health conditions.

- The **National Organization for Medicines** (EOF), responsible for the evaluation, authorisation and placing on the market of medicinal products.
- The **Institute of Medicinal Research and Technology** (IFET), responsible for statistical analysis of the pharmaceutical market and the distribution of pharmaceutical products.
- The **National Evaluation Center of Quality and Technology in Health** (EKAPTY), responsible for certification, quality control and research on medical devices.
- The **Organization Against Drugs** (OKANA), responsible for planning, coordinating, and implementing policies against drug dependence.
- The **Therapy Centre for Dependent Individuals** (KETHEA), responsible for supporting people with pathological addictions, including alcohol, gambling, and the Internet.
- The **National Blood Donation Centre** (EKEA), scientific centre and administrative body for transfusion medicine.
- The **National Transplant Organization** (EOM), responsible for transplant management.
- The **National School of Public Health** (ESDY), responsible for postgraduate training of health professionals.
- The **Hellenic Centre for Mental Health and Research** (EKEPSYE), responsible for research, prevention, and mental health.
- The **Hellenic Pasteur Institute** (PASTEUR), responsible for the study of infectious, autoimmune, and neurodegenerative diseases, their pathogenesis, and the development of new therapeutic strategies.

[7] https://eody.gov.gr/en/npho/

- The **Institute of Child Health** (IYP), responsible for research, educational and preventive activities related to children.
- The **National Centre for Diabetes Mellitus** (EKEDI), responsible for monitoring and coordinating diabetes research, prevention, and treatment.
- The **Greek DRG Institute** (ESAN) established in September 2014 to develop and manage a transparent, fair, valid, and reliable system for measuring the cost of hospital medical procedures based on Diagnostic-related Groups (DRGs).
- The **National Health Operations Centre** (EKEPY) coordinates the institutions responsible for responding to emergency situations and disasters dangerous to public health.
- The **National Central Procurement Authority for Health** (EKAPY), established in May 2017 is responsible for the national procurement policy in the health sector and the annual supply of products and services to the public health organisation.

Providers

The providers that make up the Greek health care offer are:

- **Primary health care units**, rural health centres and their outpatient clinics, as well as urban outpatient medical facilities, governed and incorporated in PEDY (National primary health care network) which administratively and economically constitute decentralised units of the YPE (Regional Health Authority).
- **Hospitals** can be classified in turn into four categories according to their legal status:
  - **public law bodies**: autonomous self-governing bodies under the jurisdiction of the Ministry of Health and accountable to their own Regional Authority (YPE). These include National Health System hospitals and University Hospitals.
  - **private law institutions**: established by charitable foundations and operating under the supervision of the Ministry of Health as non-profit institutions (e.g., Onassis Heart Surgery Centre in Athens and Papageorgiou Hospital in Thessaloniki).
  - **private clinics**: profit-making organisations, usually in the form of limited liability companies, with doctors usually being the shareholders.
  - **special status hospitals**: including military hospitals operating under the supervision of the Ministry of Defence to cover the needs of military personnel and hospitals for prisoners operating under the supervision of the Ministry of Justice, Transparency and Human Rights.

Primary Health Care unit – Regional and local Health Authorities – YPEs/PEDY/Health Centers

The decentralisation of ESY for the governance of primary health care has been a key issue since its inception in 1983. There have been many attempts to introduce regional health administrations with strong decision-making power and budgetary autonomy. The legislative reforms of 2001 and 2003 had initiated an explicit and formal process to establish seventeen regional health and welfare authorities and assign them operational authority over social and health policies. The idea was that the Ministry of Health would maintain a strategic planning and coordinating role at the national level, while the regional health and welfare authorities would be responsible for the actual organisation, operation and management of all health and welfare units. The establishment of regional health authorities can be seen as the first step towards the decentralisation of planning, management, and regulation of the health system; in a country where there is no long experience of decentralised administration or strong traditions of regional and local government. In 2004, new legislation[8] led to the creation of Regional Health Authorities (YPEs), the number of which was reduced from seventeen to seven in 2007 to contain their operational costs and limit bureaucracy. On paper, they were given wide-ranging responsibilities: planning, organising, coordinating, and supervising all public health and welfare services within their catchment area; advising the Ministry of Health on the effective and efficient delivery of social and health services according to the needs of their population; and monitoring the implementation of health programmes and policies. Each of the YPEs was thus theoretically responsible, for its catchment area, for coordinating and implementing health policies, preparing management plans, organising health facilities, and deciding on resources, managing health personnel, and preparing, approving, and monitoring budgets and their implementation. In practice, however, regional health and welfare authorities could only operate on a proactive basis, requiring the approval of the central ministerial authority for implementation, coordinated, and related to the Ministry of Health through regulatory and planning bodies (see KESYPE); they also lack authority and autonomy to manage their own budgets. In 2014, specific jurisdiction over primary care facilities was formally transferred to the YPEs with the task of coordinating the National primary health care network (PEDY) and its Health Centres. In 2017, further primary health care reform[9] expanded the concept and scope of Health Centers, which now include decentralized units, where health services are provided at the first level of primary health care, by **Local Health Units**, **Regional Medical Offices**, **Regional Multipurpose Medical Offices**, **Regional Specialized Medical Offices**, **Local Medical Offices**, and other primary health care units.

Currently[10], the 7 regional health authorities (YPE) in Greece are divided as follows[11]:

- 1st YPE (Attiki)
- 2nd YPE (Piraeus & Aigaio)

[8] Low 3329/2005.
[9] Low 4486/2017
[10] 2019
[11] Census of health centres and other units providing primary health care services: year 2019 (https://www.statistics.gr/en/statistics/)

- 3rd YPE (Makedonia)
- 4th YPE (Makedonia & Thraki)
- 5th YPE (Thessalia & Sterea Ellada)
- 6th YPE (Peloponnisos, Ionia Nisia, Ipeiros, Dytiki Ellada)
- 7th YPE (Kriti)

formally plan, coordinate, supervise and control the operations of all health service providers within their territories. Specifically, their areas of intervention are:

- planning, coordinating, and controlling the operations of all health service providers within the boundaries of the relevant regional health authority. The following are defined as Health Service Providers: hospitals, health centres and social assistance units, mental health units, rehabilitation centres, other legal entities under public law and private law of the public sector, which carry out activities in the field of health and social security and are supervised by the Minister of Health.
- drafting suggestions, measures and proposals to the Minister of Health aimed at the effective provision of health and social security services to the population of their region.
- monitoring the implementation of the policy prepared by the Ministry of Health.

Hospitals

The supervision of hospitals is generally carried out by the Ministry of Health, except for special status hospitals. The National System of Quality Infrastructure (ESYP), a private liability company operating in the public interest, is responsible for monitoring the quality of care and managing the accreditation and certification of health facilities. It incorporates the Hellenic Accreditation System and the Hellenic Organisation for Standardisation as autonomous decentralised operational units. Since 2010, a quality committee has been established in each public hospital with a capacity of more than 400 beds. The role of the committee is to adopt benchmarking criteria and accreditation procedures for the improvement of service quality.

The table below provides a summary and overview of the main actors presiding over the healthcare provision of interest to this report and their governance and regulatory bodies[12].

[12] Adapted from Economou C, Kaitelidou D, Karanikolos M, Maresso A. Greece: Health system review. Health Systems in Transition, 2017; 19(5):1–192.

	Planning	Accreditation	Tariff	Quality	Financing
Public Health Services	ESYDY	ESYDY	Not applicable	ESYP	ESYDY
Outpatient care (primary and specialist)	YPEs, PEDYs, EOPYY	ESYDY EKAPTY Regional administrations	ESYDY EOPYY	ESYP	EOPYY Private Insurers
Hospital care	ESYDY YPEs Other Ministries[13]	ESYDY EKAPTY Regional administrations	ESYDY EOPYY Private Insurers[14]	ESYP	EOPYY Private Insurers
Long-term assistance	ESYDY YPEs	Regional administrations	ESYDY EOPYY	ESYP	EOPYY

- ESYDY – Ministry of health
- ESYP – National Quality Infrastructure System
- YPE – Regional Health Autority
- PEDY – National Primary Health Care Network
- EOPYY - National Organization for the Provision of Health Services
- EKAPTY - National Evaluation Center of Quality and Technology in Health

Regulatory and planning bodies

Greece does not have a tradition of studies and research focused on defining the social determinants of health or the impact of health development on the economy to determine priorities in planning. The planning of health services is therefore not based on the assessment of needs or the measurement of the output of health services, but rather on purely political considerations. Various semi-autonomous bodies contribute to the regulation and planning of the public health system. The most important of these are:

- The **Central Health Council** (KESY), a body mainly advisory on health-related issues concerning the planning, regulation, and operation of the health system, but also on issues of postgraduate training of health workers (specialisations).
- The **National Public Health Council** (ESYDY), an independent body in charge of scientific supervision and coordination of public health organisations.

[13] Depends on legal status of hospitals.
[14] Private hospitals.

- The **Central Council of Health Regions** (KESYPE) coordinates the policies of YPEs and maintains their cooperation with the Ministry of Health.
- The **Health Procurement Committee** (EPY), which acts as a single central purchasing body for hospitals, with the aim of reducing procurement costs, improving payment times, standardising medical requirements, transferring redundant materials from one hospital to another and improving the management of expired products.
- The **National eHealth Governance Council** (ESDHY), which is responsible for developing the e-health strategy and the overall operation, funding, and monitoring of e-health projects.
- The **Body of Inspectors for Health and Welfare Services** (SEYYP), responsible for management control of public and private health and welfare services to improve their quality, productivity, and effectiveness.

In 2008, the Ministry of Health launched a public consultation process and formulated a public health plan for 2008-2012, covering 16 action areas, including cancer, HIV/AIDS, rare diseases, smoking, drugs, alcohol, and oral health. However, progress has been slow and partial. Only a few measures have been introduced, including a ban on smoking in all enclosed public places. The development of a Health and Well-being Map as a fully-fledged planning tool, launched in 2008 as a pilot project to foster a rational distribution of health and care services across the territory, and to match the needs of the population with health care, was suspended in 2017 due to budget problems.

After 2010, even the pressure under the Economic Adjustment Programme to achieve immediate results in terms of reducing health expenditure did not focus specifically on the health needs of the population, with the emphasis instead on operational, financial and management aspects. However, a noteworthy initiative in prioritisation was the collaboration between the Greek Ministry of Health with the WHO Regional Office for Europe to develop a roadmap containing three axes of reform and 100 priority actions, presented in the National Health Strategy and Health Sector Actions in the National Strategic Reference Framework 2014-2020[15].

Regarding health policy planning, at the end of 2017 Greece had not yet developed a programme of health objectives to set priorities or a national plan for the implementation of a universal health policy. However, progress has been made as in January 2017 the Ministry of Health and EOPYY produced a health atlas, which maps the resources available in the health sector across Greece[16].

Third-party payers – EOPYY e Private Insurers

[15] Ministry of Health (2014). National health strategy and health sector actions in the National Strategic Reference Framework 2014–2020. Athens, Ministry of Health (in Greek).
[16] Ministry of Health (2018). Health atlas [website]. Athens: Ministry of Health (https://healthatlas.gov.gr/#!/).

The Greek National Health System and health care are financed through a system of mixed public and private resources involving EOPYY and the State Budget on the one hand, and private health insurance companies on the other.

Historically, in Greece, social security funds have played a very important role in the coverage, financing, and provision of health services (especially outpatient services). Until 2010, there were many employment-based Social Health Insurance (SHI) funds (which, in fact, were the health branches of larger insurance funds that also administered pensions). As a result, there were a variety of schemes, differences in contribution rates, coverage, benefits, and the conditions for granting these benefits, leading to inequalities in access to and financing of health services[17]. In 2011, a major reform of the health system brought the health branches of all SHI funds under EOPYY, which is given the function of "buyer" of medicines and health services for policyholders, thus increasing its bargaining power with providers[18]. Between 2011 and 2014, EOPYY was gradually transformed into a unified health fund: taking advantage of the existing administrative infrastructure, contributions were collected from the individual SHI funds and transferred to EOPYY, thus consolidating its role as the sole purchaser of health services. Since 2017, this function has been taken over by a single organisation, the Unified Social Security Fund (EFKA), which is responsible for collecting all health and pension contributions. Until 2014, EOPYY was also the country's main body in charge of primary care management, with the role of coordinating primary care, regulating contracts with all health care providers, and setting quality and efficiency standards, with the broader aim of relieving pressure on specialist and emergency care in public hospitals. In 2014, responsibility for the provision of primary care was transferred to the National Primary Health Care Network (PEDY) and coordinated by the Regional Health Authorities (YPEs)[19], which have jurisdiction over all primary care facilities, including health centres and their outpatient clinics, as well as facilities previously belonging to the various health insurance branches that were merged into EOPYY.

EOPYY is currently governed by a nine-member board of directors, four of whom, including the President, are appointed by the Ministry of Health, which therefore plays a substantial supervisory role within the fund's autonomy. EPOYY's main financial sources include contributions from employees, employers, and pensioners, plus a variety of smaller sources of income. However, due to its large deficits, EOPYY receives subsidies from the state budget. EOPYY is therefore administered as an autonomous public body operating under the supervision of the Ministry of Health. This is an important change from the pre-2011 period when health insurance funds were under the jurisdiction of the Ministry of Labour, Social Security and Welfare. However, the Ministry of Labour, Social Welfare and Welfare still plays a significant role as health insurance contributions are not paid directly by employees and employers to EOPYY but, since 2017, are collected through EFKA, which collects all health insurance contributions and transfers the corresponding share to EOPYY.

[17] Economou C. (2010), Health Systems in Transition, Vol. 12, n. 7, Greece Health System Review - European Observatory on Health Systems and Policies.
[18] The reform was introduced with Law 3918/2011.
[19] Low 4238/2014.

EOPYY operates in a market situation characterised by the centralisation of demand by a single economic entity and the impossibility for other buyers to enter this market. Therefore, EOPYY is the only purchaser of healthcare services, creating the necessary conditions for contractual commitments with healthcare providers.

As for the private component of health care financing, it mainly takes the form of direct payments for services not covered by social security, or for those covered but not reimbursed because purchased outside the formal system, of participation fees and of private expenditures. The role of private health insurance remains marginal, given that only a small proportion of the population has private coverage, with a relatively low contribution to total health expenditure.

1.2.2 Provision of services

The National Health System (ESY) comprises both public and private elements, and provides emergency, ambulatory and inpatient primary health care through rural clinics, health centres and public hospitals. The NHS therefore provides both primary and specialised care, and in rural areas it remains the main provider, although the role of the private sector is becoming more important. The private sector plays an important role in the provision of health services, although it has no direct involvement in the design, financing, and regulation of the public system. It includes for-profit hospitals, diagnostic centres and independent doctors, financed mainly by out-of-pocket (OOP) payments and, to a lesser extent, by private health insurance. Most private facilities have supply contracts for primary and outpatient care with the National Organization for the Provision of Health Services (EOPYY). Rehabilitation services (e.g., physiotherapists) and care services for the elderly (geriatric homes) are mainly provided by the private sector.

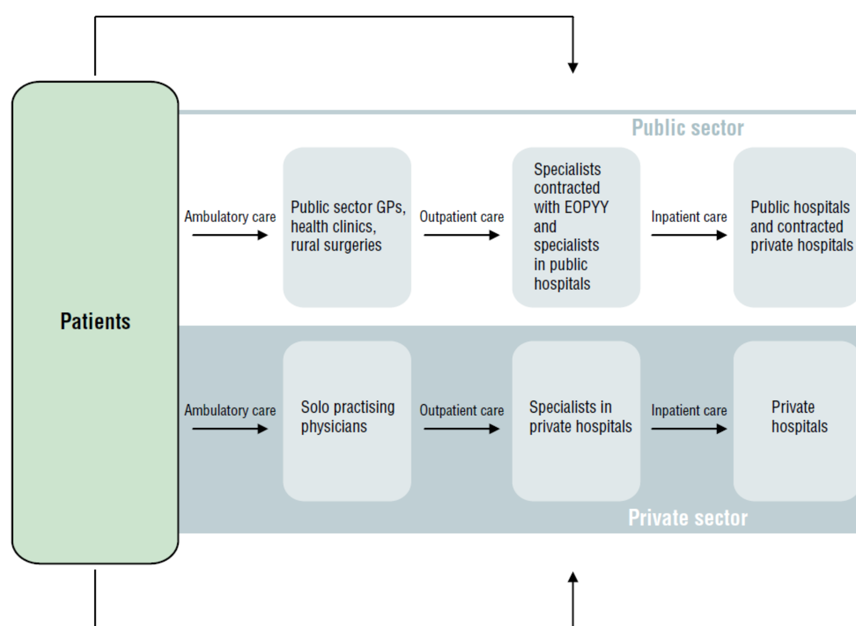
Primary health care is provided through outpatient services at public hospitals and rural health centres, which are administratively linked to hospitals and financed through hospital budgets. The health centres are staffed by general practitioners and specialists, who provide basic carefree of charge, as doctors working in public hospitals and health centres are full-time employees who are not allowed to practice privately and are already paid. There are also health clinics with public medical staff on the territory, which are administratively dependent on the health centres. However, there is no filtering mechanism and patients can go directly to specialist care services. Basic care is also provided through health centres and special units belonging to the social security funds, which manage them, clinics and wellness centres run by municipalities, and doctors working in private practices. Specialist and long-term care is provided through both public and private hospitals. There are public hospitals, some of which operate outside the national health system, private for-profit hospitals, and social security fund hospitals, which are mainly financed by the social security fund.

First aid assistance is provided through the National First Aid Centre, with headquarters in Athens and offices throughout the country. Pharmaceutical care is universal and prescribed drugs are reimbursed by social insurance, although part of the cost is borne by patients. Depending on the patient's health status (chronic diseases) and income level, exemptions or reductions in the participation fee may be granted. Planning and implementation of pharmaceutical policy is the responsibility of the central authority.

Patient Pathways

Patients accessing healthcare services follow different pathways depending on whether they use public or private facilities. High utilization of private healthcare services has always been a feature of the Greek healthcare system, however, the economic crisis, with its impact on patients' ability to disburse OOP payments, has resulted in a significant increase in the utilization of public sector services. Currently (2017), there is no intake or referral mechanism, and patients can access care directly and indifferently in urban ESY facilities, rural health centers, or hospital outpatient clinics (paradoxically, instead, patients covered by private health insurance contracts are forced to first go through a first contact service that will later refer them to specialist or hospital care). The physician can prescribe medications or diagnostic tests or refer the patient to a specialist, whether EOPYY, public or private. Because of this direct, unregulated method of access, long waiting lists occur for some specialties; and, consequently, long waiting lists in the public (e.g., for screening tests) may drive some patients to private specialists and diagnostic centers, paying OOP for these services.

Inpatient care can be provided in either the public or private sector, in which case the costs are largely borne by the patient or his or her VHI. Patients, then, often prefer to access Athens or large university hospitals that offer expensive, high-tech services because district hospitals are often understaffed and, in some cases, lack infrastructure. Many patients then access emergency rooms at public or contracted private hospitals for free, bypassing primary care touch points. Many of these visits are, of course, unwarranted and put pressure on these departments.



Patient pathway[20]

Primary outpatient care

Primary outpatient care in Greece is provided by a mix of public and private providers. There are three main modes of use

- through the ESY, including the National Centre for Emergency Care; rural health centres and their outpatient clinics; and public hospital outpatient clinics.
- through the private sector, including doctors' offices, laboratories, diagnostic centres and outpatient medical consultations at private hospitals. This is financed through direct payments or private insurance or through EOPYY.
- to a lesser extent, through local authorities and NGOs, including clinics and care services offered free of charge by municipalities and civil society organisations, which only cover a narrow range of needs and are mainly used by uninsured people and (in particular) refugees and migrants.

Following the formation of the National Primary Care Network (PEDY) and the definition of the Regional Geographical Areas (YPE), within which both public and private providers could form local networks and provide community-based care, a new Primary Care Plan was formulated by the Ministry of Health, with implementation planned over three years and two main axes of intervention. The first intervention axis foresees the establishment of a network of local primary care units (TOMYs), decentralised, community-oriented, which, together with family doctors, should constitute the first level of care and the first point of contact within the health system.

[20] Economou C, Kaitelidou D, Karanikolos M, Maresso A. Greece: Health system review. Health Systems in Transition, 2017; 19(5):1–192.

TOMYs have multidisciplinary health teams consisting of family doctors, nurses, health care assistants, social workers and staff and their aim is to address major health problems at community level, reduce avoidable hospitalisations, provide patients with care as close to their homes as possible, and prevent public health problems through behavioural education and reduction of risk factors[21].

The second plan of action consists of health centres functioning as referral points for the provision of primary, acute and emergency care out of hours, and for specialist and diagnostic outpatient services, thus integrating care[22].

The aim is to achieve better management of health problems by placing the doctor in the primary health care team as the care coordinator, thus ensuring continuity in the management of common health problems, including and especially at the patient's home; to prevent illness and promote health; to establish a referral system and an appropriate patient care pathway through the health care system; and to develop an e-health care network.

In addition to public ambulatory care services, there are private clinics and diagnostic centres, most of which are equipped with higher quality (and cost) instruments and equipment than public ones. Most of the private facilities are in Athens and Thessaloniki. EPOYY contracts private practices, laboratories, and diagnostic centres to provide health services to the insured, providing services directly to uninsured patients as well, subject to direct payment by the patients or through private insurance. Rehabilitation services and services for the elderly are mainly provided by the private sector[23].

Specialist outpatient care

Specialist outpatient care is provided by private specialists, individually or in association, and by the specialist outpatient clinics of public hospitals. Many of the specialists work with EOPYY in their private practices or within diagnostic centers, providing services on a fee-for-service basis, with a maximum limit of 200 visits per month per specialist. The uneven geographic distribution of EOPYY physicians represents the biggest problem; most are concentrated in large cities, particularly Athens and Thessaloniki, while other areas of the country lack some specialties[24]. The majority of specialists are from internal medicine, cardiology, obstetrics/gynecology, and orthopedics. Specialty outpatient departments at public hospitals provide services within the ESY, cover all specialties, and are the primary providers of specialty outpatient care in urban areas. They provide free services during the morning hours and visits are scheduled by appointment. In 2001[25], the option was introduced for the same public physicians working in the

[21] Economou C, Panteli D. Monitoring and documenting systemic and health effects of health reforms in Greece. Copenhagen: WHO Regional Office for Europe; 2019.
[22] [ibidem]
[23] Economou C (2015). Barriers and facilitating factors in access to health services in Greece. Copenhagen, WHO Regional Office for Europe.
[24] Karakolias SE, Polyzos NM (2014). The newly established unified healthcare fund (EOPYY): current situation and proposed structural changes, towards an upgraded model of primary health care, in Greece. Health, 6:809–821.
[25] Low 2889/2001.

hospital to provide afternoon services of private consultations by appointment in hospital outpatient clinics. They are paid on a fee-for-service basis directly by patients, and the fee is shared between the hospital (40%) and the physician (60%). Initially, this was provided only in hospitals with the necessary infrastructure to support full-time clinics, but in 2010 this became mandatory, and this mechanism was extended to all public hospitals to increase access to health services, to meet extra demand and to increase revenues.

Hospital care

The Greek healthcare system is heavily centered on hospitals. In 2014, there were 283 hospitals, of which 124 were public, four were private nonprofit, and 155 were private for-profit[26], all with outpatient care departments. Depending on the services offered, Greek hospitals are classified as general or specialized. The former includes departments of medicine, surgery, pediatrics, and obstetrics/gynecology, supported by imaging services and analytical laboratories. They include both large general hospitals in large urban areas, district hospitals located in a main administrative district, and small hospitals in semi-urban and inner-city areas. Specialty hospitals, on the other hand, are referral centers for a single specialty (e.g., obstetrics, pediatrics, cardiology, or psychiatry). University Hospitals, linked to medical schools, offer the most complex and technologically sophisticated services.

Operationally, hospitals face a range of problems: the management model is generally outdated, and political interference is widespread, particularly among hospital executives and board members. Human resource management is also problematic, including recruitment processes, the absence of substantive staff evaluations, and the absence of a culture of accountability for staff performance inefficiencies. Finally, funding and cash flow are still problematic given that the DRG system has not yet been fully developed (2017).

In 2011, several hospitals restructuring proposals were presented by a committee of experts appointed by the Minister of Health[27], with the aim of achieving economies of scale, rationalizing resource allocation, making operations more efficient and reducing total costs. The final plan, after several hearings and public consultations in the various regional health administrations, was announced in July 2011[28]. The results produced were the replacement of the governing bodies of public hospitals with 82 boards responsible for the administration of all hospitals. In addition, five hospitals that belonged to IKA were transferred to ESY, becoming branches of the five main public hospitals. The total number of beds in ESY hospitals was reduced and the number of medical departments and units of hospital staff. In addition, changes were made to the use of

[26] This count excluded hospitals with special status (e.g. military or prison hospitals).
[27] Liaropoulos L et al. (2012). Restructuring the hospital sector in Greece in order to improve effectiveness and efficiency. Social Cohesion and Development, 7(1):53–68.
[28] Ministry of Health and Social Solidarity (2011a). Proposal for the functional reorganization of national health system units. Athens, Ministry of Health, and Social Solidarity (in Greek).

eight small hospitals, which were transformed into urban health centers, support and palliative care units, and short-term inpatient and rehabilitation hospitals[29].

Day care centers

Day care units have been slow to develop in Greece. Past attempts have been fragmented and have not generated the organizational culture required by this type of healthcare practice. The 2011 legislation[30] stalled due to the failure to issue a presidential decree defining operational and technical criteria. Three years later, Act 4254/2014 established public and private day care centers that must provide diagnostic, curative services and simple surgical procedures that do not require complex anesthesiologic interventions or hospitalizations exceeding one day. Public hospitals, PEDYs, health centers, clinics, and private practices may establish day care units. A subsequent ministerial decision[31] defined the criteria and specific equipment to obtain authorization to operate as day care centers, as well as their specialties.

Emergency care

Emergency care is provided free of charge in the emergency departments of public hospitals and EKAV facilities[32]. A person with a serious medical emergency may choose to go directly to the emergency room of a public hospital or call EKAV. EKAV was founded in 1985 and is responsible for providing emergency medical first aid to all citizens, as well as free transportation to health units. It also provides training to doctors, nurses, and other health care personnel on all aspects of emergency medicine and health care. Its central service center is in Athens, with 11 regional stations in major cities and substations in smaller towns. EKAV's Command and Coordination Center is the first point of contact for emergency care. It receives all calls for emergency medical care through two national telephone numbers (166 or 112) and classifies them according to severity and based on medical protocols. It also selects and mobilizes the most appropriate response, leads ambulance crews, provides specialized life support, and manages coordination with hospital emergency departments. It also activates ambulances and other units during major disasters. Hospital departments also provide emergency care. They work closely with the EKAV center and directly receive patients who go to the emergency room or who are referred to an emergency by a physician or the EKAV. The economic crisis and austerity measures implemented after 2010 have had a negative impact on the adequacy and quality of EKAV's services. Horizontal cuts in health care spending, failure to renew fixed-term contracts, and a lack of turnover of retired staff have led to a reduction of approximately one-fifth of the national ambulance fleet due to crew shortages, lack of repairs and maintenance, and failure to purchase new ambulances.

[29] Nikolentzos A et al. (2015). Reengineering NHS hospitals in Greece: redistribution leads to rational mergers. Global Journal of Health Science, 7(5):272–287.
[30] Low 4025/2011.
[31] Ministerial resolution n. A6/G.P.oik.103516.
[32] Papaspyrou E et al. (2004). International EMS systems: Greece. Resuscitation, 63:255–259.

In addition to EKAV, all public hospitals with a capacity of more than 300 beds operate 24 hours a day through freestanding emergency departments staffed by physicians in the specialties of surgery, anesthesia, internal medicine, cardiology, pulmonology, orthopedics, and general medicine with proven experience and knowledge of emergency medicine or specialization in intensive care medicine. Emergency departments perform admission, triage, and immediate treatment in life-threatening situations.

The proper functioning of emergency departments is hindered organizationally by the absence of gatekeeping, which results in many unnecessary visits and accesses to these departments, increasing their workload. Third, budget cuts have led to a shortage of staff to triage patients. Paramedic staffing shortages in emergency departments often result in ambulance crews having to assume the role of paramedic staff.

Rehabilitation and intermediate care

Intermediate care in Greece has remained largely underdeveloped with few services provided by ESY or local authorities. To remedy this, in 2015, the Ministry of Health launched a pilot project to develop home and intermediate care services nationwide. In the initial phase, a network of 11 hospitals and four health centers provided home health care to patients who had been admitted to the hospital and needed post-hospital care and to people with chronic, non-communicable diseases or injuries and disabilities who required short- or long-term health care. The health care teams consisted of a medical specialist (internist, anesthesiologist, surgeon, or GP), two nurses, and a community nurse.

Long-term care

For people with chronic and incurable diseases and those who are not self-sufficient, long-term hospital care services in Greece are provided primarily by a network of 25 national public infirmaries. A few private clinics also provide long-term care for elderly patients with disabling conditions. In 2013, these independent public entities became decentralized units of the newly established social care centers funded by the state budget and SHI.

Church organizations also provide services and facilities for people with incurable diseases, infirmaries for chronic diseases, institutions for the disabled, and physical therapy centers. There are also private clinics affiliated with EOPYY that provide long-term care, primarily for the terminally ill. In 2013, legislation stipulated that each regional administration should establish a social care center and transform a wide range of former residential-oriented rehabilitation centers into decentralized units of these social care centers.

An organizational problem is that the physical medicine and rehabilitation centers are under the jurisdiction of the YPEs, as units of public hospitals, while the social care centers are under the jurisdiction of the regional authority, raising the question of integration and interconnection

between the two networks. Long-term care for the elderly involves both community-based and residential care. More specifically, four types of community care services can be identified[33]:

Care centers open to the elderly.

These are public law entities, funded by the Ministry of Health and managed by municipalities. They provide psychosocial support, health education services (on diet, injury prevention and personal hygiene),

preventive medical services (e.g., blood pressure measurement, blood glucose testing and physiotherapy) and recreational services; thus, aiming to improve patients' well-being while they continue to live in their social and personal contexts. There are more than 900 such centers across the country that are staffed by teams consisting of social workers, community nurses, occupational and physical therapists, and family caregivers.

Friendship Club.

These associations operate at the neighborhood level and offer various services to the elderly, including recreational activities, occupational therapy, physiotherapy, visits to cultural sites, art initiatives, day trips, walks and assistance in adapting to age-related conditions in old age. These also provide a supportive environment, particularly for those who do not have adequate financial means or family members able to care for them. They are created in areas and neighborhoods lacking care centers open to the elderly, and where health care is provided in part by municipal health centers.

Home Help Program for Retirees.

This replaced an earlier program, Home Help for Elderly, in 2012 and aims to provide home care to retired seniors, primarily the frail and those living alone, to improve their quality of life, to ensure they maintain their independence, and to keep them active in their family and social environment, thereby reducing the need for institutional hospital care. This program funds regular services and home visits provided by a social worker, nurse and domestic worker. These individuals offer help and assistance, including psychological support, with daily tasks. The eligibility criteria for the new program are age, income, marital status, health status and disability, and the sources of funding are now exclusively national (funding under the old program was split between EU (75%) and national (25%) funds). Responsibility for running the program is given to the IKA while the provision of services is entrusted, on a competitive basis, to nonprofit (NGOs, social cooperatives) and for-profit organizations that can submit their bids and be included in a register of certified providers, from which beneficiaries can choose a provider.

Day care centers for the elderly.

This alternative form of public protection and support is offered to the elderly with the goal of keeping them in their familiar environment. This service is offered to people over the age of 65 with chronic or acute conditions who are dependent on others for their care, have financial

[33] Mastroyiannakis T, Kagialaris G (2010). Prevention and rehabilitation within LTC. Athens, INTERLINKS.

problems and face social and family problems. Services include daily care and coverage of basic needs, psychological and emotional support, as well as the assured provision of pharmaceutical care.

Several public residences for the elderly operate under the supervision of the Ministry of Health and provide housing, food, psychological support, counseling and medical care to their residents. There are also private for-profit and not-for-profit residences for the elderly, the latter operated primarily by church organizations that provide residential care of last resort for the frail elderly.

In total, nursing homes serve about 2% of the population over the age of 65. The Greek Care Homes Association, which represents all legal residential care units for the elderly, estimated (2017) in Greece, about 120; with a total capacity of 10 000 beds. However, there were also a considerable number of residences that were not registered and operated illegally to avoid state inspections and legal standards.

A scientific review published in the 2000s, aimed at evaluating community services for older people, raised serious concerns about the adequacy of funding, the effectiveness and quality of services provided, and equity of access. It also highlighted the shortcomings of residential care, referring to the low quality of services, old buildings, staffing shortages, and lack of affordability[34].

Although no new and recent evaluation actions have been undertaken, it is very unlikely that significant improvements in the situation have been seen since 2010, given, among other things, the reduction in resources available under austerity policies.

Existing services therefore cover only a limited portion of needs. The long-term care sector has been developing very slowly and in a very fragmented way. There is no integration in the provision of services to vulnerable groups of the population, particularly the elderly, and there is no general systematic assessment of needs, let alone timely assessment based on needs related to gender, age, health status, ethnicity and any other relevant characteristics. Thus, informal care within the family, provided by informal or privately hired caregivers, still plays the most important role in meeting the needs of the population[35].

Services for informal caregivers

Support for family caregivers of loved ones still remains a low priority on the social policy agenda in Greece, and measures to recognize the value of informal care, protect the informal caregiver, and provide them with access to support services are almost non-existent.

Informal caregivers do not enjoy legal benefits and are seen primarily as a resource that does not need support. In addition, there is no in-depth research or study on the size of the family caregiving phenomenon or its needs, and no national data are available on the number, age,

[34] Economou C (2010). Greece: health system review. *Health Systems in Transition*, 12(7): 1–180.

[35] Petmesidou M et al. (2015). Health and long term care in Greece. Athens, Observatory for Economic and Social Developments, Institute of Labour of the Greek General Confederation of Labour (Study 35).

gender, income, hours and tasks of caregiving, education level, and employment status of family caregivers. However, a good picture of the situation regarding the profiles of caregivers and the support services available to them is provided by two national reports submitted in the framework of two international projects: EUROFAMCARE[36] (2003–2005) and INTERLINKS[37] (2009–2011), supporting family care for the elderly in Europe.

The results of the EUROFAMCARE project, based on a sample of 1014 family caregivers, showed that:

- family care is largely provided by women (80.9%).
- more than three quarters (76.4%) of family caregivers were married or cohabiting.
- 17.1% of family caregivers cared for their spouse, 55.4% cared for an elderly parent, and 13.9% cared for their in-laws.
- the educational level of family caregivers was relatively low: 37.4% had a low level of schooling; 40.6% had an intermediate level (had completed higher education); and 22.1% had a high level of education.
- just over 50% of family caregivers shared the same household as the dependent.
- 47.2% of family caregivers reported working, outside of the care setting, an additional 40 hours (with a maximum of 140 hours) per week.
- the average number of hours of care provided was 51 hours per week.
- the income of family caregivers was on average low, and no more than 1100 euros per month for 55.1% of respondents.
- the majority of family caregivers (80.9%) cared for only one elderly person, 16.8% cared for two dependent elderly persons and 2.3% cared for three or more dependent elderly persons.

The report also highlighted the non-existence of pension and insurance rights or benefits for caregivers. In contrast, it appeared to be common practice for family caregivers to use pensions and disability benefits provided by SHI funds and social assistance services to their caregivers in order to return financially from their caregiving activities.

The INTERLINKS project confirmed these findings and raised another important issue regarding the increasing use of private family caregivers, often resident migrants[38], most of them women, employed irregularly and without social security and in many cases even without a residence

[36] Triantafillou J, Mestheneos E, Prouskas C (2006). Services for supporting family carers of older dependent people in Europe: characteristics, coverage and usage: The national survey report for Greece. Hamburg, EUROFAMCARE.
[37] Kagialaris G, Mastroyiannakis T, Triantafillou J (2010). The role of informal care in long-term care. Athens, INTERLINKS.
[38] [ibidem]

permit and adequate knowledge of the Greek language. Of course, due to their status, it was not possible to determine their exact number.

The lack of formal support has led to the creation of self-support groups and voluntary organizations for the support of family caregivers and the provision of advice, information, guidance and training on primary health care management and services[39].

Another issue of great concern is the low levels of education and limited access to training programs for informal caregivers in Greece who, despite these shortcomings, perform a range of tasks (from spending to disease management) that greatly impact on the quality of care and safety, both of patients and caregivers themselves. In this regard, the i-CARE EU project[40] highlighted the need for a whole range of educational and support needs that would improve the skills of caregivers. It highlighted the need for training in health aspects: illness, medication administration, hygiene, and safety; both for carers and for the carers themselves. In addition, it highlights how both formal and informal family caregivers would benefit enormously from the use of information and communication technologies, which would allow them to have access to various services especially educational and support services, specifically recommending the development of open e-learning and user-friendly programs.

1.3 Comparative analysis

Classifications of health care systems have traditionally been based on financing mechanisms or prevailing contractual relationships between health care providers and payers. However, in the community setting, it has been repeatedly emphasized that in order to understand the factors that affect health care spending and overall performance, one must also know the organizational aspects of health care systems. More precisely, *the levels of health expenditure are the result of the interaction between the factors that leverage demand and those that leverage supply and the way in which health services are financed and delivered, that is, the organizational aspects of health systems*[41]*.*

The OECD, already in 2008, having noted the paucity of information available on the organizational and institutional aspects of health systems, had launched a survey to collect information among its member countries[42], on the basis of which it identified groups of countries

[39] Courtin E, Jemiai N, Mossialos E (2014). Mapping support policies for informal carers across the European Union. Health Policy, 118:84–94.
[40] Kaitelidou D et al. (2016). *Report on practices and skills identification of caregivers. Scientific desk research on education, VET, skills and regulation framework of caregivers. Collection of best practices in dealing with caregivers' skills and career development.* Cardiff, i-CARE.
[41] Council of the European Union, 2010
[42] Paris, V., M. Devaux and L. Wei (2010), "Health Systems Institutional Characteristics: A Survey of 29 OECD Countries", OECD Health Working Papers, No. 50, OECD

characterized by similar institutions[43], even if, in terms of efficiency, this grouping process did not reveal *more important differences within each institutional group than differences between institutional groups, suggesting that there is no type of health system more efficient than another*[44].

On the supply side, other relevant information regarding the ownership, management, and financing of health care facilities, or hospital governance, was collected and evaluated on a comparative basis across Europe[45]. This analysis, which is for informational purposes only and which refrains from drawing conclusions about the efficiency of hospital systems, explored a very important field in terms of institutional set-up and the way health services are delivered, as hospitals purchase goods (medicines, medical devices) or services (health professionals), make investments and are also heavily involved in the testing, development, and deployment of ICT applications in the health sector.

1.3.1 Main models and classifications

Health Care Financing

About the type of financing of health systems, three main models can be distinguished [46]:

- the Beveridge model.
- the Bismarck model.
- the mixed model.

The Beveridge model corresponds to systems financed through public tax revenues, in which funding comes from fiscal instruments. This model is also known as the "national health system" and generally provides universal coverage.

The Semashko model is also based on the same principle as the Beveridge model, in which financing comes from tax revenues and health coverage is universal, but the State has a more extensive control function than in the Beveridge model about the financing, management and ownership of health facilities. The Semashko model, in which healthcare services are provided primarily by the hospital system, was widespread in Central and Eastern European countries before the reforms, initiated in the early 1990s, were implemented[47].

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[43] Joumard, Isabelle and Andre, Christophe and Nicq, Chantal (May 27, 2010), Health Care Systems: Efficiency and Institutions. OECD Economics Department Working Paper No. 769, Available at SSRN: https://ssrn.com/abstract=1616546 or http://dx.doi.org/10.2139/ssrn.1616546

[44] Council of the European Union, 2010

[45] Hospitals in the 27 Member States of the European Union - Hope & Dexia, 2009

[46] Busse, M., & Hefeker, C. (2007). Political risk, institutions and foreign direct investment. European journal of political economy, 23(2), 397-415.

[47] Hospitals in the 27 Member States of the European Union - Hope & Dexia, 2009

Under the Bismarck model, the financing of the health care system is covered by mandatory social insurance contributions generally paid by both employers and employees. It is also known as the health and social insurance system.

In the mixed model, private funding from voluntary insurance schemes or direct payments is significant. This model is also known as the private health insurance system.

Institutional aspects of health systems

Based on information gathered through a survey of member countries[48], a set of indicators were defined to assess the efficiency of health systems, and then six groups of countries sharing similar institutional characteristics were identified[49]. This classification is based on the degree to which health systems make use of market mechanisms to regulate the demand and supply of health services, in particular:

- Group 1 includes countries that make extensive use of market mechanisms for both the regulation of insurance coverage and the provision of services, with the result that private providers play an important role in health care.
- Groups 2 and 3 include countries with basic insurance coverage and extensive use of market mechanisms for service delivery. Thus, private providers continue to play an important role. In group 2, services not included in the basic package are covered predominantly by private health insurance, whereas in group 3 there is limited coverage beyond basic services.
- Group 4 includes countries in which private provision is limited, but choice of providers is wide.
- Groups 5 and 6 include countries with largely regulated public systems, in which provider choice is limited and determined by the existence of a filter system (group 5) or by budgetary constraints (group 6).

As a general conclusion of this group analysis, the authors noted that *most countries with decentralized systems tend to regulate health care resources and/or prices more than the OECD average. A high level of decentralization is often associated with relatively little consistency of accountability functions across levels of government, suggesting that in decentralized systems there tends to be overlapping responsibilities for health care management*[50]*.*

Hospital governance

[48] Paris, V., M. Devaux and L. Wei (2010), "Health Systems Institutional Characteristics: A Survey of 29 OECD Countries", OECD Health Working Papers, No. 50, OECD

[49] Joumard, Isabelle and Andre, Christophe and Nicq, Chantal (May 27, 2010), Health Care Systems: Efficiency and Institutions. OECD Economics Department Working Paper No. 769, Available at SSRN: https://ssrn.com/abstract=1616546 or http://dx.doi.org/10.2139/ssrn.1616546

[50] [ibidem]

The analysis of the hospital sector in Europe[51] provides comparative information on hospital governance, based on which a classification of hospital management systems has been developed in terms of:

- decentralization,
- centralization,
- "devolution".

Decentralization of hospital management systems entails the transfer of powers, at various levels, from the State to local and regional authorities; where this devolution has not occurred, centralist management of the hospital sector prevails; "devolution", on the other hand, implies that management continues to be centrally controlled, but is carried out at the territorial level through local or regional agencies or territorial branches of central government.

One of the general conclusions drawn by the authors is that *the more decentralized a health system is, the more so is the hospital system*[52].

1.3.2 The role of local and regional authorities

The previous types of classification do not highlight the role of local and regional authorities within health management systems or consider this role only in relation to one criterion, as in the case of the hospital management classification.

When examining financing mechanisms, we find that they do not provide any information regarding the territorial organization of health systems, since health systems that are financed, for example, by public tax revenues may be largely decentralized or centrally controlled. Nor do the type of funding and the service provider provide insights into the institutional arrangement of health management systems, since public providers are present in both centralist and decentralized systems. Moreover, there are only a few systems based on only one of these types of relationships, since in many member states mixed public and private services are provided regardless of the source of funding.

"Decentralization" and "devolution" are only two of the indicators used by the OECD in its grouping exercise, which highlights the institutional characteristics of health management systems in relation to efficiency, and they are not decisive, since in the same group both centralist and decentralized health management systems can be found (for example, group 6 includes Ireland and Italy, characterized respectively by a centrally controlled system, the former, and by decentralized management, the latter). Moreover, these indicators refer exclusively to the

[51] Hospitals in the 27 Member States of the European Union - Hope & Dexia, 2009
[52] [ibidem]

decision-making autonomy of sub-national governments with respect to key issues pertaining to health spending.

On the other hand, it appears that there is a correlation between types of hospital governance and the level of decentralization of health management systems.

In line with the objectives of this study, the proposed typology is based on a series of dimensions, directly or indirectly related to the classifications already illustrated, but all characterized by an evident regional and/or local contribution.

Criteria considered

To define the typology of health management systems, considering their territorial organization, the following criteria were considered:

1. Presence/absence of local and regional government responsibility for financing health care spending and degree of financing of health care at the sub-national level, as a percentage of total sub-national public sector spending.
2. Presence/absence of powers/responsibilities of local and regional authorities with respect to the following functions: health care legislation, planning and delivery (implementation) of health care services.
3. Ownership and/or management of health care facilities, particularly hospitals, by local and regional authorities.

Criterion 1: Financing of health care by local and regional authorities

Public spending by local and regional authorities to finance health care delivery is an indicator of active involvement in the operation of health care management systems; in cases where funds are raised locally through tax or other levies, the role of financing also presumably highlights a level of autonomy with respect to spending. In addition to responsibility for financing health care spending, the level of funding was also considered.

Criterion 2: Powers and responsibilities of local and regional authorities about legislation, planning and implementation in the health sector

The presence/absence of powers and responsibilities in relation to the functions indicated is clearly and directly linked to the level of decentralization of healthcare management systems.

Criterion 3: Ownership and management of healthcare facilities by local and regional authorities

The transfer of powers in the hospital system from the central to the local level is a step toward decentralization. Ownership of facilities generally entails responsibilities in terms of financing and, in most cases, management functions that can be performed directly by the entities themselves or contracted out to service providers.

1.3.3 Conclusions

The conducted study reveals several differences between the two healthcare systems under examination, above all as regards the role played by local and regional players.

The analysis of the healthcare frameworks relative to the two countries shows how the Italian model is essentially a Beveridge-type model, while the Greek model is a mixed model, in which insurance systems and direct payments play a significant role.

About the institutional aspects considered and based on what emerges from the study, Italy and Greece belong to two different groups, respectively 6 and 3.

Finally, in Italy, the hospital management system appears to be decentralized, while Greece presents a "devolved" hospital management system.

This evidence is summarized in the following table:

	ITALY	GREECE
Funding mechanism	Beveridge model	Mixed public/private model
Institutional aspects of health systems	Group 6	Group 3
Hospital management system	Decentralized	“Devolved”

As far as the role of local and regional authorities is concerned, and based on the criteria adopted, it emerges that (criterion 1) in Italy, the territorial authorities are entrusted with the responsibility for the financing of health care, with high levels of financing for medicines, apparatus and equipment, outpatient, hospital and public health services, and research and development activities related to health care, something not found in Greece.

On the other hand, about the powers and responsibilities of local and regional authorities for legislation, planning and implementation in the health sector (Criterion 2), the following emerges:

- Legislation:
  i. In Italy, local and regional authorities have legislative power for health-related issues.
  ii. In Greece, legislative power for health-related matters lies exclusively with the central levels of governance.
- Planning:
  i. In Italy, local and regional authorities are entrusted with the responsibility for deciding policy or programming in the health sector.
  ii. In Greece, this responsibility is devolved only partially to local authorities and only at the planning level.
- Implementation:
  i. In Italy, as well as in Greece, local and regional authorities perform direct implementation functions of different kinds and at different levels, albeit with varying degrees of freedom.

Finally, about the ownership and management of healthcare facilities by local and regional authorities (criterion 3), the following emerges:

- Ownership:
  i. In Italy, health facilities belong to local and regional authorities.
  ii. In Greece, health facilities belong to the central government.
- Management:
  i. In Italy, as owners, local and regional authorities are responsible for the management of health facilities.
  ii. In Greece, local and regional authorities are responsible for the management of health facilities without being the owners.

In conclusion, regarding the comparative analysis of the two healthcare systems, it can be inferred from the study that:

ITALY

►Highly decentralized system, in which responsibilities are transferred to the regions

►Provides almost universal coverage, mostly free at the point of care

►Health spending is financed primarily by public funds, through taxation by the state and regions

►Provides mixed public and private services

GREECE

►Centralized system, although structured at the territorial (regional) level

►Provides theoretically universal coverage, but in practice the system is not yet fully effective

►Health spending is financed both by public funds, through social security and tax revenues, and by private funds

►Provides mixed public and private services.

Italy, therefore, presents a de facto "regional health management system", i.e., a management system in which responsibilities for regulation, operation and even co-financing are delegated to regional administrations. Greece, on the other hand, presents a centralized health management system at the national level, but structured at the territorial level in which most of the competencies are attributed to the central government, although implementation takes place at the territorial level through bodies or agencies representing the central administration; in addition, local and regional authorities manage the health care structures.

2.

LEGAL FRAMEWORK **ON PRIVACY AND PERSONAL DATA PROTECTION**

As above mentioned, the analysis of this report is not intended to be in any way exhaustive of the specificities of the two systems, neither from data protection perspective. The main objective is to be able to identify and outline the key elements and consequent application methods to enable technology transfer of the solution.

2.1 European framework

The EU Charter of Fundamental Rights[53] (art. 8) and the Article 16(1) of the Treaty on the Functioning of the European Union (TFEU[54]) stipulate that all EU citizens have the right to protection of their personal data. Such data must be processed fairly for specified purposes and based on the consent of the person concerned or some other legitimate basis laid down by law. Furthermore, everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.

Following this very high level acts, the General Data Protection Regulation (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, so called GDPR), applicable since 25 May 2018, strengthens the individual's right to personal data protection, reflecting the nature of data protection as a fundamental right for the European Union.

It provides for a single set of rules directly applicable in all the Member States legal orders and guarantees the free flow of personal data between EU Member States, therefore improving business opportunities.

Pursuant art. 3, the Regulation applies to the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union, regardless of whether the processing takes place in the Union or not[55].

First, we should clarify the meaning of some terms, accordingly to GDPR art. 4:

'personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

[53] CHARTER OF FUNDAMENTAL RIGHTS OF THE EUROPEAN UNION (2012/C 326/02), available https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012P/TXT&from=EN

[54] Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union - 2012/C 326/01, available https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT

[55] See Guidelines 3/2018 on the territorial scope of the GDPR (Article 3) – version adopted after public consultation, Available https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-32018-territorial-scope-gdpr-article-3-version_en

Among personal data there are different types, especially the following, relevant in healthcare sector:

'data concerning health' means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status.

'genetic data' means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question.

'biometric data' means personal data resulting from specific technical processing relating to the physical, physio- logical or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data.

Regarding the different players, acting in the data protection scenario, we can find:

'**controller'** which is the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law; where two or more controllers jointly determine the purposes and means of processing, they shall be joint controllers.

According to art. 24, the controller, considering the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for the rights and freedoms of natural persons, shall implement appropriate technical and organisational measures to ensure and to be able to demonstrate (principle of accountability) that processing is performed in accordance with Data Protection Regulation. Those measures shall be reviewed and updated where necessary[56].

'**processor'** means a natural or legal person, public authority, agency, or other body which processes personal data on behalf of the controller.

Regarding the activity carried out by a data controller or a processor, '**processing'** means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

[56] See Guidelines 07/2020 on the concepts of controller and processor in the GDPR, version 2.0 adopted 07.07.2021, available https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-072020-concepts-controller-and-processor-gdpr_en

GDPR art. 5 sets, also, some fundamental principles for correct and lawfull processing of personal, which should be:

(a) processed lawfully, fairly and in a transparent manner in relation to the data subject (**principle of lawfulness, fairness, and transparency**[57]).

(b) collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes (**principle of purpose limitation**).

(c) adequate, relevant, and limited to what is necessary in relation to the purposes for which they are processed (**principle of data minimization**).

(d) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased, or rectified without delay (**principle of accuracy**).

(e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organizational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject (**principle of storage limitation**).

(f) processed in a manner that ensures appropriate security of the personal data, including protection against unauthorized or unlawful processing and against accidental loss, destruction, or damage, using appropriate technical or organizational measures (**principle of integrity and confidentiality**).

Last principle, but not for importance, is **principle of accountability** which states that the controller shall be responsible for and be able to demonstrate compliance with all other principles listed above.

Another important couple of principles are those set in art. 25, where is stated that taking into account the state of the art, the cost of implementation and the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for rights and freedoms of natural persons posed by the processing, the controller shall, both **at the time of the determination of the means** for processing and at **the time of the processing itself**, implement appropriate technical and organisational measures, such as pseudonymisation, which are designed to implement data-protection principles, such as data minimisation, in an effective manner and to integrate the necessary safeguards into the processing in order to meet the

[57] See Guidelines on Transparency under Regulation 2016/679 (wp260rev.01), available https://ec.europa.eu/newsroom/article29/items/622227/en

requirements of the Regulation and protect the rights of data subjects. These principles are, respectively, called **Privacy by design and Privacy by default**. Even Recital 78 of the GDPR states that controllers should adopt internal policies and implement measures which meet, in particular, the principles of data protection by design and data protection by default to demonstrate compliance with the GDPR itself[58].

In execution of principle of lawfulness, art. 6 states that every processing activity should be carried out only on a legal basis.

Legal basis for lawfulness of processing of personal data, set in art. 6, are:

- **consent** to the processing of his or her personal data for one or more specific purposes.
- processing is necessary for the **performance of a contract** to which the data subject is party or to take steps at the request of the data subject prior to entering into a contract.
- processing is necessary for compliance with a legal obligation to which the controller is subject.
- processing is necessary in order to **protect the vital interests** of the data subject or of another natural person.
- processing is necessary for the performance of a task carried out in the **public interest or in the exercise of official authority** vested in the controller.
- processing is necessary for the purposes of the **legitimate interests** pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, where the data subject is a child.

It must be noted that the last legal basis shall not apply to processing carried out by public authorities in the performance of their tasks.

Generally, as prescribed in art. 9, which refers to personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation, processing this kind of special categories of data is prohibited.

Nevertheless, this prescription will not apply if:

(a) the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition above referred may not be lifted by the data subject.

(b) processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller or of the data subject in the field of employment and social security and

[58] See Guidelines 4/2019 on Article 25 Data Protection by Design and by Default, available https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-42019-article-25-data-protection-design-and_en

social protection law in so far as it is authorised by Union or Member State law or a collective agreement pursuant to Member State law providing for appropriate safeguards for the fundamental rights and the interests of the data subject.

(c) processing is necessary to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent.

(d) processing is carried out in the course of its legitimate activities with appropriate safeguards by a foundation, association or any other not-for-profit body with a political, philosophical, religious or trade union aim and on condition that the processing relates solely to the members or to former members of the body or to persons who have regular contact with it in connection with its purposes and that the personal data are not disclosed outside that body without the consent of the data subjects;

(e) processing relates to personal data which are manifestly made public by the data subject.

(f) processing is necessary for the establishment, exercise or defence of legal claims or whenever courts are acting in their judicial capacity.

(g) processing is necessary for reasons of substantial public interest, on the basis of Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

(h) processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards.

(i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy.

(j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

This said, a controller should take in account these fundamental duties, for a correct activity processing:

- choosing the valid legal basis (one or more); if consent is the chosen one, it should be freely given, specific, informed, unambiguous, and documented (art. 7)[59].
- properly informing data subjects providing information listed in GDPR art. 13 and art. 14.
- assuring that data subjects can easily exercise their rights as stated in art. 15 (Right of access), art. 16 (Right to rectification), art. 17 (Right to erasure ('right to be forgotten')[60]), art. 18 (Right to restriction of processing), art. 20 (Right to data portability)[61], art. 21 (Right to object); furthermore, the data subject shall have the right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her (art. 22)[62].
- maintaining a record of processing activities under its responsibility, as prescribed by art. 30[63]. That record shall contain all of the following information:
    - the name and contact details of the controller and, where applicable, the joint controller, the controller's representative, and the data protection officer.
    - the purposes of the processing.
    - a description of the categories of data subjects and of the categories of personal data.
    - the categories of recipients to whom the personal data have been or will be disclosed including recipients in third countries or international organizations.
    - where applicable, transfers of personal data to a third country or an international organization, including the identification of that third country or international organization and, in the case of transfers referred to in the second subparagraph of Art. 49(1), the documentation of suitable safeguards.
    - where possible, the envisaged time limits for erasure of the different categories of data.
    - where possible, a general description of the technical and organizational security measures referred to in Art. 32.

[59] See Guidelines 05/2020 on consent under Regulation 2016/679, available https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-052020-consent-under-regulation-2016679_en

[60] See Guidelines 5/2019 on the criteria of the Right to be Forgotten in the search engines cases under the GDPR (part 1), available https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-52019-criteria-right-be-forgotten-search-engines_en

[61] See Guidelines on the right to data portability under Regulation 2016/679, WP242 rev.01, available https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-right-data-portability-under-regulation-2016679_en

[62] See Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679 (wp251rev.01), available https://ec.europa.eu/newsroom/article29/items/612053/en

[63] See Position Paper on the derogations from the obligation to maintain records of processing activities pursuant to Article 30(5) GDPR, available https://edpb.europa.eu/our-work-tools/our-documents/guidelines/position-paper-derogations-obligation-maintain-records_en

- Appointing a Data Protection Officer as prescribed by art. 37[64], which is in charge of the following tasks (art. 39):
    - to inform and advise the controller or the processor and the employees who carry out processing of their obligations pursuant to this Regulation and to other Union or Member State data protection provisions.
    - to monitor compliance with this Regulation, with other Union or Member State data protection provisions and with the policies of the controller or processor in relation to the protection of personal data, including the assignment of responsibilities, awareness-raising and training of staff involved in processing operations, and the related audits.
    - to provide advice where requested as regards the data protection impact assessment and monitor its performance pursuant to Article 35.
    - to cooperate with the supervisory authority.
    - to act as the contact point for the supervisory authority on issues relating to processing, including the prior consultation referred to in Article 36, and to consult, where appropriate, with regard to any other matter.
- Establishing a procedure in order to comply with art. 33 concerning data breach notification to competent supervisor authority, due in 72 hours after having become aware of breach[65].
- Carrying out a Data Protection Impact Assessment as prescribed by art. 35.
- Implementing appropriate technical and organizational measures to ensure a level of security appropriate to the risk, as prescribed by art. 32, taking into account the state of the art, the costs of implementation and the nature, scope, context, and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, including inter alia as appropriate:[66]
    - the pseudonymization and encryption of personal data.
    - the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services.
    - the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident.

[64] See Guidelines on Data Protection Officers ('DPOs') (wp243rev.01), available https://ec.europa.eu/newsroom/article29/items/612048/en
[65] See Guidelines on Personal data breach notification under Regulation 2016/679, WP250 rev.01, available https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-personal-data-breach-notification-under_en
[66] See Guidelines on Data Protection Impact Assessment (DPIA) (wp248rev.01), available https://ec.europa.eu/newsroom/article29/items/611236

- a process for regularly testing, assessing, and evaluating the effectiveness of technical and organizational measures for ensuring the security of the processing.

- Giving instructions to the possible processor and any person who has access to personal data acting under the authority of the controller.
- If processing is to be carried out on behalf of a controller, as prescribed by art. 28, the controller shall use only processors providing sufficient guarantees to implement appropriate technical and organizational measures in such a manner that processing will meet the requirements of the Regulation and ensure the protection of the rights of the data subject. The Processing by a processor shall be governed by a written contract or other legal act.
- Transferring personal data to third countries or international organizations, only in accordance with art. 44 and following articles, concerning adequacy decision, appropriate safeguards, Binding corporate rules, etc.

Beside this General Regulation, another act should be taken in account. It's the so called ePrivacy Directive[67], whose Article 5 states that storing of information on the user's device or gaining access to the information already stored is allowed only if (i) the user has given consent or (ii) the storage and/or access is strictly necessary for the information society service (e.g., the app) explicitly requested (i.e., installed and activated) by the user.

In this context, the COVID-19 pandemic has created unprecedented challenges for the Union and the Member States, their healthcare systems, way of life, economic stability, and values. Digital technologies and data have a valuable role to play in fighting the COVID-19 crisis. Mobile applications typically installed on smartphones (apps) can support public health authorities at national and EU level in monitoring and containing the COVID-19 pandemic and are particularly relevant in the phase of lifting containment measures[68].

In fact, since the world is facing a significant public health crisis that requires strong responses, which, as we are actually experiencing, have an impact beyond the emergency, automated data processing and digital technologies can be key components in the fight against COVID-19.

Governments and private actors are turning toward the use of data driven solutions as part of the response to the COVID-19 pandemic, raising numerous privacy concerns.

Anyway, the data protection legal framework was designed to be flexible and as such, is able to achieve both an efficient response in limiting the pandemic and protecting fundamental human rights and freedoms[69].

[67] DIRECTIVE 2002/58/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), available https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0058&from=EN

[68] COMMUNICATION FROM THE EU COMMISSION Guidance on Apps supporting the fight against COVID 19 pandemic in relation to data protection,
available https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0417(08)&from=EN

[69] Statement of the EDPB from 19.3.2020 on the general processing of personal data in the context of the COVID-19 outbreak

Data protection rules (such as the GDPR), in fact, do not hinder measures taken in the fight against the COVID - 19 pandemic, because the GDPR is a broad piece of legislation and provides for several provisions that allow to handle the processing of personal data for the purpose of scientific research connected to the COVID-19 pandemic in compliance with the fundamental rights to privacy and personal data protection. The GDPR also foresees a specific derogation to the prohibition of processing of certain special categories of personal data, such as health data[70].

When processing of personal data is necessary for managing the COVID-19 pandemic, data protection is indispensable to build trust, create the conditions for social acceptability of any solution, and thereby guarantee the effectiveness of these measures.

The identification of who is deciding on the means and purposes of the data processing (the data controller) is crucial in order to establish who is responsible for compliance with the EU personal data protection rules, and in particular: who should provide information to the individuals who download the app about what is going to happen with their personal data (already existing or to be generated through the device, such as a smartphone, on which the app is being installed), what their rights will be, who will be responsible in the case of data breach, etc. Given the sensitivity of the personal data at hand and the purpose of data processing described below, the Commission is of the view that the apps should be designed in such a manner that the national health authorities (or entities carrying out task in the public interest in the field of health) are the controllers (8). The controllers are responsible for the compliance with the GDPR (accountability principle) [71].

A determining factor for individuals to trust the apps is demonstrating that they remain in control of their personal data. To ensure this, the Commission considers that in particular the following conditions should be met:

- The installation of the app on their device should be voluntary and without any negative consequences for the individual who decides not to download/use the app.
- health authorities should provide the individuals with all necessary information related to the processing of his or her personal data (in line with Articles 12 and 13 of the GDPR and Article 5 of the ePrivacy Directive).
- the individual should be able to exercise his/her rights under the GDPR (in particular, access, rectification; deletion). Any restriction of the rights under the GDPR and ePrivacy Directive should be in accordance with these acts and be necessary, proportionate and provided in the legislation.

available at https://edpb.europa.eu/our-work-tools/our-documents/other/statement-processing-personal-data-context-covid-19-outbreak_en

[70] European Data Protection Board (EDPB) Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak, Adopted on 21 April 2020

[71] See COMMUNICATION FROM THE EU COMMISSION Guidance on Apps supporting the fight against COVID 19 pandemic in relation to data protection
available https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0417(08)&from=EN

- the apps should be deactivated at the latest when the pandemic is declared to be under control; the deactivation should not depend on de-installation by the user.

As said above, all processing of personal data concerning health must comply with the principles relating to processing set out in Article 5 GDPR and with one of the legal grounds and the specific derogations listed respectively in Article 6 and Article 9 GDPR for the lawful processing of this special category of personal data.

According to EDPB[72], the consent of the data subject, collected pursuant to Article 6 (1) (a) and Article 9 (2) (a) GDPR, may provide a legal basis for the processing of data concerning health in the COVID-19 context. However, it has to be noted that all the conditions for explicit consent, particularly those found in Article 4 (11), Article 6 (1) (a), Article 7 and Article 9 (2) (a) GDPR, must be fulfilled. Notably, consent must be freely given, specific, informed, and unambiguous, and it must be made by way of a statement or "clear affirmative action". As stated in Recital 43, consent cannot be considered freely given if there is a clear imbalance between the data subject and the controller. It is therefore important that a data subject is not pressured and does not suffer from disadvantages if they decide not to give consent.

2.2 Italian framework

Republic of Italy has implemented the General Data Protection Regulation (Regulation (EU) 2016/679) ('GDPR') by amending the italian Privacy Code (Legislative Decree n. 196/2003), which contains provisions to bring national legislation in line with the General Data Protection Regulation (Regulation (EU) 2016/679) and repealing sections directly in conflict with the GDPR. This was a due step in consideration that provisions contained in the GDPR are preminent in respect of internal ones, and these would have been implicitly repealed, creating potential misunderstand in interpretation. The amendment activity was performed by Legislative Decree No. 101 of 10 August 2018, which modified the text of the Legislative Decree n. 196/2003 in order to adapt it to GDPR.

Supervision on the application of the Regulation is carried out by the Italian Data Protection Authority ("Garante"), which, among other things, receives data subject complaints, provides specific data protection measures for data controllers and data processors, and adopts guidelines to assist organisations in complying with the GDPR.

One of the most important provision of the internal regulation is art. 2-ter of the Privacy Code, which states that personal data may be communicated between controllers for the performance of a task carried out in the public interest or in the exercise of official authority only if either: this is provided either by a law or, where so provided for by a law, or a regulation; or this is necessary

[72] Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak. Adopted on 21 April 2020

to carry out tasks in the public interest or to fulfil institutional duties and the Garante has been previously informed.

Furthermore, pursuant to Art. 2-ter, 1-bis of the Privacy Code, introduced by Article 9 of Decree Law No. 139 of 8 October 2021, public administrations, independent authorities, as well as public-controlled companies are always allowed to process personal data if necessary for the performance of a task carried out in the public interest or for the exercise of public powers granted to the same. Where the purpose of the processing is provided neither by a law nor a regulation, the purpose of the processing is indicated by the same administration/the state-controlled company in line with the task performed or the powers exercised. It must be noted that this provision applies to generic personal data only and not to special categories.

Processing necessary for substantial public interest reasons

Art. 2-sexies of the Privacy Code, which addresses the exceptions set forth by Article 9(1)(g) GDPR, provides that the processing of special categories of personal data for reasons of substantial public interest shall be carried out only if both pertaining to the areas indicated in Article 2-sexies of the Privacy Code and it is provided under EU or Italian laws or, where so provided for by a law, or regulations.

Processing health data

Art. 110 of the Privacy Code permits the processing of health data in the medical, biomedical, and epidemiological fields without data subject consent for archiving in the public interest, scientific or historical research. Such processing is permitted if either EU or Italian law or, where so provided for by a law, regulation authorizes the scientific research and the controller performs a DPIA which is made publicly available, or if informing data subjects involves disproportionate effort or is likely to render impossible or seriously impair the achievement of the research purposes (under the conditions set forth under the Code). Finally, Article 110(2) of the Code provides that controllers processing personal data in these circumstances that receive a data subject rectification or completion request pursuant to Article 16 GDPR must record the request without modifying the data if the rectified or completed data do not produce significant effects on the outcome of the research.

Processing of genetic, biometric, and health data

Article 2-septies of the Code provides that the processing of genetic, biometric, and health data shall be carried out only if both the processing complies with Article 9(2) GDPR and certain security measures (such as encryption, pseudonymization, and minimization) are implemented. Such security measures will be established by the “Garante” on, at least, a two-year basis. However, so far the Italian authority has not adopted new safeguards since the GDPR took effect.

Pandemic period

During pandemic, Decree Law n.18/20, converted in Law n. 27/20, was enacted to tackle specific needs in data protection processing. Its art. 17-bis states:

1. Until the end of the state of emergency decided by the Council of Ministers on 31 January 2020, for reasons of public interest in the field of public health and, in particular, to ensure protection from the public health emergency of a cross-border nature caused by the spread of COVID-19 by means of appropriate prophylaxis measures and to ensure the diagnosis and health care of the infected persons or the emergency management of the National Health Service, in accordance with Article 9(2)(g), (h) and (i) and Article 10 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 and Article 2-sexies(2)(t) and (u) of the Code referred to in Legislative Decree no. 196 of 30 June 2003. 196, the entities operating in the National Civil Protection Service, referred to in Articles 4 and 13 of the code referred to in Legislative Decree 2 January 2018, no. 1, and the implementing entities referred to in Article 1 of the Order of the Head of the Civil Protection Department no. 630 of 3 February 2020, as well as the offices of the Ministry of Health and the Higher Institute of Health, the public and private facilities operating within the National Health Service and the entities deputed to monitor and ensure the execution of the measures ordered under Article 2 of the Decree-Law no. 25 March 2020, no. 19, also with a view to ensuring the most effective management of personal data flows and interchange, may carry out processing, including communication between them, of personal data, also relating to Articles 9 and 10 of Regulation (EU) 2016/679, which are necessary for the performance of the functions assigned to them in the context of the emergency caused by the spread of COVID-19.
2. The communication of personal data to public and private entities, other than those referred to in paragraph 1, as well as the dissemination of personal data other than those referred to in Articles 9 and 10 of the aforementioned Regulation (EU) 2016/679, shall be carried out in cases where they are indispensable for carrying out the activities related to the management of the ongoing health emergency.
3. The processing of personal data referred to in paragraphs 1 and 2 shall be carried out in compliance with the principles set out in Article 5 of the aforementioned Regulation (EU) 2016/679, adopting appropriate measures to protect the rights and freedoms of the data subjects.
4. Having regard to the need to balance the requirements of managing the ongoing health emergency with the need to safeguard the confidentiality of the persons concerned, the persons referred to in paragraph 1 may grant the authorizations referred to in article 2-quaterdecies of the code referred to in Legislative Decree no. 196 of 30 June 2003, in a simplified manner, also verbally.
5. In the current emergency context, pursuant to article 23, paragraph 1, letter e) of the aforementioned Regulation (EU) 2016/679, without prejudice to the provisions of article 82 of

the code referred to in Legislative Decree no. 196 of 30 June 2003, the entities referred to in paragraph 1 of this article may omit the information referred to in article 13 of the same Regulation or provide simplified information, subject to oral communication to those concerned by the limitation.

6. At the end of the state of emergency referred to in the resolution of the Council of Ministers of 31 January 2020, the subjects referred to in paragraph 1 shall adopt appropriate measures to bring the processing of personal data carried out in the context of the emergency within the scope of ordinary competences and rules governing the processing of personal data.

2.3 Hellenic framework

Hellenic Republic has enacted Law NO. 4624 published on 29 August 2019, regarding Hellenic Data Protection Authority (HDPA), measures for implementing Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data, and transposition of Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016, and other provisions.

The purposes of the aforementioned Law, as far as this is concerned, are stated in art. 1:

(a) to replace the legislative framework governing the establishment and operation of the Data Protection Authority.

(b) to adopt measures for implementing Regulation (EU) 2016/679.

(c) to transpose Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences, or the execution of criminal penalties, and the free movement of such data, and repealing Council Framework Decision 2008/977/JHA.

The provisions of the Law are applicable to the processing of personal data wholly or partly by automated means and to the processing other than by automated means of such data, which form part of a filing system or are intended to form part of a filing system carried out by public bodies or private bodies, unless the processing is carried out by a natural person in the course of a purely personal or household activity.

Article 4 contains some definitions, for the purposes of the Law, i.e.:

(a) '**public body**' means public authorities, independent and regulatory administrative authorities, legal persons governed by public law, first and second-level local government authorities with their legal persons and their legal entities, state-owned or public undertakings and agencies, legal persons governed by private law which are state-owned or regularly receive at least 50% of their annual budget in the form of state subsidies, or their administration is designated by the state.

(b) ‘**private body**’ means any natural or legal person or group of persons without legal personality which does not fall within the definition of a ‘public body’.

(c) ‘**competent supervisory authority**’ means the Hellenic Data Protection Authority (hereinafter: the Authority).

Legal basis for the processing of personal data by public bodies are set in Art. 5:

Public bodies may process personal data where processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority conferred on the controller.

In CHAPTER C, supplementary measures for the implementation of the GDPR regarding the processing of personal data are provided.

They concern the consent of minors; it shall be lawful where the minor is at least 15 years old and gives his or her consent. Where the minor is below the age of 15 years, the processing is lawful only if consent is given by the legal representative of the minor.

Pursuant art. 22, when processing of special categories of personal data, by way of derogation from Art. 9(1) of the GDPR, public and private bodies are allowed, if necessary:

(a) for the purpose of exercising the rights arising from the right to social security and social protection, and for fulfilling the obligations arising therefrom.

(b) for the purposes of preventive medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or the management of health or social care systems or pursuant to a contract with a health professional or other person who is subject to a duty of professional secrecy or supervised by him/her.

(c) for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, in addition to the measures referred to in the second subparagraph of paragraph 3, the provisions ensuring professional secrecy provided for in a law or code of conduct must in particular be complied with.

By way of derogation from Article 9(1) of the GDPR, public bodies within the meaning of Article 9(1) of the GDPR are allowed to process of special categories of personal data, where it is:

(a) strictly necessary for reasons of essential public interest.

(b) necessary for the prevention of major threats to national or public security; or

(c) necessary for taking humanitarian action, in which case the interests in the processing override the interests of the data subject.

In the aforementioned cases, all appropriate and specific measures shall be taken to safeguard the interests of the data subject. Taking into account the state of the art, the cost of implementation and the nature, scope, context, and purposes of processing as well as the risks

of varying severity for rights and freedoms of natural persons posed by the processing, such measures may include in particular:

(a) technical and organizational measures to ensure that the processing complies with the GDPR.

(b) measures to ensure that ex post verification and determination of whether and by whom personal data have been entered, amended or removed is possible.

(c) measures to raise awareness among staff involved in the processing.

(d) access rights restrictions to controllers and processors.

(e) pseudonymization of personal data.

(f) encryption of personal data.

(g) measures to ensure the ability, confidentiality, integrity, availability and resilience of processing systems and services relating to the processing of personal data, including the ability to rapidly restore the availability and access in the event of a physical or technical incident.

(h) procedures for regularly testing, assessing, and evaluating the effectiveness of technical and organizational measures for ensuring the security of the processing.

(i) specific rules to ensure compliance with this Law and the GDPR in case of transfer or processing for other purposes.

(j) designation of a DPO.

Article 24 sets rules for processing of personal data for other purposes by public bodies, stating that the processing of personal data by public bodies for a purpose other than that for which they were collected shall be permitted where such processing is necessary for the performance of the tasks assigned to them and provided that it is necessary:

(a) for the verification of the information provided by the data subject because there are reasonable grounds for believing that such information is incorrect.

(b) for the prevention of risks to national security, defence or public security, or for securing tax and customs revenue.

(c) or the prosecution of criminal offences.

(d) for the prevention of serious harm to the rights of another person.

(e) for the production of official statistics.

At last, art. 26 set rules when public bodies transfer of personal data. In this case, the transfer of personal data by a public body to another public body shall be permitted, where necessary for the performance of the tasks of the transmitting body or the third party to whom the data were transferred, provided that the conditions enabling the processing under Article 24 are met. The third party to whom the data have been transferred shall process them only for the purpose for

which they were transferred. Processing for other purposes shall be permitted only if the conditions laid down in Article 24 are met.

Public bodies shall be permitted to transfer personal data to private bodies, provided that:

(a) the transfer is necessary for the performance of the tasks of the body transferring the data, and the conditions set out in Article 24 are met.

(b) the third party to whom the data have been transferred has a legitimate interest in being aware of the transfer, and the data subject does not have a legitimate interest in not transferring the data relating to him or her; or

(c) the processing is necessary for the establishment, exercise or defence of legal claims and the third party has pledged to the public body which has transferred the data that he or she will process the data only for the purpose for which they were transmitted. Processing for other purposes shall be permitted if the transfer is authorised in accordance with paragraph 1 and the transmitting body has consented to the transfer.

The transfer of special categories of personal data within the meaning of Article 9(1) of the GDPR shall be permitted provided that the conditions set out in paragraph 1 or paragraph 2 are met and one of the exemptions in Article 9(2) of the GDPR or in accordance with Article 22 hereof applies.

The Hellenic Data Protection Authority is a constitutionally established independent public authority, which has as its mission the supervision of the application of the General Data Protection Regulation (GDPR), national laws 4624/2019 and 3471/2006, as well as other regulations concerning the protection of the individual from the processing of personal data.

During pandemic, Hellenic Data Protection Authority, recognizing the special circumstances in the area of protection of personal data and respect for the fundamental rights and freedoms of citizens, created by the extremely urgent and unforeseen need to address the negative consequences of the emergence of the COVID-19 coronavirus, has enacted GUIDELINES 1/2020, concerning Processing of personal data in the context of the management of COVID-19.

One of the most important provision fo the Guidelines is that to the extent that personal data are processed by the competent public authorities for the purpose of taking the necessary measures, where appropriate, in accordance with the relevant PNR, to prevent the risk of occurrence or spread of coronavirus which may have serious public health implications, the GDPR shall apply under the conditions set out in points 1 and 2 above. 1(c) (processing is necessary for compliance with a legal obligation of the controller), (d) (processing is necessary to safeguard the vital interests of the data subject or another natural person) and (e) (processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller) and Article 9(1)(c) (processing is necessary for compliance with a legal obligation of the controller), (d) (processing is necessary to safeguard the vital interests of the data subject or another natural person) and (e) (processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the

controller). 2(b) (processing is necessary for the performance of obligations and for the exercise of specific tasks in the exercise of official authority). rights of the controller or of the data subject in the field of labor law and social security and social protection law), e' (processing relates to personal data which have been manifestly made public by the data subject), h' (processing is necessary for the purposes of a preventive or occupational medical assessment of the fitness for work of the worker, medical diagnosis, the provision of health or social care or treatment or the management of health and social welfare activities, or for the purposes of the processing of personal data which are manifestly made public by the data subject), f' (processing is necessary for the purposes of the processing of personal data which are manifestly made public by the data subject), g' (processing is necessary for the purposes of the processing of personal data which are manifestly made public by the data subject). 4624/2019 in accordance with the Authority's Opinion No. 01/2020, in conjunction with any more specific legislation on the protection of personal data, including the relevant provisions of the PNR and the ministerial decisions implementing them.

2.4 Comparative Analysis

The study reveals only some differences between the two health systems under review, from a data protection point of view.

In fact, the common European framework establish a set of principles and rules directly applicable in both legal systems (art. 3 GDPR), with only minor personalization due to the freedom that the GDPR gives member states regarding health data, detectable from the above analysis.

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