S H A P E S

Smart and **H**ealthy **A**geing
through **P**eople **E**ngaging in supporting **S**ystems

D8.3 – Assessing the Regulatory Frameworks Facilitating Pan-European Smart Healthy Ageing

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Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations

Acronym	Full Term
AI	Artificial intelligence
CFR	Charter of Fundamental Rights
CJEU	Court of Justice of the European Union
CRPD	United Nations Convention on the Rights of Persons with Disabilities
DMA	Digital Markets Act
DSA	Digital Services Act
EDF	European Disability Forum
EIP-AHA	European Innovation Partnership on Active and Healthy Ageing
EPSR	European Pillar of Social Rights
ERA	European Research Area

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EU	European Union
GDPR	General Data Protection Regulation
IoT	Internet of Things
IVDR	In Vitro Diagnostic Medical Devices Regulation
LTC	Long-term care
MDR	Medical Devices Regulation
NCPs	National Contact Points
PRD	Patients' Rights Directive
R&D	Research and development
R&I	Research and innovation
SGEI	Services of General Economic Interest
SSGI	Social Services of General Interest
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
TPWCD	Directive on Transparent and Predictable Working Conditions
WHO	World Health Organisation
WLBD	Work Life Balance Directive

Keywords

EU Health law, EU Internal Market Law, Free Movement of people, EU law of new health technologies, New Health Technologies, Artificial Intelligence, Stakeholders, Marketplace.

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Executive Summary

Work Package (WP) 8 focuses on the SHAPES Action's ethical and legal dimensions, tackling the crosscutting legal issues encompassed by SHAPES.

As part of WP8, this **Deliverable (D8.3) assesses the Regulatory Frameworks Facilitating Pan-European Smart and Healthy Ageing**. It discusses the various **legal dimensions associated with features of the SHAPES project**, including the European Union (EU) regulatory frameworks relevant to smart digital solutions and users engaging with the SHAPES digital solutions and platform. In that regard, D8.3. addresses the right to health of older people and people with disabilities and their free movement rights, and the freedom of caregivers and service providers to provide services across internal EU borders within the EU internal market. This Deliverable is **complemented by an annex (D8.3.1)** that focuses on the EU regulatory framework for the SHAPES Integrated Platform. This annex (D8.3.1) is attached at the end of this document.

When it comes to the right to health and its realisation within the EU, the primary legislative point of reference is the EU's Patients' Rights Directive, which provides for the right of individual patients to obtain medical treatment in a Member State different from their home country (or the country in which they are socially insured) and to receive reimbursement for medical expenses incurred abroad from their home. The project also considers caregivers within the EU. Furthermore, cross-border healthcare encompasses the right of health service providers to provide services across internal EU borders within the EU internal market. Hence, this D8.3 addresses free movement provisions and EU legislation impinging on the provision of services, such as public procurement legislation, State aid and competition rules, taking into account the Court of Justice of the European Union (CJEU) case law. While focusing on the EU legal framework, where appropriate national legislation implementing EU law is considered.

Further to the introductory section, this Deliverable provides an overview of the core competences of the EU that are relevant to the SHAPES Ecosystem and Platform. Then, this Deliverable summarises the regulatory framework supporting the SHAPES Integrated Care Platform, which is discussed thoroughly in D8.3.1. The deliverable moves on to examine relevant regulatory provisions related to the SHAPES users and stakeholders: namely, Care Recipients and Caregivers, and service providers. In this respect, the Deliverable questions if the current legislation can support the relevant stakeholders to work together to scale-up the Integrated Care Platform and digital solutions to facilitate cross-border health care delivery. The Deliverable assesses the rules underpinning the SHAPES Marketplace and governance models, questioning how the EU rules can support the co-creation and EU-wide distribution of affordable, effective and trustworthy solutions. Finally, the Deliverable concludes by providing recommendations on the regulatory framework needed to foster the large-scale deployment and adoption of digital solutions and new integrated care-services in Europe.

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It is beyond the scope of this research to discuss issues relating to copyright or other IP rights related to the digital solutions, consumer protection legislation, product liability and taxation of digital goods.

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1 Introduction

1.1 Aims of the Deliverable

The aims of Deliverable D8.3. are:

1) to identify and discuss the multifaceted EU regulatory framework that is relevant to the creation of pan-European systems for smart healthy ageing.
2) to assess the right of health service providers to provide services across internal EU borders within the EU internal market and the legislative supports for the delivery of smart digital solutions for relevant users.
3) to provide guidelines, including a set of priorities dedicated to standardisation and supporting key stakeholders to foster the large-scale deployment and adoption of digital solutions and new integrated-care services in Europe.

D8.3. contributes to the guidelines that WP8 will provide for the SHAPES project and solution (see Table 4 below). The specific D8.2 activity 'Baselining for Project Ethics' was completed in collaboration with WP8 in M6. This involved designing guidelines and templates for research integrity and for the ethics management of the SHAPES project.

The updated and final version of this deliverable D8.3 is to be provided in M42.

Table 4 - WP8 deliverables

Deliverable	Timetable	Focus and Content
Baseline for Project Ethics D8.2	M6	Provides guidelines and templates for research integrity and for the ethics management of the SHAPES project.
SHAPES Ethical Framework D8.4 and D8.14	M7 and M18	Provides ethical requirements for the SHAPES Integrated Care Platform (technology and services, user processes and training, business/governance and ecosystem models). It provides guidelines to develop SHAPES in compliance with common ethical standards. Legal frameworks for Smart and Healthy Ageing and for Privacy and Data Protection will be investigated in more detail later on in separate deliverables, D8.11 and D8.12.
SHAPES Data Management Plan 8.13	M6 + updated version in M24	Provides Data Management Plan for: 1) SHAPES solutions (data processed on the SHAPES platform) 2) SHAPES R&D process (research data collected and processed during the SHAPES project).
Regulatory Frameworks for Pan-European Smart and Healthy Ageing D8.3	M42	Analyses the extent to which current legal frameworks facilitate the creation of pan-European systems for healthy ageing. Considering the complexity and broad nature of this task, the analysis is spilt into a main Deliverable (D8.3 Assessing the

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		Regulatory Frameworks Facilitating Pan-European Smart Healthy Ageing) complemented by an annex (D8.3.1 The SHAPES Integrated Platform, the SHAPES DIGITAL Solutions in the EU Legal Context)
SHAPES Privacy and Data Protection Legislation and Impact Assessment D8.11 and D8.12	M24 and M48	Elaborates the privacy and data protection regulation (based on the initial requirements defined in D8.4) and provides Privacy and Data Protection Impact Assessments of the SHAPES solutions to be piloted.
Privacy and Ethical Risk Assessments D8.8 and D8.9	M12 and M24	Analyses risks and mitigation strategies and actions related to the ethical and privacy risks of the SHAPES solutions (technology and services, user processes and training, business/governance and ecosystem models.)

1.2 SHAPES Innovation Action

SHAPES Innovation Action (IA) is a pan-European endeavour seeking to build, pilot and deploy a large-scale, EU-standardised open platform. The integration of a broad range of technological, organisational, clinical, educational and societal solutions seeks to facilitate long-term healthy and active ageing and the maintenance of a high-quality standard of life (SHAPES 2019).

- ✓ SHAPES Integrated Care Platform is an open, EU-standardised platform based on four factors: home, behaviour, market and governance. Big data analytics and artificial intelligence (AI) analyse information pertaining to health, environment, lifestyle and individual needs, and create user profiles and deliver personalised solutions. Adherence to EU data protection rules ensures user privacy, safety, security, trust and acceptance.
- ✓ SHAPES Digital Solutions include assistive robots, eHealth sensors and wearables, Internet of Things (IoT)-enabled devices and mobile applications (apps).
- ✓ SHAPES Ecosystem is a network of relevant users and key stakeholders working together to scale-up the platform and digital solutions.
- ✓ SHAPES Marketplace seeks to connect demand-and-supply across health care delivery and to facilitate the co-creation of affordable, effective and trustworthy solutions. A dynamic catalogue of solutions and services allows the transparent expansion of the market offer, prevents vendor lock and enhances the competitiveness of the EU H&C industry.
- ✓ SHAPES Recommendations provide guidelines, a roadmap and an action plan, including a set of priorities dedicated to standardisation and to supporting key EU stakeholders to foster the large-scale deployment and adoption of digital solutions and new integrated-care services in Europe. This will be based on evidence-based results from SHAPES, i.e. the recognised added-value of the SHAPES platform to

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support Active and Healthy Ageing (AHA); extend independent, empowered and socially connected living; and improve the long-term sustainability of delivery systems in Europe (SHAPES 2019).

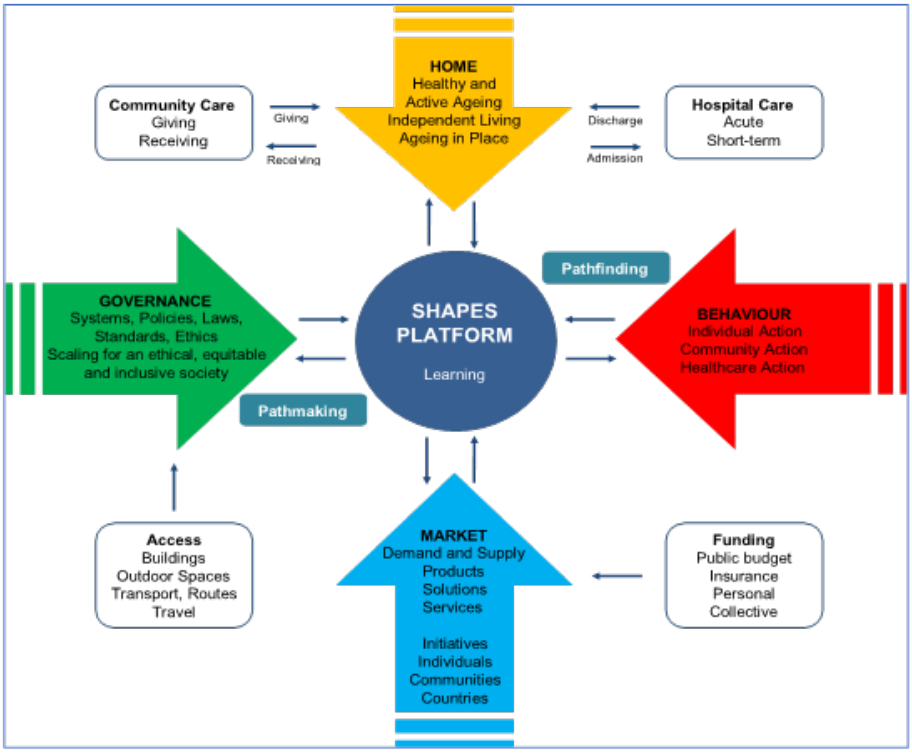

Figure 1 The SHAPES Integrated Care Platform (Figure sourced from SHAPES 2019, 85)

The SHAPES Platform is designed for all older individuals, whereby promoting inclusive, smart and healthy ageing. SHAPES emphasises that the home is much more than a house-space; it entails a sense of belonging, a place and a purpose in the community. Caregiving in the community is a crucial element of this support, along with older individuals feeling empowered to make decisions about how and from whom they receive care. The Platform is continually learning from the needs and preferences expressed in the active behaviour of different users. The Platform facilitates the cross-over of individual, community and clinical action-taking and integrating interaction. This high level of integration is key to the Platform user's sense of coherence; of being at home with it and ageing in place. SHAPES' interactions necessarily constitute a market for products, services and opportunities. This market must be managed to allow equitable access for all and utilising a range of funding mechanisms. SHAPES embraces market shaping to ensure fairness in access and competition in innovation, locally, nationally, across Europe and globally. The Platform is secure and reliable; allowing users the degree of anonymity they choose, while also providing them with the benefits of a population level evidence-based resource. SHAPES promotes ethical, equitable and inclusive values, which will be achieved through good platform governance. It promotes and scales-up good practices through directly engaging with local and national authorities, ensuring that the broader systems and policy context is

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contributing to and learning from the Platform; priming itself for innovation and evolution. The Platform facilitates pathfinding through the complexities of referral processes, clinical services, community supports, welfare entitlements and citizens' rights. It also facilitates path-making through, for instance, community engagement, contributing to local events, mapping age-friendly routes (SHAPES 2019). WP3 is tasked with identifying the optional form of governance and ownership of the Platform. Task 3.4 examines the different levels at which the Platform's ownership is distributed and identifies and analyses the suitability and appropriateness of governance models with older individuals' participation in mind. WP8 is mindful that the legal and ethical aspects of governance is an important aspect of this analysis and where appropriate cross-references to WP3 are noted in this Deliverable.

1.3 Scope and Structure of the Deliverable

Deliverable D8.3 supports other Work Packages, by examining the **overarching EU regulatory frameworks underpinning the SHAPES Integrated Care Platform** and scrutinises the ability of such frameworks to facilitate pan-European Smart and Health Ageing. A collaborative and flexible approach is taken to ensure that the scope and structure of the Deliverable reflects and complements other SHAPES Innovation Action.

As an EU funded project, SHAPES must endeavour to promote and protect fundamental rights, in line with Art. 2 Treaty on European Union (TEU) and Art. 6 TEU and the Charter of Fundamental Rights (CFR). It also aims to promote the rights of persons with disabilities as articulated in the UN Convention on the Rights of Persons with Disabilities (CRPD) (UN General Assembly, 2006), ratified by the EU by means of Council Decision 2010/48 (Council of the European Union, 2009a). Fundamental rights have been discussed in the Ethical Framework, and will be also discussed in this Deliverable, in relation to the Users.

The research focuses on the EU legal framework and does not discuss national legislation. It refers to the role of the EU (vis-à-vis its Member States) in laying down provisions that are relevant to the SHAPES IA in its components. This research moves beyond the mere description of how all forms of new technologies are regulated at an EU level, to question how different stakeholders' and users' rights are protected when engaging with the platform. D8.3. does not claim to provide an exhaustive discussion. Rather, it identifies relevant regulatory tools and their limitations, recognising, as Rissland *et al* (2003) put it, that the relationship between digital solutions and the law is a source of both problems and inspiration, and requires continuous updates.

D8.3 is structured as follows. Section 2 discusses the main EU competences relevant to SHAPES; namely EU competences pertaining to health, disability, and older persons. Respectively, the Deliverable details the extent of the EU's competence to legislate and how this competence has been exercised to date. The Deliverable continues to examine how the current legal framework supports the key aspects of the

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SHAPES Innovation Action and the Ecosystem of Platform users. In this regard, Section 3 sets out the legislative provisions underpinning the SHAPES Integrated Care Platform, which are discussed in further detail in D 8.3.1. Section 4 details the taxonomy of the SHAPES Platform users and examines the protection of fundamental rights particular to healthcare/care recipients, and caregivers and care service providers. Section 5, on the Marketplace, explores the scope for the cross-border provision of the SHAPES Digital Solutions, taking into account the EU provisions that regulate the internal market and will underpin the SHAPES Platform governance models. The final section offers recommendations as to the EU legal rubric required to support a large-scale, EU-standardised open platform for the provision of health and care services. AS noted above, the Deliverable is complemented by an annex (D8.3.1) that focuses on the relevant regulatory framework for the SHAPES Digital Solutions and Platform

1.4 Terminology

D8.3. recognises the importance of using a consistent terminology and in that connection, Table 5 below explicates the terms that will be used in this Deliverable D8.3. and in its annex (D8.3.1). The terminology aligns with, and is informed by, the regulatory frameworks identified.

Table 5 - Terminology

Term	Definition
Stakeholders	When referring to 'stakeholders' the Deliverable is referring to the project stakeholders as identified in the SHAPES proposal. The SHAPES stakeholders include: relevant users, public bodies and care providers, industry, academia and members of civil society within the network of the SHAPES Ecosystem. This includes two organisations of persons with disabilities as consortium partners (WFDB and EUD). The Deliverable only uses the term stakeholder when referring to all those interested groups.
Users	When referring to SHAPES 'users' the Deliverable is specifically referring to: Care Recipients and Caregivers. SHAPES Care Recipients consist of older persons living across the EU Member States, independently, in their own homes, or in residential care facilities. As separately defined below, in relation to Caregivers, a distinction can be made between caregivers who provide care on an informal basis, by virtue of a familial or social relationship, and those providing care formally on the basis of an employment arrangement.
Older Persons	The Deliverable preferably uses the terms older persons. The term 'older person' is commonly used in most United Nations documents and is consistent with a rights-based approach to ageing. Occasionally, the term "elderly persons" will be used when referring to provisions included in the

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	Charter of Fundamental Rights or in other EU legislation where the term is used. Notably, in line with SHAPES ethos, the Deliverable is endorsing a non-discriminatory and dignified approach to old age. The European Pillar of Social Rights (EPSR) refers to "everyone in old age". The latter expression "old age" can be used occasionally when referring to the EPSR. The Deliverable only uses these terms when discussing the implementation and remit of the EPSR.
Persons with disabilities	Persons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others. This definition is the one provided by the CRPD and also adopted in EU law. Occasionally the Deliverable refers to 'disabled persons/people', but always in line with the CRPD's understanding of disability (i.e. in line with the social-contextual model of disability).
Healthcare/care recipient	This general term refers to those who receive care and will be generally used instead of client or customer. If appropriate, the word patient will be used. We acknowledge that the recent European Care Strategy (European Commission 2022e) uses the term "care receivers" to encompass a broad range of people availing of care through their life span.
Patient	The word patient is defined in the Directive 2011/24/EU as "any natural person who seeks to receive or receives healthcare in a Member State" (Article 3 lett. h of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, p. 45–65). When the term patient is used it is discussed in this context.
Care Services Provider	This general term covers the provider of healthcare and social services (long-term/short-term), regardless its national legal status or the economic nature of its activity. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45–65) defines "'healthcare provider' as "any natural or legal person or any other entity legally providing healthcare on the territory of a Member State" (Article 3 lett. g). The word "care providers" is more general to encompass healthcare and other social services. In the EPSR the word "care services" is used: "Everyone has the right to affordable long-term care services of good quality, in particular home-care and community-based services" (principle 18). We acknowledge however that: • The Medical Device Regulation (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC OJ L 117, 5.5.2017, p. 1–175) uses the wording 'health institution' to refer to "an

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	organisation the primary purpose of which is the care or treatment of patients or the promotion of public health" (Article 2 para 36).
Services of General Economic Interest (SGEI)	SGEIs "are economic activities which deliver outcomes in the overall public good that would not be supplied (or would be supplied under different conditions in terms of quality, safety, affordability, equal treatment or universal access) by the market without public intervention". (Communication from the European Commission, 'A Quality Framework for Services of General Interest in Europe', COM(2011)900 at 3).
Social Services of General Interest (SSGI)	SSGI "include social security schemes covering the main risks of life and a range of other essential services provided directly to the person that play a preventive and socially cohesive/inclusive role" (Communication from the European Commission, 'A Quality Framework for Services of General Interest in Europe', COM(2011)900 at 3-4).
Caregiver	The term caregiver will be used to include workers providing personal care and other family members providing support to a relative, or to a person who lives in the same household. The word carer will be used as a synonym. The latter term is used in Directive (EU) 2019/1158 of the European Parliament and of the Council of 20 June 2019 on work-life balance for parents and carers and repealing Council Directive 2010/18/EU PE/20/2019/REV/1 (OJ L 188, 12.7.2019, p. 79–93). This Directive states that: "carer' means a worker providing personal care or support to a relative, or to a person who lives in the same household as the worker, and who is in need of significant care or support for a serious medical reason, as defined by each Member State (Article 3 lett. d of Directive (EU) 2019/1158). The word informal carer can be used to refer to a relative/family member/ or someone who has caring responsibility, which is not related to his/her employment contract.
Standards	International standards are technical guidelines or requirements for products, services, materials or processes developed by international standards organisations. European standards are developed by European Standards Organisations providing voluntary guidelines on technical specification for products, services, and process within the EU. Harmonised standards are a category of European Standard that are adopted following a request (a mandate) from the European Commission. Article 2 of Regulation (EU) No 1025/2012 states that: "(1) 'standard' means a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory, and which is one of the following: (a) 'international standard' means a standard adopted by an international standardisation body; (b) 'European standard' means a standard adopted by a European standardisation organisation;

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	(c) 'harmonised standard' means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation; (d) 'national standard' means a standard adopted by a national standardisation body"
Accessibility	Accessibility is a broad concept that is considered a precondition to full and equal participation by all members of society. Under Article 9 CRPD, this includes access "to the physical environment, to transportation, to information and communications, including information and communications technologies and systems, and to other facilities and services open or provided to the public, both in urban and in rural areas." As recognised in EU accessibility legislation, it includes the prevention and elimination of obstacles that pose problems for persons with disabilities in using products, services and infrastructures.
Medical Devices	The European Medical Agency defines medical devices as "products or equipment intended generally for a medical use" which, under EU law, must "undergo a conformity assessment to demonstrate that they meet legal requirements to ensure they are safe and perform as intended" (EMA, 2019). Definitions of 'medical device' and '*in vitro* diagnostic medical device' are set out in Article 2(1) MDR and Article 2(2) IV MDR respectively for the purposes of appropriate classification thereunder.
Assistive Technology	This refers to the application of organised knowledge and skills related to assistive products, including systems and services, i.e. those that maintain or improve an individual's functioning and independence, thereby promoting their well-being (WHO, 2021).
Artificial Intelligence	The European Commission, in its 2021 Proposal for a Regulation laying down harmonised rules on artificial intelligence, offers a "single future-proof" definition of AI as software (developed with one or more of the techniques and approaches listed in Annex I) "that can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with" (Article 3(1)).

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2 At the Cross-road of Health, Disability and Ageing: The Extent of EU Competences relevant to the SHAPES Innovation Action

2.1 Introductory Overview

The European Union (EU) exercises a net of competences that are relevant to the SHAPES Innovation Action in its multifaceted components.

It is worth recalling that a competence refers to a material field in which the EU has the power to adopt legislative acts. Under the principle of conferral, the EU can only act within the limits of the competences conferred upon it by the Treaties to attain the objectives provided therein (Article 5(2) Treaty on the European Union-TEU). The Treaty on the Functioning of the European Union (TFEU) clarifies the division of competences between the EU and its Member States in Articles 2-6 TFEU. There are 3 main categories of competences: exclusive competences; shared competences; and supporting competences. Exclusive competences (Article 3 TFEU) are fields in which the EU alone can legislate and adopt binding acts. For the purpose of this project the EU exclusive competence on "the establishing of competition rules necessary for the functioning of the internal market" is particularly relevant, with specific regard to the SHAPES marketplace. Shared competences (Article 4 TFEU) are fields in which the EU and its Member States can legislate and adopt legally binding acts. EU Member States exercise their own competence when the EU does not exercise its own competence. There are several shared competences relevant to SHAPES. Those include: internal market; social policy; economic, social and territorial cohesion (regional policy); consumer protection; shared safety concerns in public health matters, limited to the aspects defined in the TFEU; and research, technological development, space. Supporting competences (Article 6 TFEU) are those areas in which the EU can only intervene to support, coordinate or complement the action of EU Member States. Legally binding EU acts cannot entail harmonisation of national laws. Supporting competence particularly relevant to SHAPES is that related to the protection and improvement of human health.

In areas in which the EU does not have exclusive competences, the principle of subsidiarity allows EU intervention only when the objectives of an action cannot be sufficiently achieved by the Member States alone but can be achieved more effectively at Union level (Article 5(3) TEU). The principle of proportionality requires that the actions of the EU must be limited to what is necessary to achieve the objectives set out in the Treaties (Article 5(4) TEU).

The EU can adopt secondary legislation (i.e. directives, regulations and decisions) in the areas of its own competence. EU directives must be transposed into national law by the Member States. Article 288 TFEU provides that a directive is binding as to the result to be achieved, but it leaves to the Member States' to decide on the form and means of transposition of the directive. Regulations are immediately applicable in EU

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Member States, and they do not require implementation into national law. Decisions are binding on those individuals to which they are addressed.

Article 290(1) TFEU allows for the delegation to the European Commission of powers to adopt 'non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act'. Article 291(2) TFEU allows for the conferral on the Commission of implementing powers 'where uniform conditions for implementing legally binding Union acts are needed'. Moreover, Article 291(3) TFEU requires that 'the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers' be set out by regulation.

Further to these introductory remarks, the following subsections explore the extent of EU competences in the cross-cutting areas of health, disability, and older persons which are relevant to SHAPES. The EU competences pertaining to technology are separately discussed in Section 3. Respectively, the following subsections examine the source and extent of the EU competence, and assesses how it has been exercised by the EU to date, whether in binding legislative instruments or in policy 'soft-law' measures. Section 4 then maps and places the responsibilities and rights attached to the SHAPES users, 'Care Recipients and Caregivers'.

2.2 The EU and Health

As noted above, the SHAPES Platform is designed to promote inclusive, smart and healthy ageing. Health is one of the core legal/policy areas which is relevant to SHAPES.

The protection of human health is one of the objectives of the EU. According to Article 3(1) TEU, the 'Union's aim is to promote peace, its values and the *well-being of its peoples'*. Greer suggests that even though this is an open reference to health, it is an indirect reference to it. The World Health Organization's (WHO) definition of health, "health is a state of complete physical, mental and social *well-being* and not merely the absence of disease or infirmity" offers a more comprehensive and inclusive approach.

Article 9 TFEU is a cross-cutting provision that requires that the EU in defining and implementing its policies and actions, "shall take into account requirements linked to the […] protection of human health." The EU CFR, which has the same status as Treaty law and is legally binding on the EU institutions and Member States when implementing EU law, addresses healthcare in Article 35, and provides that "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities".

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However, the protection and promotion of health as a constitutional objective is not boosted by a clear EU competence to act. By contrast, Article 6 TFEU states that the Union has the competence to carry out actions "to support, coordinate or supplement the actions of the Member States" with regard to the "protection and improvement of human health". Article 4(2)(k) TFEU provides that the Union shares competence with the Member States with regard to "common safety concerns in public health matters", but this is considered a narrow exception to the otherwise limited competence of the EU.

Title XIV of the TFEU focuses on health. The Title consists of a single article, Article 168 TFEU. This provision confirms that subject to certain exceptions related to "common safety concerns in public health matters", the EU's role is to support, coordinate and supplement the measures of Member States with regard to public health, and that the competence to regulate healthcare lies with the Member States. Furthermore, Article 168(7) TFEU makes clear that "Union action shall **respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care**. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them".

Article 168 TFEU, however, entrusts the EU with the power to legislate with a view of "high standards of quality and safety for medicinal products and devices for medical use". The EU can also "adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States". On the whole, scholarship has stated that Article 168 TFEU is a "weak legal basis" that allows the Union to spend "small sums of money to promote European networks that connect people and organizations, put items on the agenda for the future, and sometimes produce research" (Greer, 2014).

The exercise of other competences in the internal market field, however, allows the EU to legislate in the field. The most important piece of legislation on health is the Patient's Rights Directive, which is based on Article 114 TFEU. The Patients' rights in cross-border healthcare (Directive 2011/24/EU) concerns the rights of patients who receive medical treatment in a Member State other than the one where they reside or are insured. This directive also aims to ensure a high quality of healthcare throughout the EU.

In sum, the "EU is engaged in many ways in the essential functions of a health system" (Greer et al. 2019). In that connection, Greer suggests that "there is no European Union health system but there is EU health policy" (Greer et al., 2019, p. 1). This means that Member States of the EU have primary responsibility in regulating, organising and delivering healthcare systems. However, the EU has progressively developed a Union health law and policy which has been encompasses legal rules

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and policy provisions which regulate certain actions, or the refraining from certain actions, in the provision of health care and the protection of public health (Hervey, 2020; de Ruijter, 2019).

EU law regulates procedures on the marketing and monitoring of pharmaceuticals and medical devices. More broadly, a regulatory framework has been in place since 1990 ensuring the safety and efficacy of medical devices and facilitating patients' access to devices in the European market. In 2017, two updated regulations respectively on medical devices (MDR) and in vitro diagnostic medical devices (IVDR) were adopted to establish 'a modernised and more robust EU regulatory framework to ensure better protection of public health and patient safety', which are discussed in annex (D8.3.1). In light of the impact of the Covid-19 pandemic, general application of the MDR was postponed by one year to 26 May 2021. The IVDR has applied as of 26 May 2022 as planned. The Regulations are directly applicable in the Member States, subject to various transitional periods the details of which can be found in annex 8.3.1.

Competition law and State aid are also relevant. The promotion of competition within the Internal Market is embedded in the TFEU, which prohibits anti-competitive agreements, cartels, and outlines permissible use of mergers and state aid provisions and sets rules for the purchases of public services of general interest. Public bodies must adhere to public procurement, competition and in certain circumstances State aid rules, when purchasing health related supplies or services.

As discussed at various points in other deliverables for WP8, it is notable to recall that the creation of a "European Health Data Space" is one of the EU key 2019 – 2025 priorities, and is discussed in D8.4. Importantly for the SHAPES project, the development of the data space will promote greater access to health data for health related research, while protection citizen's health data as set out in Article 20 of the GDPR.

2.3 The EU and Disability

Article 19 TFEU (former Article 13 EC) remains the main provision that confers legislative competence on the EU in relation to combating discrimination on the ground, *inter alia*, of disability. In addition, Article 10 TFEU requires that, 'in defining and implementing its policies and activities, the Union shall aim to combat discrimination based on […] disability […]'. That horizontal clause allows the EU to integrate the fight against discrimination into all EU actions.

The Charter of Fundamental Rights of the EU, proclaimed in 2000 and now legally binding and with the same status as the Treaties, contains different provisions related directly or indirectly to disability. The most notable among them are: Article 20, which provides for equality before the law; Article 21(1), which provides for an all-embracing prohibition on discrimination; and Article 26 on the integration of persons with disabilities.

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The EU has also ratified the UN Convention on the Rights of Persons with Disabilities (CRPD) (Council of the European Union, 2009a). The CRPD is currently an 'integral part of EU Law' and enjoys a quasi-constitutional status in the EU legal system, beneath the Treaties but above secondary law (Waddington, 2011). As a consequence, EU secondary law must be interpreted in light of the CRPD: if the wording of secondary EU legislation is open to more than one interpretation, preference should be given, as far as possible, to the interpretation which renders the European provision consistent with the Convention. The Court recognises the existence of this duty of consistent interpretation, by virtue of the 'sub-constitutional' rank of international agreements in the EU legal framework. More generally, the CRPD has become the benchmark against which EU disability initiatives must be measured (Waddington, 2011, pp. 431; Hosking, 2013, pp. 73).

In the last twenty years, the EU has also passed several regulations and directives that protect or address, often incidentally, the rights of persons with disabilities. Among those, Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation (Employment Equality Directive – Council of the European Union, 2000), which marked the first legislative intervention designed to address discrimination on the grounds of disability (among others), remains the cornerstone of EU disability legislation.

There are also a number of soft law instruments that promote to varying degrees the rights of persons with disabilities.

The **European Pillar of Social Rights (EPSR)** was proclaimed in 2017 by the European Commission, with the aim of guiding social and employment policies within the EU. The Pillar is structured around three chapters: equal opportunities and access to the labour market, fair working conditions, and social protection and inclusion. It sets out 20 key principles and rights "essential for fair and well-functioning labour markets and welfare systems in 21st century Europe". (EPSR, Preamble, para 14). It reaffirms some of the EU social *acquis*, as well as introducing new principles to address the challenges arising from societal, technological, and economic developments. Principle 17 on the Inclusion of people with disabilities provides that "People with disabilities have the right to income support that ensures living in dignity, services that enable them to participate in the labour market and in society, and a work environment adapted to their needs".

As a policy initiative, the EPSR does not itself have any binding force, but relies on appropriate measures being adopted at both Union level and Member State level within their respective competences (EPSR, Preamble, para 17). In furtherance of the principles and rights set out in this "social rulebook", the Commission launched an Action Plan to accelerate its implementation through concrete initiatives at EU-level to complement those of the Member States. It also puts forward three EU-level targets in the areas of employment, skills, and social protection, to be achieved by 2030.

Furthermore, the EU has progressively undertaken a comprehensive policy approach to disability. On 3 March 2021, the Commission presented its new Strategy for the

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Rights of Persons with Disabilities 2021-2030 (the 'Strategy') (European Commission, 2021b). The Strategy builds on the aims of its predecessor, the European Disability Strategy 2010-2020 (European Commission, 2010a), and contributes to the implementation of the EPSR.

The Strategy aims to facilitate the implementation of the CRPD and sets out the focus of EU disability policy for the next decade. The influence of the CRPD is demonstrated by the Strategy's embracing of the social-contextual model of disability, based on a human rights approach to disability. The Strategy recognises the diversity of disability and adopts an intersectional perspective, addressing specific barriers faced by those who are at the intersection of identities, including gender, racial, ethnic, sexual, religious, or socioeconomic disadvantage. In particular, it acknowledges the exacerbating effect that the Covid-19 pandemic has had in respect of the obstacles and inequalities faced by persons with disabilities.

The Strategy's policies and initiatives are centred on three key themes: enjoying EU rights, decent quality of life and living independently, and equal access and non-discrimination while renewing its commitment to accessibility as under the preceding strategy. The Commission endeavours to lead by example, relying on a "strong commitment" from Member States and regional and local authorities to deliver on the proposed actions. With Member States retaining competence in important areas such as health, education and culture, the supporting role of the EU in soft law measures may promote inclusivity, nevertheless, it is a notable weakness in achieving harmonisation, particularly of areas related to social protection.

2.4 The EU and Older Persons

The TFEU explicitly refers to age in its non-discrimination provisions: Article 19 on EU competence to enact legislation to combat discrimination, and in the cross-cutting clause provided for in Article 10 which requires that the EU aims to combat discrimination when defining and implementing its policies and activities.

The CFR also refers to age as a ground upon which discrimination is prohibited under Article 21, which contains a general prohibition on discrimination; while Article 25 CFR recognises and respects the rights of the elderly "to lead a life of dignity and independence and to participate in social and cultural life".

Demographic ageing in Europe means that the proportion of older people is expanding, while the number of people of working age is falling (Eurostat, 2020, pp. 16). It is projected that there will be almost 130 million people aged 65 or more living in the EU by 2050 (Eurostat, 2020, pp. 16). As discussed above, the EU lacks a clear competence to act in the area of health, its role limited to that of supporting, encouraging cooperation, and complementing action by the Member States (TFEU, article 168(2)). Nevertheless, confronted with the various challenges posed by an ageing society, the promotion of active and healthy ageing has become a focus of EU

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health policy (Walker & Maltby, 2012, pp. 121). The Council of the EU, in its 2009 Conclusions on Healthy and Dignified Ageing, invited Member States to make healthy and dignified ageing a priority and to shift the focus to preventative measures as a strategy to improve quality of life and reduce the burden of illness and disability (Council of the European Union, 2009).

The Commission has long adopted "active ageing" as its policy response towards supporting people to stay longer in employment and to contribute to the economy and society (European Commission, 2002). In its contribution to the 2nd World Assembly on Ageing, the Commission defined active ageing as an orientation towards:

> … lifelong learning, working longer, retiring later and more gradually, being active after retirement and engaging in capacity enhancing and health sustaining activities. Such practices aim to raise the average quality of individual lives and at the same time, at societal level, contribute to larger growth, lower dependency burdens and substantial cost savings in pensions and health. They therefore represent win-win strategies for people of all ages. (Commission of the European Communities – now European Commission, 2002, pp. 9).

The Europe 2020 Strategy for smart, sustainable and inclusive growth identified the EU's changing demographic as a key challenge (European Commission, 2020b). Under the 2020 Strategy, the European Innovation Partnership (EIP) on Active and Healthy Ageing (AHA) was launched as a flagship initiative with the objective of supporting active and healthy ageing to both improve quality of life for older persons and allow them to continue to contribute to society.

In June 2020, the Commission adopted its first-ever Report on the impact of Demographic Change in Europe (European Commission, 2020b). With reference to the Covid-19 pandemic, the Report highlights the significance of demographic structures in responding to challenges. Its findings demonstrate that Europeans are living longer, with increased healthy life years (European Commission, 2020b, pp. 7). In the last 50 years, life expectancy has increased by about 10 years for both men and women (European Commission, 2020b, pp. 7). By 2070, it is estimated that 30% of the European population will be aged 65 or more, up from approximately 20% currently, while the proportion of the population over 80 years is projected to double (European Commission, 2020b, pp. 10). The Report illustrates the need to address the impact that the demographic change will have on economic growth and sustainability, employment, health and long-term care in the EU.

Following from the Report's findings, in January 2021, the Commission adopted the Green Paper on Ageing (European Commission, 2021a). It invites citizens and organisations from all Member States to engage in a broad policy debate on ageing, to discuss how to anticipate and respond to the challenges it entails (European Commission, 2021a). Recognising that the competences relevant to the effects of

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ageing remain largely with the Member States and, equally, the diversity regionally and nationally, the Green Paper aims to identify the possible policy approaches to best support Member States in adapting to the change. However, worryingly the Commission has yet to indicate if it plans to introduce a White Paper on Ageing proposing specific actions based on the discussion stimulated in the Green Paper.

Notably, in September 2022, the Commission has released its European Care Strategy for caregivers and care receivers (European Commission, 2022e). The Strategy highlights the importance that "high-quality and affordable long-term care empowers older people by helping them to maintain their autonomy and to live in dignity" (European Commission, 2022e). It also states that long term care is:

> particularly important in a context of demographic change, where Europeans are living longer and healthier lives, and the demand for care is increasing exponentially. Active ageing policies, as well as early intervention, health promotion and disease prevention can further support longer independent, healthy and active living and delay the onset of care needs.

2.5 The Role of Next Generation EU in the Health, Disability and Ageing Domains

On 27 May 2020, in response to the impact of the unprecedented Covid-19 pandemic, the Commission proposed a temporary recovery instrument: Next Generation EU (NGEU), to ensure the "sustainable, even, inclusive and fair" recovery across the Member States (European Commission, 2020d). With the agreement of the European Council on 21 July 2020, this created a temporary fund worth €750 billion which will operate from 2020 until the end of 2023. This will operate alongside additional targeted funding to the EU's long-term budget to support the economic and social recovery across the Member States. Combined, this amounts to over €2 trillion (in current prices at the time of writing) and constitutes the largest stimulus package ever financed in Europe. The NGEU package is financed through borrowing by the Commission at favourable rates on the markets using a diversified funding strategy. On 15 June 2021, the Commission raised €20 billion in its first transaction under the NGEU by way of a ten-year bond, which is the largest sum the EU has raised in a single transaction (European Commission, 2021c).

NGEU creates three pillars for the investment of funding: support to Member States with investments and reforms, kick-starting the EU economy by incentivising private investments, and addressing the lessons of the crisis. Within this structure, various funding mechanisms are established. Of particular note:

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- ✓ The Recovery and Resilience Facility of €560 billion offer financial support for investments and reforms, which will include those in relation to green and digital transitions and the resilience of national economies. It comprises of €310 billion to be distributed in grants and €250 to be made available in loans. While it is intended that this will be focused in those Member States worst impacted by the effects of the pandemic, support is accessible to all Member States.
- ✓ EU4Health is a new health programme aimed at rebuilding and strengthening the health sector and to ensure its preparedness for future health crises. With a budget of €9.4 billion, it aims to provide funding to eligible entities, health organisations and NGOs. It identifies as its primary goals the improvement of health, protection from cross-border health threats, improvement of medicinal products and devices, and strengthening of health systems including through digitalisation.
- ✓ rescEU, the EU Civil Protection Mechanism, is to receive investment of €2 billion to increase EU capacity and preparedness to respond to future crises.

Beyond addressing the impact of the pandemic, NGEU investment is intended to further the long-term policy objectives of the EU. In this regard, it emphasises the transition to a "greener, more digital and more resilient" Europe, and places priority in the European Green Deal, the European Single Market, and fair and inclusive recovery for all. Particular focus is placed on digitalisation in the development and connectivity of the single market through 5G networks, cybersecurity and new technologies, while improvement of digital skills is recognised as a priority in addressing unemployment.

Crescenzi et. al (2021) separately note that as the pandemic has somewhat diluted a rising sense of Euroscepticism, the recovery funds should be further used to reinforce cohesion and transformation in the EU. Against this background and in relation to healthcare services, the NGEU funds should be utilised to address the structural weaknesses in health systems identified during the pandemic. Specifically, funds are available to strengthen the capacity, quality and resilience of health systems. Additional reforms and investments in individual EU healthcare systems are required to not only assist in the preparation of future health crises, but to assist Member States in managing increased demand resulting from the ageing EU population (European Commission, 2021c).

Specifically, NGEU funds have been ring-fenced for investment in research and innovation to develop vaccines and cancer treatments, increased access to new hospital technologies and medical supplies, and for medical and healthcare professionals. These broad and overarching objectives permeate recent 'Europe's Beating Cancer Plan', the 'Pharmaceutical Strategy for Europe', and the proposal for a European Health Data Space Regulation (European Commission, 2021c). These cross-cutting policy objectives and legislative proposals aim to accommodate the digital transformation of healthcare systems by facilitating scientific developments, enhancing the resilience of supply chains for active pharmaceutical ingredients and

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medicines, and improving the standards of diagnosis, treatment, and a high quality of life. These funds will therefore lay the foundations for the construction of a pan-European smart and healthy system. However, the success of the NGEU is dependent on the commitment of Member States to apply for funding to improve health infrastructure and the subsequent rigours monitoring and evaluation by the European Commission.

2.6. Conclusion

This part of the Deliverable has briefly outlined the extent of EU's competences in areas that are relevant to the SHAPES Innovation Action. While the EU competences pertaining to technology will be discussed in the next chapter, this section focussed on three cross-cutting areas: health, disability and ageing. In that regard, while the EU has traditionally stepped aside from legislating on health matters, it plays a central role in the regulation of the supply of safe medicines and the promotion of cross-border health services. However, after the Covid-19 crisis, in recent months, the EU has indicated its willingness to extend its use of financial instruments and soft-law policies to rebuild and strengthen the health sector and to ensure its preparedness for future health crises.

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3 Constructing a SHAPES platform in an evolving Digital Single Market

The SHAPES Platform and the SHAPES digital solutions represent important technological developments. An array of EU competences is relevant in this respect.

3.1 The Internal market

The establishment of the internal single market is enshrined in Article 3 TEU as an "essential task" of the EU (Quigley, 2015). The concept of the EU internal market is defined as "an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties" (Article 26(2) TFEU). According to Cuyvers, the internal market aims to make trade between the Member States as easy as trade within a single state (Cuyvers, 2017). The achievement of this objective depends on two complementary elements: negative integration to remove national barriers to intra-EU trade, and positive integration to harmonise national laws (Schutze, 2014).

While the EU is tasked with adopting measures with the aim of establishing or ensuring the functioning of the internal market (Article 26(1) TFEU), its competence in this respect is shared with the Member States (Article 4 TFEU). However, the EU's capacity to affect positive integration is enhanced through its competence to adopt 'measures for approximation' of laws. This broad power to enact legislation necessary for the establishment and functioning of the internal market is contained in Article 114 TFEU. Furthermore, Article 115 TFEU allows the Council, acting unanimously in accordance with a special legislative procedure, to 'issue directives for the approximation of such laws, regulations or administrative provisions of the Member States as directly affect the establishment or functioning of the internal market'.

Weatherill notes that the Article 114 competence is "functionally driven": it is determined by the internal market objective as opposed to the subject area of the measure (Weatherill, 2011). However, the decision of the CJEU in *Germany v Parliament and Council (Tobacco Advertising case)* demonstrates that Art. 114 TFEU does not grant total discretion; there must be a real connection between the aim of the legislation and the establishment or functioning of the internal market. In that case, the CJEU held that Article 114 TFEU did not provide a proper treaty basis for a ban on the advertising of tobacco products as it did not have the improvement of the internal market as its genuine objective.

Article 114 TFEU is extensively relied upon by the EU legislature and has provided bases for a wide variety of legislative measures, including where the EU would otherwise lack competence (Kellerbauer, 2019). In relation to technology, relevant to the SHAPES Platform, Article 114 provides the Treaty basis to several EU acts including:

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- ✓ European Accessibility Act (Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services)
- ✓ Web Accessibility Directive (Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies)

Furthermore, Article 114 is the legal bases of the Copyright Directive in the Digital Single Market (Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC); Marrakesh Regulation (Directive (EU) 2017/1563 of the European Parliament and of the Council of 13 September 2017 on the cross-border exchange between the Union and third countries of accessible format copies of certain works and other subject matter protected by copyright and related rights for the benefit of persons who are blind, visually impaired or otherwise print-disabled).

The EU's 'legislative train' for transforming the regulation of digital markets based on Article 114 TFEU is on route and an abundance of legislative proposals have been published in the last two years (Ackman, 2022). The most ambitious proposals advanced in 2020 within the Digital Services Package, comprising of the Digital Services Act (DSA) and the Digital Markets Act (DMA) (European Commission, 2020e and 2020f) were approved by the EU legislator and enacted in July 2022. They were published in the Official Journal in October and November 2022 respectively (European Parliament and Council of the European Union, 2022a and 2022b). They form a single set of rules that apply across the whole EU and will be *in toto* effective from 2024. They aim to create a safer digital space and to protect fundamental rights of all users of digital services, but also to build a more cohesive EU digital market and establish a level playing field to foster innovation, growth, and competitiveness. The DSA and DMA are discussed in annex D 8.3.1. Namely, the Consortium Partners should be conscious of the potential obligations set out in the DSA, which establishes new rules to govern 'gatekeeper online platforms' (European Parliament and Council of the European Union, 2022a).

The Commission in January 2021, published a proposal to introduce a set of principles for a human-centred digital transformation. The proposed European Declaration on Digital Rights and Principles aims to be used as reference framework for people, and as a guide for industry and policy-makers. (European Commission, 2022d). The Commission, Parliament and the Council reached an agreement on the Declaration in November 2022.

Alongside the Digital Services Package, the Commission has further presented a new Standardisation Strategy which aims to ensure the interoperability of products and services, reduce costs, improve safety and foster innovation (European Commission, 2022b). As discussed further in D8.3.1, the proposed Strategy includes a proposal for an amendment to the Regulation on standardisation. In particular, the amendment proposed aims to improve the governance in the European standardisation system

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and is based on a public-private-partnership between the Commission and the standardisation community (European Commission, 2022b). As with the proposed changes mentioned above, the legal basis for this amendment is also Article 114 TFEU.

3.2 Health Services within the Internal Market

The promotion of a pan-European system of smart and healthy ageing is further supported by the Services Directive. The Services Directive (2006/123/EC) removed existing legal and administrative barriers to the trade of services in the internal market. It eased the establishment of services by simplifying procedures and formalities, and strengthened the rights of consumers and businesses (European Parliament and Council of the European Union, 2006). For the most part, healthcare services provided by health professionals to "assess, maintain or restore the state of patients" health where those activities are reserved to a "regulated health profession" are not covered by the Directive (Recital 22, Services Directive). As the Directive requires Member States to take a central screening role in the regulation of services, it was not advisable or practical for the Directive to apply the same restrictions to both health services and all other commercial services, as such a generic process would fail to take into account the specificity of the healthcare sector (Baetan, 2017).

However, services not directly intended for the treatment of patients or not reserved to regulated health professions or provided to healthcare institutions or healthcare staff fall within the remit of the Directive. The Directive is also applicable to: ancillary healthcare services such as the supply, monitoring and use of medical equipment; social services provided by private operators including care services for older persons; and intellectual property-related services (Article 2, Services Directive). It is therefore imperative for SHAPES partners to hold an understanding of possible responsibilities and obligations arising from the Directive. An underlying aim of the Directive is to promote cross-border trade by ensuring compliance with the fundamental freedom to provide services. This freedom promotes competitive cross-border trade by prohibiting Member States from imposing nationality requirements on service providers (Articles 26 (internal market), 49 to 55 (establishment) and 56 to 62 (services) of the TFEU). However, certain non-discriminatory restrictions may be justified for reasons of public health and public policy, once the restrictions do not extend beyond what is necessary to achieve their objective. The Services Directive eased and facilitated the cross-border trade of services. In this respect, SHAPES users willing to use and test services designed and supplied by service providers established in another Member State will benefit from this Directive.

Separately, the EU competence in the areas of research and technological development support the facilitation and provision of smart healthcare services.

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3.3 The European Research Area

Pursuant to Article 4(3) TFEU, EU competence in the areas of "research, technological development and space" is shared with the Member States. However, notably, the exercise by the EU of its competence in these areas does not preclude Member States from also exercising theirs (Article 4(3) TFEU).

Introduced with the Treaty of Lisbon in 2009, Article 179 TFEU provides that the EU has to pursue "the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry". In furtherance of this objective, the EU must encourage companies, research centres and universities in their research activities and support their cooperation with one another, in particular, across borders and in access to the internal market (Article 179(2) TFEU). Various Treaty articles specifically provide for promotion of research activities, including in the areas of common agricultural policy (Article 41 TFEU), medical health (Article 168 TFEU), and industry (Article 173 TFEU). Article 182(5) TFEU envisions EU competence to legislate for measures necessary for implementation of the European Research Area (ERA), as under Article 179 TFEU.

In 2011, the European Council called for the completion of the European Research Area and for the creation of a single market for knowledge, research and innovation (European Council, 2011). In particular, it referenced improved mobility for researchers and graduate students. As part of its Strategic Plan for Research and Innovation 2020-2024, in September 2020, the Commission launched the new ERA for Research and Innovation, reaffirming its commitment to the ERA and proposing a new approach to boost Europe's green and digital transformation, strengthen Europe's resilience and preparedness to face future crises, and to support Europe's competitive edge in the global race for knowledge (European Commission, 2020a). The Commission proposed four new strategic objectives with corresponding actions to be implemented with Member States and stakeholders under a roadmap continuing to 2024 (European Commission, 2020a).

1. Prioritising investments and reforms in research and innovation (R&I) to support green and digital transformation of the EU's society and economy.
2. Improving access to excellence. The Commission notes that access to R&I investment is uneven across the EU, disparity in Member State investment ranging from 0.5% to 3.3% of GDP, which can translate to a divide in quality. It proposes to support the Member States whose R&D investment is below the EU average to increase this by 50% over the next five years. The ERA4You initiative will create dedicated mobility measures in industry and academia to support researchers in Member States with low R&I performance, while a dedicated work stream is to be created in the ERA for Transition to support Member States in this regard.
3. Translating R&I results into the economy. The Commission regards investment as essential in addressing commercial R&D intensity within the EU, which currently lags behind global competitors. EU initiatives such as

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Horizon Europe and the New European Industrial Strategy, along with the European Innovation Council provide the framework to support the private sector, as well as Member States, to maximise research output and the value of knowledge creation.

4. Deepening the ERA. In order to attract and retain researcher talent, the Commission proposes a toolbox of supports for researchers including a Researchers Competence Framework to monitor trends in research jobs, skills and talent; a mobility scheme to support exchange between industry and academia; targeted training under Horizon Europe; and an ERA Talent Platform. It also proposes a number of measures aimed at furthering the integration between national R&I policies through the sharing of research data, world-class R&I infrastructures, and strengthening the research role of universities. Lastly, gender equality plans will be developed to promote greater participation of women in R&I

Several EU framework programmes for R&I have been enacted since the first programme in 1983 (European Parliament, 2017). The most recent programme, Horizon Europe, covers the period 2021 to 2027 and, with a budget of €95.5 billion, is the largest EU R&I programme to date. It follows on from the Horizon 2020 programme which, under the Europe 2020 strategy, managed the financial implementation under the 'Innovation Union' flagship initiative. The Horizon Europe programme centres around three key pillars: Excellent Science, Global Challenges and European Industrial Competitiveness, and Innovative Europe; and it identifies five principle mission areas: adaption to climate change and societal transformation, cancer, oceans and waters, climate-neutral and smart cities, and soil health (European Commission, 2020c; European Parliament and Council of the European Union, 2021). Horizon Europe builds on many of the achievements of the preceding Horizon 2020 programme, while also introducing some key novelties. The European Innovation Council is one of the most significant innovations under the new programme. It is described as a 'one-stop-shop' for researchers and innovators providing funding and support, particularly for SMEs and where risks deter private investors.

D3.4 further analyses the role of research development and innovation (R&D&I) in relation to governance models in the context of rules, resources, environment, division of labour and dependencies, including procedures, policies and norms.

3.4 Artificial Intelligence (AI)

Separate to these developments, this Deliverable takes into account that the SHAPES Platform falls within the scope of what is considered AI for the purpose of EU law.

The **legislation listed in the European Commission's White paper on Artificial Intelligence is of relevance** and is directly connected to the seven key requirements identified in the Guidelines of the High-Level Expert Group: Human agency and oversight, Technical robustness and safety, Privacy and data governance,

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Transparency, Diversity, non-discrimination and fairness, Societal and environmental wellbeing, and Accountability.

Hence, the SHAPES Platform as AI service or provider must comply with the following pieces of relevant EU legislation:

- ✓ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety
- ✓ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products
- ✓ Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin
- ✓ Council Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation
- ✓ Council Directive 2004/113/EC of 13 December 2004 implementing the principle of equal treatment between men and women in the access to and supply of goods and services
- ✓ Directive 2006/54/EC of the European Parliament and of the Council of 5 July 2006 on the implementation of the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation
- ✓ Directive (EU) 2016/680 on the protection of natural persons 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 on the free movement of such data.
- ✓ Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services
- ✓ Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act)
- ✓ Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive')
- ✓ Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council

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- ✓ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

In addition to these rules, the Commission published its Coordinated Plan on Artificial Intelligence and a Proposal for a Regulation laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) on 21 April 2021. The Proposal adopts a risk-based approach to classification of AI systems according to the potential impact on fundamental rights and safety and will be applicable to apply to all providers of AI systems irrespective of whether they are established within the EU or a third country, to all users of AI systems within the EU, and to providers and users of AI systems established in a third country where the output produced by the system is used within the EU (European Commission, 2021). Therefore, it is foreseen that the rules will be applicable to the SHAPES digital solutions and organisational arrangements, marketplace and platform.

3.5 Summary of Relevant legislation

Leaving aside privacy and data governance and cybersecurity which are dealt with in Deliverable D 8.4 (also dealt with in Deliverable D 8.14), the following table (Table 6) summarises the regulatory framework which will underpin the SHAPES Platform and Digital Solutions. All these pieces of legislation are discussed in the annex (D 8.3.1.).

Table 6 - Summary of regulatory framework which will underpin the SHAPES Platform and Digital Solutions

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Title of Legislation	Details
	SAFETY
The General Product Safety Directive (Directive 2001/95/EC)	The purpose of this Directive is to ensure that products placed on the market are safe. "Product" within the remit of the Directive means any product that is intended for consumers and is supplied, in the course of a commercial activity, and whether new, used or reconditioned.
Directive 85/374/EEC on liability for defective products	The Council Directive focuses on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.
	DIVERSITY AND NON-DISCRIMINATION
Race Equality Directive (Directive 2000/43/EC)	The Council Directive focuses on implementing the principle of equal treatment between persons irrespective of racial or ethnic origin.
Directive on equal treatment in employment and occupation (Directive 2000/78/EC)	The Council Directive establishes a general framework for equal treatment in employment and occupation.
Council Directive 2004/113/EC implementing the principle of equal treatment between men and women in the access to and supply of goods and services	The Council Directives further implements the principle of equal opportunities and equal treatment of men and women in the access to and supply of goods and services.
Directive 2006/54/EC on the implementation of the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation	The Council Directives further implements the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation.
	ACCESSIBILITY
European Accessibility Act Directive (EU) 2019/882	The Act sets out the accessibility requirements for products and services.
Directive (EU) 2016/2102 on the accessibility of the websites and mobile applications of public sector bodies	The Directive provides people with disabilities with better access to the websites and mobile apps of public services.
	CONSUMER RIGHTS
The Unfair Commercial Practices Directive (Directive	Directive 2005/29/EC:

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2005/29/EC) and the Consumer Rights Directive (Directive 2011/83/EC)	• defines the unfair business-to-consumer commercial practices which are prohibited in the EU. • applies to any act or omission directly related to the promotion, sale or supply of a product by a trader to consumers and • ensures the same level of protection to all consumers irrespective of the place of purchase or sale in the EU. Directive (EU) 2019/2161 on better enforcement and modernisation of EU consumer protection rules amends Directive 2005/29/EC, addressing new developments of the market, in particular in the digital area.
	MEDICAL DEVICES
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.	The purpose of these rules is to create an environment that supports the development of innovative companies, thus improving access to high-technological healthcare services and medical devices. The Regulations have a staggered transitional period, with the full application of the Regulations been delayed due to the Covid-19 pandemic.

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4 Mapping the SHAPES Users

4.1 Introduction

Through the development of the Integrated Care Platform, SHAPES aims to sustain and extend healthy and independent living of older persons within the EU. Equally, it endeavours to support and assist caregivers, thereby also benefitting the health and quality of life of those providing care. In that regard, it aligns with the very recent European Care Strategy (European Commission 2022e), which is "a cornerstone of the EU's approach to social policies to help adapt to demographic change, eliminate persistent gender and other inequalities, tap into the potential of the green and digital transitions" (European Commission 2022e). The Strategy suggests that

> Care services should be expanded to meet current and future needs for care. Increasing the availability of care services needs to go hand in hand with improving their quality, affordability, and accessibility (European Commission 2022e).

SHAPES can contribute to that objective making care services more accessible and suitable to the need to care recipients.

The figure (Figure 2) below identifies and maps SHAPES users:

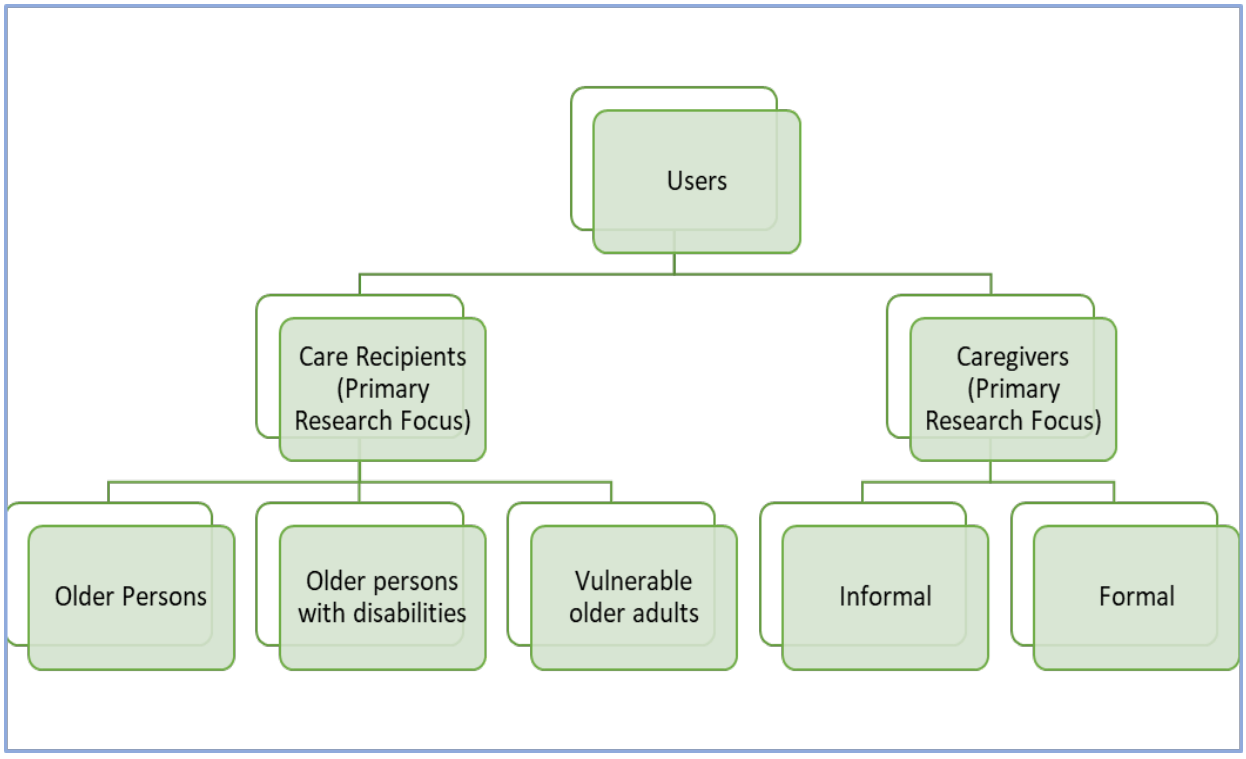

Figure 2 The Taxonomy of SHAPES Platform Users in a Legal Context

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As a pan-European, integrated care system, the SHAPES Platform encompasses a diverse usership. While, generally, the SHAPES Platform users are distinguished as Care Recipients and Caregivers, these categorisations represent a broad range of capabilities and identities.

From a legal perspective, the SHAPES Care Recipients consist of older persons living across the EU Member States, independently, in their own homes, or in residential care facilities. With Europeans living for longer, and with increased healthy life years, those aged 65 years and over represent a broad spectrum in terms of health, mobility, and functional ability (Healthy Ageing Project, 2006, pp. 17). Eurostat data for 2019, estimates the average number of healthy life years to be 65.1 years for women and 64.2 years for men (Eurostat, 2021). According to the Commission's Report on the Impact of Demographic Change, people aged over 65 account for the majority of the 50 million EU citizens who suffer from two or more chronic conditions (European Commission, 2020b, pp. 18). Amongst the SHAPES usership are persons facing health conditions or disabilities including, *inter alia*, neurodegenerative diseases such as Alzheimer's disease or dementia.

With regard to Caregivers, a distinction can be made between caregivers who provide care on an informal basis, by virtue of a familial or social relationship, and those providing care formally on the basis of an employment arrangement. However, irrespective of whether on an informal or formal basis, the majority of caring roles are performed by women (European Institute for Gender Equality (EIGI), 2020a; Eurocarers, 2017).[1] Eurostat data for 2019 shows that 63% of women provide care for dependent relatives, in contrast to 37% of men (Eurostat, 2019). Meanwhile, in respect of formal, home-based care, women represent 82% of the workforce (EIGI, 2020b, pp. 29). As further discussed in D8.4, many LTC (long-term care) roles, in particular, are performed by low-skilled and migrant women (EIGI, 2020, pp. 31). On the other hand, over-qualification is common amongst skilled migrant women in the care-sector, due to difficulty in having their qualifications recognised (EIGI, 2020b, pp.31). This section examines the EU rights, protections and policies as they pertain to caregivers; whether arising in the context of informal caring responsibilities or in an employment capacity in the case of formal carers.

4.2 Care Recipients

4.2.1 The Rights of Care Recipients as Patients in Cross Border Healthcare

As discussed in section 2.2 on the EU and Health, while the Article 35 CFR contains "the right of access to preventive health care and the right to benefit from medical treatment", EU competence in relation to healthcare, subject to certain exceptions

[1] See Lisa Waddington. (2010). Carers, gender, and employment discrimination – What does EU law offer Europe's carers? In M.A Moreau (Ed.), *Before and after the economic crisis: What implications for the 'European Social Model'. Maastricht: Edward Elgar Publishing.*

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related to safety and public health, is limited to that of supporting, coordinating, and supplementing the national public health policies of the Member States (Article 168 TFEU). However, as discussed earlier in this Deliverable, Article 114 TFEU allows the EU to enact measures for the approximation of laws in the interests of the establishment and functioning of the internal market. It is upon this legal basis that the Patients' Rights Directive (PRD) was adopted and entered into force on 25 October 2013 (European Parliament and Council of the European Union, 2011).

The PRD applies in respect of the provision of healthcare to patients, regardless of how it is organised, delivered and financed. However it does not apply to long-term assisted care, allocation of and access to organs for the purpose of transplant, or public vaccination programmes. In codifying the principles on the provision of cross-border healthcare, as developed in the jurisprudence of the CJEU, the Commission sought to enhance legal certainty for the care recipient, the healthcare provider, as well as the Member States (Quinn & de Hert, 2012). Thus, the PRD defines the allocation of responsibilities between the 'Member State of affiliation' and the 'Member State of treatment', i.e., respectively, the Member State in which the patient is socially insured as a national or resident, and the Member State in which the healthcare is actually provided.

The general principle enshrined within the PRD is that the Member State of affiliation shall ensure that the costs incurred by a patient as defined by the PRD who receives cross-border healthcare are reimbursed. The Directive applies without prejudice to Regulation 883/2004, which coordinates social security schemes in respect of EU citizens in another Member State. The obligation to reimburse applies only to the level of costs that would have been assumed by the Member State of affiliation had the treatment been carried out in its own territory. Nevertheless the Directive allows discretion to the Member State to decide to reimburse the full cost and/or other related costs (such as travel and accommodation) and extra costs which may be incurred by persons with disabilities. While the reimbursement of costs of cross-border healthcare cannot be made generally subject to prior authorisation, the Member States may provide for a system of prior authorisation in respect of certain exceptions as specified under the Directive, which must be necessary and proportionate to the objective to be achieved. Further, the Directive places responsibility on the Member State of affiliation to ensure that information is available to patients on their rights and entitlements in that Member State with regard to cross-border healthcare. Where a patient has received cross-border healthcare, the Member State of affiliation is obliged to ensure that the same medical follow-up is available as would have been had the treatment been provided in its territory.

The Member State of treatment must ensure that healthcare is provided in accordance with EU legislation as well as its national laws, standards and guidelines on quality and safety. It must also ensure, *inter alia*, that healthcare providers provide relevant information to patients on treatment options, quality and safety, and prices, in order

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that they can make informed choices; that complaints procedures and mechanisms are in place for patients; and that there are sufficient systems of professional liability insurance in place. Subject to where justified by overriding reasons of general interest, such as ensuring availability of healthcare treatment within its territory or the need to control the costs thereof, the Member State of treatment must not discriminate against patients from other Member States.[2] Likewise, it must ensure that healthcare providers apply the same pricing regime to cross-border patients as to domestic, or according to objective, non-discriminatory criteria where no comparable domestic pricing is available.

Article 6 PRD requires that each Member State designate a 'national contact point' (NCP) for cross-border healthcare, which must be communicated to the Commission to be made publicly available. With the objective of enabling patients to avail of their rights to cross-border healthcare, the national contact points provide information concerning healthcare providers, domestic healthcare standards and guidelines, and national laws governing patients' rights, complaints procedures, remedies, and dispute resolution mechanisms. Such information must be made available by electronic means and easily accessible, including to persons with disabilities.

As a Directive, the choice of form and method of implementation of the PRD is left to each Member State. Article 20 PRD requires the Commission to report on the operation and implementation of the Directive every three years; the most recent, at time of writing, being in 2022 (European Commission 2022f). The 2022 report while recognising the extraordinary circumstances witnessed during the Covid-19 pandemic, acknowledged some fundamental issues with the operation of the Directive. Specifically, the report acknowledges that the Prior Authorisation procedures are implemented by various means across Member States, and attempts to curtail Member States discretion in this regard by offering recommendations to streamline and simplify the procedures. Additionally, the report argues that the administrative procedures introduced by certain Member States are effectively creating barriers to patients seeking cross-border healthcare under the remit of the Directive. Lastly, the report criticises the limited up-take and use of a specialised 2019-toolbox which was introduced to aid the implementation of the Directive and to address serious problems raised in previous reports (European Commission 2022f).

The European Parliament, in 2019, had also published a report on the implementation of the PRD (European Parliament 2019). It expresses disappointment at the ineffective implementation of the Directive by "a significant number" of Member States and urges that this be rectified. The Report cites four principle reasons for low patient mobility: late implementation of the Directive in some Member States, low levels of awareness of the right to reimbursement, barriers limiting cross-border healthcare in some Member States, and the unavailability of complete information regarding cross-border

[2] Ibid art 4(3).

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patients. However it notes that for certain groups of patients, due to rare diseases or geographical proximity, cross-border healthcare is the most appropriate and accessible care. In these areas in particular, the Report highlights the potential of eHealth to facilitate the sharing of research and patient data across borders[3] as well as providing a cost-effective means of improving continuity of care, while guaranteeing patient privacy. The Report cites a 2015 Eurobarometer survey which indicates that fewer than 20% of EU citizens feel well informed about their cross-border healthcare rights and concludes that patients are generally not aware of the existence of NCPs, in response to which it considers a "broad and lasting" information campaign to be vital. It was also found that NCPs websites were generally lacking in detailed information concerning undue delay, complaints procedures, dispute settlement, and processing duration for prior authorisation and reimbursement requests (European Parliament 2019). In relation to mutual recognition of prescriptions, the Report calls on the Commission to develop an action plan to address the high prices, and disparity of pricing of medicines across the Member States, and to work to ensure reimbursement of cross-border purchase of medicines.

On the whole, without such greater collaboration by the Member States in health matters, commentators remark that the rights conferred upon citizens under the PRD risk becoming somewhat of a "hollow gesture". (Horgan *et al.,* 2013).

4.2.2 The Protection of Care Recipients as Vulnerable Adults

Previous sections within this Deliverable examine EU competence as it pertains to health, disability, older persons. However, the EU treaties and fundamental rights instruments do not confer onto the EU any specific competence in respect of the category of adults that may be described as vulnerable, nor on the regulatory aspects of legal capacity, i.e., the legal construct which is generally recognised in persons of majority age, enabling them to have rights and obligations (Council of Europe, 2012, pp. 7).

The term 'vulnerable adults' refers to persons aged 18 or more who experience difficulties in protecting their personal interests, whether temporarily or permanently, 'due to an impairment or insufficiency in their personal faculties' (European Parliament, 2021b). Primarily governed by the domestic laws of the Member States, the protection of vulnerable adults within the EU varies considerably from one State to another (European Law Institute, 2020, pp. 9). The lack of uniformity or mutual recognition across the EU Member States is particularly problematic in cross-border situations, which, with the greater mobility of both individuals and their assets, arise on an increasing basis (European Law Institute, 2020, pp. 9). Examples of such circumstances include where protections are sought in a State other than that in which

[3] Ibid 5.

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the adult concerned is habitually resident, or where powers of representation are conferred in a jurisdiction other than that in which they are to be executed (European Law Institute, 2020, pp. 9). Scholarship point to the detrimental impact of this lack of harmonisation may have on the exercise by vulnerable adults of their fundamental rights, including the right to move and reside freely within the EU (Franzina & Long, 2016, pp. 118).

The CRPD (discussed earlier in this Deliverable), in Article 12, obliges States Parties to the equal treatment of persons with disabilities before the law and to recognition of legal capacity on an equal basis with others in all aspects of life. Article 12(4) CRPD provides that States Parties shall ensure for "appropriate and effective safeguards" to prevent abuse in respect of all measures that relate to the exercise of legal capacity. Such safeguards must ensure that any measures in relation to exercise of legal capacity are proportionate and tailored to the individual's circumstances; apply for the shortest time possible and are subject to review by an independent and impartial authority; that the rights, will and preferences of the person are respected, and are free from conflicts of interest or undue influence. As is further discussed in Deliverable 8.4 and 8.14, the CRPD Committee has made it clear that measures providing for substituted-decision making, in denial of legal capacity, are incompatible with the social-contextual model underpinning the CRPD (CRPD Committee, 2014). Although the CRPD is binding on both the EU and the Member States, its impact, to date, has been undermined by the generally slow implementation by the Member States and the complex division of competence that limits EU action.

Separately, D8.14 sets out procedural ethical requirements which are based on the CRPD to ensure the inclusive participation of older persons in pilot activities. Such requirements include the need for partners to provide a process for the implementation of services for single end-users (older persons) and for the assessment of the suitability of the services from time to time (including a process to assess the digital literacy of the end-user and adapt the services according to end-user needs and capabilities). This process should include more time to discuss choices or have an advocate regarding important appointments in order to make notes and help the person understand or remember choices. An additional requirement requires partners to provide a detailed process to determine if the older person is able to decide on accessing the services and secondly if she/he is able to give informed consent and re-consent for the collection of the information. In these circumstances, project partners are required to consider and comply with national regulatory frameworks.

Furthermore, the Hague Convention on the International Protection of Adults (HCIPA) 2000 sets out comprehensive rules to govern jurisdiction, applicable law, international recognition and enforcement, and cooperation in respect of measures for the protection of vulnerable adults in cross-border scenarios. Article 3 HCIPA details the types of measures envisaged within the scope of the Convention such as the determination of incapacity and the institution of a protective regime; the placing of an

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adult under the protection of a judicial or administrative authority; representation in respect of the person or their property; the placement of the person in a care establishment; and the management of their property.

The HCIPA provides uniform rules to determine jurisdiction. In this regard, Article 5 grants primary jurisdiction to the judicial or administrative authorities of the State in which the adult is habitually resident. In the case of refugees or persons whose habitual residence cannot be established, the authorities of the State in which they are present shall have jurisdiction. Where property belonging to an adult is located in a Contracting State, the authorities of that State have jurisdiction to take measures for the protection of that property. While, in cases of urgency, the authorities of the State in which the adult or their property is present have jurisdiction to take protective measures. Generally, the applicable law is that of the State having jurisdiction, however the laws of another State, with which the situation has a substantial connection, may exceptionally be taken into consideration to the extent necessary to protect the interests of the adult.

While the HCIPA of 2000 is widely recognised as the most significant international legal instrument regarding the protection of adults, ratification of the Convention has been limited, with 13 Contracting States to date. Within the EU, 10 Member States have ratified the Convention; namely Austria, Belgium, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Latvia, and Portugal. While scholarship in this area indicates that EU-wide ratification of the HCIPA would increase effectiveness and efficiency of protection of vulnerable adults (Franzina & Long, 2016, pp. 157), ratification is not open to international organisations, such as the EU. Therefore, it is likely that greater political willingness and cooperation by both the EU institutions and the Member States is required if greater harmonisation under the Hague Convention is to be achieved.

4.3 Caregivers

4.3.1 Formal v Informal Caregivers

The increase in life expectancy alongside demographic ageing of the EU population has led to a growing incidence of age-related health conditions and, with that, increased demand for care and help with the activities of daily living. Eurostat data for the year 2018 indicates that around 100 million people in the EU have care responsibilities, with more than 12 million people providing care for relatives who are ill, older persons, or with disabilities (Eurostat, 2018). In respect of long-term care (LTC), it is estimated that approximately 80% of this care is provided, unpaid, by spouses, relatives and friends. This is commonly characterised as ‘informal’ care, i.e. support or aid from a member of the social network that is beyond that required as part of normal everyday life (Walker, Pratt, and Eddy, 1995). On the other hand, formal

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care may be characterised as provided in exchange for payment, by a professional, or by a formal organisation (Rogero-García, *et al*, 2008).

The OECD, in its report on Long-term care for Older Persons, places emphasis on the carer's existing social relationship with the person to whom they provide care, rather than the receipt of payment as a defining factor in distinguishing formal and informal care (Lundsgaard, 2005). It makes the distinction between payment as if purchasing a service in the case of formal care, and income transfers or informal payments, which do not negate the informality of the caring relationship. In this regard, it considers an employment contract as the basis underpinning formal care arrangements, whether in relation to professionally trained or untrained care assistants, and regardless of whether self-employed or working for an agency, public or private organisation or firm. Accordingly, "[t]he difference between formal and informal care is first of all not about the type of care, but who provides it" (Lundsgaard, 2005).

Alternatively, it is submitted that a dichotomous understanding of formal and informal care as "composed of different economic relations, values and motives" is overly simplistic, hierarchical, and fails to take account of the diversity of non-market practices (Williams, 2010).

For the purposes of this research, classification of caregiving as formal and informal is appropriate given the differing legal implications.

4.3.2 Informal Caregivers Rights

Informal care is considered "a cornerstone" of LTC systems in Europe and with growing policy preference for community-based care, its role is set to increase (European Commission, 2017a). According to the European Network of National Human Rights Institutions report on family carers, over half of carers in some EU countries provide over twenty hours of informal care per week. It notes the impact that care responsibilities can have on carers lives, including limiting career continuity and employment options, on mental and physical health, as well as on finances (ENNHRI, 2017).

Article 5 CFR provides that no one shall be held in slavery or servitude, or required to perform forced or compulsory labour. Article 31 CFR provides for fair and just working conditions in which the health, safety and dignity of workers is protected, and for maximum working hours, allowing for daily and weekly rest periods, and to annual leave. However, despite the very particular challenges faced by informal carers, unpaid care work is not expressly addressed by international human rights instruments and is often overlooked in human rights implementation assessments (ENNHRI, 2017).

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It is submitted that the nature of caregiving places carers in a different position to non-carers in employment, and in the absence of specific protection in the EU Treaties, informal carers face discrimination in much the same way as that based on age or sex (Caracciolo di Torella, 2017). Caracciolo di Torella and Masselot make the case that the interrelationship between work and informal care on an EU-level necessarily impacts internal market functioning and, in this respect, brings it within the remit of EU competence (Caracciolo di Torella, 2017. Caracciolo di Torella & Masselot, 2020).

Nevertheless, LTC arrangements and the role of informal care is increasingly identified as a key policy area at both EU and Member State level, with many Member States having implemented reform of their LTC systems in recent years (European Commission, 2017). The EPSR, in Principle 18, provides that "[e]veryone has the right to affordable long-term care services of good quality, in particular home-care and community-based services" (EPSR, 2017). It equally recognises the role of caregivers, in Principle 9, which provides for the rights of parents and people with caring responsibilities to suitable leave, flexible working arrangements and access to care services.

Principle 9 EPSR supports the Work-life Balance Directive 2019 (WLBD) (European Parliament and Council of the European Union, 2019a), which was to be transposed by the Member states into their respective national legal systems by the deadline of 2 August 2022. It sets out minimum requirements related to working arrangements and leave entitlements of parents and carers. Under the WLBD, a "carer" is defined as "a worker providing personal care or support to a relative, or to a person who lives in the same household as the worker, and who is in need of significant care or support for a serious medical reason" (Article 3(d)). Article 2 further clarifies that the WLBD applies to "all workers, men and women, who have an employment contract or employment relationship as defined by the law". This strict definition has received criticism from carers organisations as only applying to those carers that are in employment and, thereby, also to the exclusion of those in self-employment or atypical forms of employment (Eurocarers, 2020). Additionally, it is submitted that its application should be extended beyond next of kins and cohabitants to include all people providing support and care on a voluntary basis (Eurocarers, 2019, 2020). Furthermore, the definition of care should further be extended to reflect the diversity in care giving roles. For example, the role of interpreters, guide interpreters, assistants and support persons (whereas formal or informal/professionally trained or not) is also key for persons with disabilities, and their effective participation in society and inclusion.

The WLBD provides for a minimum carers' leave of five working days per year (Article 6). It is left to Member States to decide whether payment or an allowance is available in respect of carers' leave, however such payment is encouraged by the Directive in the interests of effective take-up (Recital 32). Carers and parents of young children have the right to request flexible working arrangements, the duration of which may be subject to reasonable limitation (Article 9). Employers must consider, and respond to

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such requests within reasonable time, and must provide reasons in the event of refusal or postponement (Article 9(2)). Workers availing of their rights to leave under the WLBD are entitled to return to their jobs under no less favourable conditions, and to the rights acquired by them prior to such leave (Article 10), and shall not be treated any less favourably on the basis of having applied for or availed of such leave (Article 11).

Although the WLBD may be considered a breakthrough in recognising specific rights of informal carers, it is submitted that its narrow application and reliance on the benevolence of employers arguably weakens its potential (Eurocarers, 2020). However, in this regard, it is noted that EU competence to address caregiving is limited to the concept of work understood as "genuine economic activity" (Caracciolo di Torella & Masselot, 2020).

The EU Treaties enshrine the freedom of EU citizens to move within the territory of the Member States. Specifically, the free movement of workers has existed as a principle of EU law since the 1960's and has been developed over the years through secondary legislation and the case law of the CJEU (Kennedy, *et al*, 2020). The freedom of EU workers to move freely between the Member States, contained in Article 45 TFEU, prohibits discrimination between workers based on nationality, remuneration, and conditions of work and employment. Thus, it grants EU citizens the right to seek and to accept offers of employment in another Member State, to move freely within the EU and to reside in another Member State for this purpose, and to remain after having being employed there (Article 45(3) TFEU). The main provisions governing the exercise of this freedom are currently contained within Directive 2004/38/EC on the right of citizens and their family members to move and reside freely, Regulation 492/2011 on freedom of movement of workers, and Regulation 2019/1149 establishing a European Labour Authority.

Particularly relevant in the case of informal caregivers is Directive 2004/38/EC, which provides for a right of residency of family members of workers on a derivative basis, by virtue of this relationship. The Directive defines "Family member" as the spouse or registered partner (where the host Member State recognises such as equivalent to marriage), direct descendants who are under the age of 21 or are dependents and those of the spouse or partner, and dependent direct relatives in the ascending line and those of the spouse or partner (Article 2(2)). Further, family members retain the right of residence in the event of the death or departure of the worker (Article 12), or in the event of divorce, annulment of marriage, or termination of registered partnership (Article 13), subject to certain qualifications as set out in the Directive.

The scope of Article 45 TFEU is limited to EU citizens in their capacity as workers engaged in "effective and genuine activity" as employed persons. However, the EU

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Courts have interpreted this concept broadly to circumstances including part-time work[4], indirect remuneration[5], and seeking work[6].

As SHAPES adopts an inclusive approach to the promotion of smart and integrated healthcare, it fully considers and includes the role of informal carers at each junction and Deliverable. It is hoped that the research outputs disseminated throughout the life-cycle of the project will provide evidence to further demonstrate the economic and social importance and impact of informal caregivers, which will positively inform future policies and legislation on the protection of the fundamental rights of these caregivers.

4.3.3 Formal Caregivers

The CFR confers a number of important rights on workers. Already mentioned in this Deliverable is the prohibition on slavery and forced labour in Article 5. Title II on Freedoms provides for the freedom to choose an occupation and to engage in work (Article 15) and freedom to conduct a business (Article 16), while Article 12 enshrines the right to freedom of peaceful assembly and to freedom of association, expressly including the right to form and join trade unions. Title IV on Solidarity contains the workers' right to information and consultation in their employment (Article 27), the right to collective bargaining and action (Article 28), protection in the event of unjustified dismissal (Article 30), the right to fair and just working conditions in respect of health, safety and dignity, and the entitlement to daily and weekly rest and paid annual leave (Article 31), and protection from dismissal for a reason connected to maternity or the right to paid maternity leave, or parental leave following the birth or adoption of a child (Article 33).

Further, Article 21 CFR contains the general principle of non-discrimination based on any grounds, "such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation". Article 23 provides for equality between men and women "in all areas, including employment, work and pay". In this regard, express provision is made for measures of affirmative action in favour of the under-represented sex.

The TFEU in Article 153 provides for EU shared competence in employment matters. In this respect, the EU can act to support and complement Member States' national measures for, *inter alia*, the improvement of working environment and conditions, social security and protection of workers, protection of workers on termination of employment, and information and consultation of workers (Article 153(1)). Policy objectives related to the labour market and workers' rights also feature heavily in the EPSR pertaining to, *inter alia*, gender equality and equal opportunities, support in

[4] C-53/81 *D.M. Levin v Staatssecretaris van Justitie* [1982] ECLI:EU:C1982:105.
[5] C-196/87 *Udo Steymann v Staatssecretaris van Justitie* [1988] ECLI:EU:C:1988:475.
[6] C-292/89 *The Queen v Immigration Appeal Tribunal, ex parte Gustaff Desiderius Antonissen* [1989] ECLI:EU:C1991:80.

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access to employment or self-employment, fair working conditions and wages, access to information, work-life balance, and inclusion of people with disabilities.

A number of key legislative instruments have been adopted over the last twenty-five years, mostly in the form of directives setting minimum standards for protection of workers. While the initial focus was on equal treatment of workers, subsequent progress has been made in the area of fair and safe working conditions, while the most recent directives, the Directive on Transparent and Predictable Working Conditions (TPWCD) (European Parliament and Council of the European Union, 2019b) and the WLBD, recognise the need for protection of workers in new and atypical forms of employment (European Parliament, 2020).

A notable weakness in the framework of existing directives is the absence of a single definition of a 'worker', which is generally left to the discretion of the Member States and, therefore, may lead to inconsistency in recognition of this status. The case-law of the CJEU provides guidance in this respect, stating that the essential feature is "that for a certain period of time a person performs services for and under the direction of another person in return for which he receives remuneration".[7] Notably, this definition does not include self-employed persons. However, it is submitted that, in providing this definition, the CJEU did not intend to supplant Member States discretion to determine the defining criteria of 'workers', but rather to provide a minimum standard (Risak & Dullinger, 2018).

In contrast, as discussed previously, the WLBD and the TPWCD offer a broader application to all workers having an employment contract or relationship as defined by national law. Further, under Recital 8 of the TPWCD, it shall apply to "domestic workers, on-demand workers, intermittent workers, voucher based-workers, platform workers, trainees and apprentices", provided they fall within the CJEU definition. While this excludes "genuinely self-employed persons", the TPWCD continues to state that "[t]he determination of the existence of an employment relationship should be guided by the facts relating to the actual performance of the work and not by the parties' description of the relationship".

Recently considering intra-EU labour mobility, the European Parliament recognised the "crucial role" of carers during the Covid-19 pandemic and called upon the Commission to ensure the mobility of carers to meet the needs of different Member States and regions across the EU, particularly in view of demographic ageing and potential future health crises. In addition, it called on the Member States to implement and ratify the International Labour Organisation's Convention on Domestic Workers and to establish legal frameworks facilitating the lawful employment of domestic workers and carers (European Parliament, 2021a). As with the informal caregivers, it is additionally hoped that the project's rich research outputs will provide sufficient evidence to call for and inform policymakers to consider revising the existing

[7] C-66/85 *Deborah Lawrie-Blum v Land Baden-Württemberg* [1986] ECLI:EU:C:1986:284.

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mechanisms in place protecting both formal and informal caregivers' fundamental rights. Protecting and enhancing the rights of caregivers is a necessary requirement in the construction of community-based healthcare.

4.4 Conclusion

The foregoing examines the rights and protections in respect of the network of SHAPES Stakeholders; i.e. as patients/healthcare recipients and as caregivers, whether in formal care arrangements or as informal or family carers. Equally, it highlights some recent developments and the limitations of the current regulatory framework, where the law fails to recognise the fundamental rights in respect of certain stakeholders.

As we have seen, the poor level of awareness is a significant factor in the generally low exercise by patients of the right to obtain and be reimbursed for healthcare in another Member State. While NCPs are obliged to provide information on patients' rights under the PRD, in electronic and accessible formats, the SHAPES Platform knowledge base also has a role to play in increasing awareness amongst users and stakeholders.

Divergent protection across the Member States may pose a significant challenge to the exercise by vulnerable adults of their rights, including equal recognition before the law and the right to move and reside freely, which may additionally impact on their freedom to access to healthcare. For the purposes of the SHAPES Ecosystem, it will be necessary to ascertain in respect of a vulnerable adult whether protective measures have been imposed under national law, and the implications of any such protections for legal capacity. Deliverable 8.4 further details the SHAPES approach on this point.

Further legal complexity arises in respect of vulnerable adults in the event of cross-border situations. In such cases, it will be necessary to establish, in the first instance, whether the Member States concerned have ratified the Hague Convention, and, where they have not, the national regime applicable.

Significant progress has been made in recent years for the protection of the rights relevant to carers in the EU. However, as discussed, EU competence in this regard is restricted to the economic sphere. Therefore, protections in respect of caregivers, whether informal or formal, arise only in the context of employment; to the exclusion of those who are self-employed or in atypical employment, as well as those who are unemployed in the case of informal carers. For this reason, arguably, the current framework omits to protect the rights of those informal caregivers bearing the most care responsibilities and the most vulnerable.

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5 Marketplace

5.1 Introduction

Cross-border healthcare also encompasses the right of health service providers to provide services across internal EU borders within the EU internal market. Hence, this task addresses free movement provisions and EU legislation impinging on the provision of services, such as public procurement legislation, State aid and competition rules, taking into account the CJEU case law.

WP7 is tasked with creating the SHAPES Marketplace, which will contribute to the creation of a secure and trusted open ecosystem bringing additional future proof functionalities and improve the competitive advantage of SHAPES solutions (WP7, Summary Document, 2021). Specifically, the Marketplace aims to become a reference platform integrating trusted and secure third-party solutions for the smart and healthy ageing, independent living and integrated care markets (WP7, Summary Document, 2021). This section offers a concise and easy-to-comprehend overview of the overlapping and often at times competing legal frameworks underpinning the Marketplace and potential governance models as identified in WP3. Brief overviews of the remit of national service providers and their relevance to EU law and the relationship between State aid, Competition and Public Procurement law are discussed

5.2 The EU Competition Law Framework

In preparation for the creation and operation of the SHAPES Platform and Marketplace, SHAPES partners should make themselves familiar with the potential obligations and responsibilities arising from the evolving EU Competition Law framework. The EU rules on competition law (Articles 101-13 TFEU) aim to ensure fair and equal conditions for business by prohibiting certain practices such as illegal contracts and agreements and abuse of a dominant position (Jones and Sufrin, 2016). In relation to illegal contracts and agreements, the rules explicitly prohibit price fixing, market sharing, agreements on customer allocation, agreements on production limitation and distribution agreements, amongst others (Articles. 101 – 102 TFEU).

However, certain categories of agreements concluded between companies are permissible provided that the companies have limited market power and the agreements, generally research and developments agreements, are presumed to have no anticompetitive effects (Faull, Nikpay and Taylor, 2016). In a SHAPES context, pilot partners may in some instances rely on Article 101(3) TFEU to create certain categories of research and development agreements. Separately, agreements respecting the specific conditions laid out in the Commission's Block Exemption Regulations (BERs) are exempt from the general prohibition on restrictive agreements

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and business practices.[8] There are strict conditions that undertakings must meet, such as that the technology transfer agreements must be concluded between a licensor and a licensee and must not centre on mere reproduction and distribution of software copyright protected products. The permissible use of the agreements is also dependent on the degree of market power of the companies involved and level of competition faced by competitors and the availability of substitute technologies or substitute products.

Aside from the fundamental competition law rules, separate legislation exists on State aid and public procurement to promote competition in the Internal Market. Project partners when participating in economic activities in the private market, either during or after the project, must comply with the fundamental competition law rules enshrined in Articles 101 -109 TFEU. Separately, public funders and project partners must be aware that any grants received are done so in compliance with State aid rules. State aid rules prohibit the discriminatory use of public grants. State aid occurs in circumstances where public institutions utilise public funds to support domestic companies, such activities are for the most part prohibited due to anti-competitive effects.[9] However, subsidies granted to individuals or general measures open to all enterprises do not constitute State aid. Furthermore, project partners planning to sell developed digital solutions to the public market should make themselves familiar with the rules on public procurement. EU secondary legislation on public procurement aims to prevent distortion to the market by requiring public authorities to open public contract competitions to economic operators operating within the Internal Market (European Parliament and Council of the European Union, 2014a and 201b).

5.3 National Service providers and their relevance to EU law

5.3.1 Services of general economic interest

In its 2011 Communication on a Quality Framework for Services of General Interest in Europe, the Commission states that "[i]n areas such as health care, childcare or care for the elderly, assistance to disabled persons or social housing' services provide 'an essential safety net for citizens and help promote social cohesion'" (European Commission, 2011). In this document, the Commission also elucidates that social services of general interest (SSGI) "include social security schemes covering the main risks of life and a range of other essential services provided directly to the person that play a preventive and socially cohesive/inclusive role" (European Commission, 2011). Those services may be economic or non-economic in nature, depending on how they are regulated at the national level. Only services that are economic are relevant for

[8] The BERs can be retrieved from https://competition-policy.ec.europa.eu/antitrust/legislation/block-exemption-regulations_en

[9] Case 323/82 *Intermills v Commission*; Case C-142/87 *Belgium v Commission*; Case C-303/88 *Italy v Commission*Case C-387/92, Banco Exterior de España; C-143/99, Adria-Wien Pipeline.

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the purpose of the EU law, as they fall within the scope of services of general economic interest (SGEI), or in the remit of social services of general economic interest (SSGEI).

Article 14 TFEU recognises that SGEI form part of the common values of the Union and promote social and territorial cohesion. It also requires that both "the Union and the Member States, each within their respective powers and within the scope of application of the Treaties, shall take care that such services operate on the basis of principles and conditions, particularly economic and financial conditions, which enable them to fulfil their missions". Article 36 CFR states that the EU "recognises and respects access to services of general economic interest as provided for in national laws and practices, in accordance with the Treaties, in order to promote the social and territorial cohesion of the Union". Article 106 TFEU establishes that the conduct of public undertakings and of those undertakings entrusted with special or exclusive rights must respect other Treaty norms, but provides an exception to the application of the competition rules to SGEI, in order to ensure that they can carry out the tasks assigned to them. Article 106(3) TFEU empowers the Commission to adopt directives and decisions in order to ensure the application of that Article.

The EU has retained (and exercised) an important regulatory role when it comes to SGEI. The rules currently in force were adopted by the Commission in 2012, and are commonly referred to as "SGEI Package" (or "Almunia Package"). The 2012 'SGEI Package' has introduced a differentiated approach to SGEI, taking into account their nature and the extent to which they may distort competition (Sinnaeve, 2012, pp.347). It includes four core documents, which will be further discussed in the remainder of the section: the Commission Communication on the application of the State aid rules to compensation granted for the provision of SGEI (known as 'SGEI Communication' - European Commission, 2012a); the Commission Decision on the application of Article 106(2) TFEU to State aid in the form of public service compensation granted to undertakings entrusted with the operation of SGEI (so called 'SGEI Decision') (European Commission, 2012b); the Commission Communication on the EU framework for State aid in the form of public service compensation (better known as 'SGEI Framework') (European Commission, 2012c); and the SGEI *de minimis* Regulation (European Commission, 2012d). Notably, the latter Regulation provides that SGEI compensation under the threshold of 500.000 Euro over any period of three fiscal years does not fall under State aid.

5.3.2 Social services of general economic interest

The SGEI Decision defines them as services of economic interest "meeting social needs as regards health and long term care, childcare, access to and reintegration into the labour market, social housing and the care and social inclusion of vulnerable groups". This notion rests, first and foremost, on the economic nature of the service in question. It is well-known that such economic nature is linked to the performance of an 'economic activity'. The CJEU considers as economic 'any activity consisting in

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offering goods or services on a given market'. This flexible notion of economic activity is underpinned by 'a functional and objective – rather than institutional and subjective – interpretation' (Gallo, 2011, pp.268), which deems irrelevant the legal status of the entity carrying out the activity, as well as its structure and organisation and the way in which it is financed. However, the Commission has highlighted that 'whether a market exists for certain services may depend on the specific way those services are organized and carried out in the Member State concerned'. Hence, '[t]he economic nature of the same kind of services can therefore differ from one Member State to another' and can change over time (Gallo, 2011, pp. 271). The social aim of an entity is not in itself sufficient to exclude the classification of its activity as economic.[10] Consistent case law of the CJEU has established that activities which fall within the exercise of public or sovereign powers are non-economic in nature as they 'intrinsically form part of official authority and are performed by the State'. If the pilot partners wish to commercialise the developed solutions post completion of the project, they may in certain circumstances, operate under the regulations concerning the operation of SGEIs. As EU Member States organise SGEIs at a national level, the pilot partners will need to analyse their actions on an individual basis to assess the applicability of national law. It should be noted that the SGEI regulations do not dispel free market and competition rules, in as far as the rules do not prohibit the economic operators from accomplishing their tasks in the general interest.

5.4 Public Procurement

It is often difficult to distinguish the differences between private and public health-related markets, as both have standard features including demand and supply conditions. However, the key distinguishing feature between the two markets is the public sector's pursuit of public interests versus the private sector's pursuit of profits (Bovis, 2018). Another key distinguishing factor between the two is the suite of EU secondary legislation governing the award of public contracts. The Council Directives on public procurement harmonise the procedures used by Member States when purchasing supplies and services (European Parliament and Council of the European Union, 2014a and 2014b). In 2014, the rules were updated to encourage public procurers to consider social, environmental and economic criteria when awarding contracts (Arrowsmith, 2014). In terms of preventing discrimination on the grounds of disability, procurers must include "accessibility and design for all" technical specifications to ensure persons with disabilities have access to the goods and services provided (Art. 42 of Directive 2014/24/EU).

[10] Case T-216/15 *Dôvera zdravotná poist'ovňa, a.s. v European Commission* [2018] EU:T:2018:64, para 48.

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While the rules require contracting authorities to purchase in a manner, which prevents discrimination on the grounds of disability, they do not extend to directing Member States on what products or services to purchase. The rules contain many provisions to aid contracting authorities in purchasing innovative digital solutions, and in particular, from micro and small companies. One such tool available to contracting authorities is a 'pre-commercial procurement' (PCP) process. PCP involves the successive development of innovative solutions with risks and benefits shared between economic operators and a public body under market conditions (European Commission, 2007).

Full tender competitions for the purchase of the commercialised solutions can follow the completion of the pre-commercial stage (*ibid*). This demand led activity offers procurers greater choice to define and design required solutions by interacting closely with a range of tenderers. Contracting authorities do not enjoy the freedom to interact with interested economic operators when the tender competition is ongoing.[11] This process provides start-ups and innovative companies an opportunity to work with public bodies. PCP involves procuring activities that fall for the most part outside of the Directive and require low sums of investment from public procurers (Recital 47 of Directive 2014/24/EU).

For innovative R&D contracts falling within the remit of the Directive, contracting authorities are encouraged to use the new *'innovation partnership'* procedure. This procedure assists procurers in purchasing innovative solutions, which require significant sums of public investment (Andhov, 2015). The innovation partnership procedure is suitable for contracting authorities, which require the design and development of an innovative product or service that is not commercially available on the market (Iossa, Biagi and Valbonesi, 2018). The procedure allows contracting authorities to establish a long-term partnership with economic operators for the development and subsequent purchase of the commercialised products or services. However, contracting authorities have not made best use of these tools. Extended use of these innovative procurement mechanisms can support the delivery and deployment of digital healthcare solutions.

In a post SHAPES era, pilot partners in an attempt to exploit the tested and developed digital solutions should consult with relevant contracting authorities to identify possible future public contracts at both a national and local level. Public procurers are strongly encouraged to include accessibility and innovative criteria at each stage of the procurement process to facilitate the participation of small digital businesses that can offer new solutions to assist older persons remain in their own homes. Where possible and appropriate, procurers are encouraged to engage in PCP and innovation partnerships procedures to support the delivery of innovative community healthcare. SHAPES embraces such market shaping to ensure fairness in access and competition in innovation, locally, nationally, across Europe and globally.

[11] Joined Cases C-21/03 and C-34/03 *Fabricom SA v Belgian State* [2005] ECR I-1559.

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5.5 The relationship between EU Competition Law and Policies and the Digital Economy

The promotion of competition within the Single Market is embedded in the TFEU, which prohibits anti-competitive agreements, cartels, and outlines permissible use of mergers and State aid provisions (Faull, Nikpay and Taylor, 2016). EU law and national instruments on competition aim to prevent market distortions and secure fair and equal conditions for businesses. However, the current suite of legislation fails to comprehensively cover digital markets, and in particular, fails to govern the actions of large digital platforms. A repetitive and common argument suggests there is a democratic deficit in the digital markets with the largest platforms operating without fear of legal restrictions (Cini and Czulno, 2022).

The DMA and the DSA sit separately to the suite of competition and State aid rules to address the shortcomings of the current antitrust rules in regulating the digital platform sector. One of the core criticisms raised relates to the ineffectiveness of the *ex post* nature of the antitrust rules in regulating market behaviour and actions of dominant companies (Podszun and Bongartz, 2021). While there have been some key examples of cases taken against large digital platforms and technology companies, the pragmatics of these investigations are problematic (Fazio, 2022). The timeframes for hearing these types of cases are prolonged extending to several years. This creates difficulties as the technology and market assessed has the serious potential of becoming redundant before the proceedings are finalised.

The adopted DMA and DSA address these concerns by introducing *ex-ante* obligations for online platforms designated by gatekeepers, thus supplementing the existing *ex-post* competition enforcement. The annex to this Deliverable (D8.3.1) offers a brief discussion on the scope of the DMA and DSA.

5.6 Conclusion

As described by WP7 and WP3, the SHAPES Marketplace will contribute to the creation of a secure and trusted open ecosystem bringing additional future proof functionalities and improve the competitive advantage of SHAPES solutions. The marketplace and proposed governance models will be underpinned by the fundamental EU competition law rules, placing obligations on the SHAPES project partners to ensure that activities on the marketplace will prevent market distortions and secure fair and equal conditions for businesses. Separately, project partners should be aware of the rules relating to State aid and public procurement when attempting to receive public grants or contracts to further develop or sell the piloted digital solutions post completion of the project. Where possible, project partners are

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encouraged to engage in pre-commercial procurement processes or innovative-partnerships with public bodies to exploit the benefits of the piloted solutions.

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6 Recommendations

6.1 Introduction

Task 8.2 aimed to identify the extent to which current legal frameworks facilitate the creation of pan-European systems for smart and healthy ageing. When the project commenced, the primary point of legislative reference was the EU's Patients' Rights Directive, which provides for the right of individual patients to obtain medical treatment in a MS different from their home country. In that context, the task addressed free movement provisions and EU legislation impinging on the protection of fundamental rights, and the provision of services, such as public procurement legislation on State aid and competition rules, taking into account the CJEU case law. However, as the project progressed, the complexity of the SHAPES Ecosystem as well as the developments occurred at the EU level required a broader approach to identify which regulatory frameworks were relevant.

This Deliverable D8.3 and its accompanying annex D8.3.1 sought to map the regulatory landscape, identifying and scrutinising the potential implications and responsibilities arising from the proposals for the SHAPES project and partners. This section of the report summarises the key regulatory framework underpinning the SHAPES project. It is hoped that public officials and relevant economic operators can rely on this framework when replicating and using the digital solutions disseminated on the SHAPES Platform. As noted at the start of this document, this is a point of reference document, which offers concise overviews of relevant instruments.

6.2 European level

One of the contributions of this Deliverable to the SHAPES Project is the identification of four core regulatory frameworks which are necessary and fundamental to the deployment of an inclusive, competitive and viable pan-European system for smart and healthy ageing. The idenifited EU *acquis* of Smart and Healthy ageing frameworks is compartmentalised into the following four chapters; EU Competences, Stakeholders, Technology Platform and Digital Solutions and Market Place.

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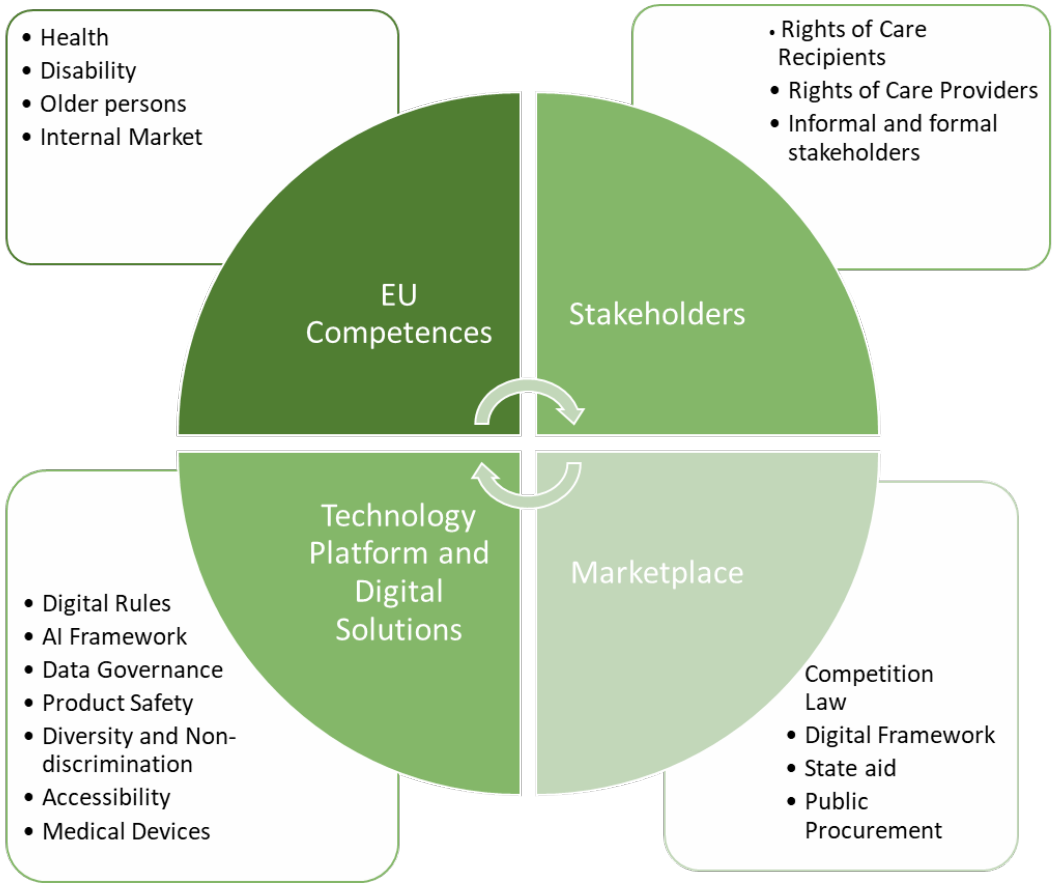

Figure 3 The Regulatory Framework supporting pan-European smart and healthy ageing

The complex framework was identified through the completion of a large scale doctrinal analysis of relevant EU law, CJEU case law and policies, and directed by the information produced in early submitted deliverables by WP8, 2, 3, 5, 6, and 11.

While the Deliverable discusses the four chapters of the framework individually, it is cognisant that EU legislation and policies often overlap and are cross-cutting as well as evolve at a very fast pace. It is also aware that this is not an exhaustive list of legislation. Rather, it highlights key EU law and policies which should be complied with to create a supporting environment to disseminate the SHAPES model in Member States. In particular, the framework pivots on the foundational legal dimensions associated with features of the SHAPES Project, the right to health of older people and people with disabilities and their free movement rights, and the freedom of caregivers and service providers to provide services across internal EU borders within the EU internal market. It is not tasked with the responsibility of analysing the individual legislative regimes of the SHAPES partner countries.

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6.2.1 The role of the EU

As discussed in Chapter 2, the EU acts within the limits of exclusive, shared and supporting competences conferred upon it by the Treaties to attain the objectives provided therein (Articles 2 -6 TFEU). For the purposes of the SHAPES Project, this Deliverable focused on the EU exclusive competence on "the establishing of competition rules necessary for the functioning of the internal market" with specific regard to the SHAPES marketplace (Article 3 TFEU). It further assessed the shared competences relevant to the project in relation to the internal market, social policy, economic, and shared safety concerns in public health matters (Article 4 TFEU). Importantly, it identified the supporting competences that provide for the protection and improvement of human health (Article 6 TFEU). In assessing the relevant competences, this Deliverable D8.3. chooses to focus on the EU competences pertaining to health, disability, technology, and older persons, and in particular, identifying how the competences are exercised in binding legislative instruments and in soft-law policy measures.

The EU's competence in relation to health policy is under a period of transformation, with plans adopted to introduce a European Health Union (Hervey, 2020; de Ruijter, 2019). However, as it currently stands, the EU plays a secondary role in the regulation of health law. Healthcare delivery and organisation is primarily regulated at a domestic level. EU health law narrowly focuses on harmonising procedures on the marketing, monitoring, safety and efficacy of pharmaceuticals and medical devices and facilitating patients' access to devices in the European Union (Greer et al., 2019). While the range and boundaries of the EU competence on health policy appears limited, the rules adequately facilitate and allow for the deployment of cross-border smart and healthy ageing solutions. Notwithstanding the EU's lack of direct competence in the development and deployment of healthcare organisation and management, the EU possesses core competences in ensuring the efficacy and safety of medical devices, IVDs and medicines, and holds broader competences for the development of a wide range of soft-law policies aimed at creating an inclusive, sustainable and economic Union.

The recent changes made to the Medical Devices Regulation (MDR) aim to address the current problems relating to the diverging interpretation of medical devices and inconsistent application of EU rules. Importantly as the rules now take the form of a Regulation, rather than a Directive, the rules are implemented uniformly, providing greater legal clarity on the distinctions between medical devices and medicinal products thus reducing company's discretions when applying for suitable CE marks (Jarman *et al*., 2020). However, the new legislative regime is not without its flaws. Jarman *et al*. (2020) argue that the new rules fail to address the current issues of market fragmentation and patient safety and further contend that the successful implementation of the rules is dependent on the harmonised support at both an EU and national level. It should be noted that powers and functions of the European

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Medicines Agency (EMA) and national competent authorities have been strengthened to support relevant bodies in conducting safety and performance assessments of medical devices and notably, national competent authorities are now responsible for classifying “borderline products” as medical devices on a case-by-case basis (EMA, 2019). Specifically, the updated rules have significantly increased the pre-market assessment and post-market surveillance of medical devices, ensuring that all devices sold and used within the Union meet the highest safety standards. It is assumed that the majority of any existing manufacturer self-assessed smart and healthy ageing IVDs will be CE marked by the end of 2022 (Ritzhaupt *et al.* 2020). The EU’s competence in health-related policy, while limited, paves the foundation for a safe and monitored pan-European smart and health ageing society.

Alongside the promotion of safe devices, the EU’s most recent policy on disability facilitates the creation of person-centered and inclusive systems. Just over a year ago, the European Commission presented its new Strategy for the Rights of Persons with Disabilities 2021-2030 (the ‘Strategy’) (European Commission, 2021b). The Strategy facilitates the implementation of the CRPD by embracing a social-contextual model that is based on a human rights approach to disability. Specifically, the Strategy, while renewing its commitment to accessibility as under the preceding strategy, also focus on independent living.

An array of strategies and policies such as the European Care Strategy will support a better coordination between the EU and Member States when it comes to healthcare. The NGEU funds are in place not only to support post-pandemic economic recovery, but also to strengthen national health systems, improve medical products and protect EU citizens from future cross-border health threats including through digitalisation (European Commission, 2020d).

6.2.2 Users

The second chapter focuses on the regulatory framework relates to stakeholders. The SHAPES project not only aims to sustain and extend the use of digital solutions to support the healthy and independent living of older persons within the EU, but also additionally, aims to assist and ease caregivers’ tasks and responsibilities. It is therefore important for this legal framework to recognise the fundamental rights afforded to project stakeholders in their capacity as care recipients and as caregivers in assessing their protection under EU law. In alignment with the other WPs, a comprehensive and inclusive network of SHAPES Stakeholders is relied upon ranging from medical care providers and recipients to informal or family carers.

This broad interpretation of relevant stakeholders is not mirrored or found in EU law. The EU treaties and fundamental rights instruments do not confer onto the EU any suitable competence in respect of the category of adults that may be described as vulnerable or in relation to their caregivers or care providers. Some economic

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protections are offered to remunerated caregivers and provided in the form of employment legislation (Article 153(1) TFEU). However, these protections do not extend to those who are self-employment or in atypical care role, as well as those who are unemployed in the case of informal carers. This Deliverable argues that the current regime fails to protect informal caregivers, and as these caregivers for the most part, bear intensive care responsibilities, their fundamental rights must be protected to ensure fairness in a smart and healthy European regime.

Separately, this Deliverable highlights the low exercise by patients of the right to obtain and be reimbursed for healthcare in another Member State. In this regard, the SHAPES Platform knowledge base should be used to increase awareness of this right amongst users and stakeholders.

6.2.3 Technology Platform and Digital Solutions

Article 114 TFEU provides the legal basis for a broad range of digital legislative measures, including the relevant European Accessibility Act, the Web Accessibility Directive, the Copyright Directive and Copyright Accessibility Regulation. As we have seen, the EU has fast-tracked their actions in developing a competitive and innovative digital Union. While the proposed AI, Data Governance, and Digital Services and Markets legislative instruments are yet to be implemented, the planned legislation and policies will facilitate and encourage the development of inclusive digital solutions whilst simultaneously protecting digital users' rights to data and access to new technologies. The combined proposed legislative instruments have the potential to accelerate the use of assistive technologies to promote independent and healthy ageing. As most of these initiatives will be introduced after the Deliverable has been submitted, this report cannot assess the potential efficacy of these innovative instruments.

6.2.4 Marketplace

In order to support the creation of a smart and healthy ageing Europe, piloted and developed SHAPES digital solutions should be widely deployed across Member States. The SHAPES Marketplace offers an innovative, secure and trusted ecosystem to promote the use of the digital solutions. As discussed in the previous chapter, the Marketplace will be underpinned by the fundamental EU competition law rules as set out in Articles 101 – 109 TFEU. Project partners must not unintentionally engage in any activities relating to illegal contracts and agreements, especially agreements which relate to price fixing, market sharing, agreements on customer allocation, agreements on production limitation and distribution agreements, amongst others (Articles 101 – 102 TFEU).

It is also envisaged that the project partners will sell their digital solutions to the public sector or receive public funds to develop or test the solutions further. In this regard,

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the regulatory framework offers an overview of the rules on State aid and public procurement. The main objective of both streams of legislation is to prevent market distortion, with State aid prohibiting the discriminatory granting of public funds and the public procurement rules prohibiting the discriminatory awarding of public contracts.

In particular, project partners are encouraged to exploit relevant and appropriate opportunities falling within the scope of services of general economic interest (SGEI), or in the remit of social services of general economic interest (SSGEI). Similarly, project partners may benefit from collaborating with public contracting authorities through the medium of pre-commercial procurement or innovative partnership procurement activities.

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6.3 Recommendations

The following Table (Table 7) provides some general recommendations for SHAPES.

Table 7 – Recommendations for the SHAPES Ecosystem

Recommendations for the legal frameworks facilitating the creation of pan-European systems for smart healthy ageing.
✓ Adopt a human rights approach to care delivery and align with the Charter of Fundamental Rights. ✓ Raise awareness of cross-border health policy, and the rights of patients across the EU. ✓ Align with and respect the rights of those receiving or providing care. ✓ Comply competition and State aid law and understand the boundaries of secondary public procurement legislation. ✓ Respect and comply with appropriate and relevant domestic legislation and policy. To strengthen this framework, the Deliverable recommends that the following actions should be introduced: ✓ Early and voluntary adherence with the provisions set out in the Declaration on Digital Rights. ✓ Alignment with and support of the realisation of the European Care Strategy. ✓ Support EU actions on the Rights of Older People. ✓ Support greater use of pre-commercial procurement and innovation partnership procurement procedures to support the development and deployment of digital solutions to assist older persons living independently.

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Smart and **H**ealthy **A**geing
through **P**eople **E**ngaging in supportive **S**ystems

Annex to Deliverable D8.3

D.8.3.1 "The SHAPES Integrated Platform, the SHAPES DIGITAL Solutions in the EU Legal Context"

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EU Digital Policies: Setting the Scene	Emma McEvoy and Delia Ferri (NUIM)
Legal Requirements For The Shapes Platform And Digital Solutions	Emma McEvoy, Delia Ferri and Evelyn Soye (NUIM)
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Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations

Acronym	Full Term
AI	Artificial intelligence
AI HLEG	High-Level Expert Group on Artificial Intelligence
AVMSD	Audiovisual Media Services Directive
CFR	Charter of Fundamental Rights
CJEU	Court of Justice of the European Union
CRPD	United Nations Convention on the Rights of Persons with Disabilities
DMA	Digital Markets Act
DSA	Digital Services Act
DSM	Digital Single Market
EAA	European Accessibility Act Directive
EU	European Union
EHDS	European Health Data Space
EMA	European Medicines Agency
GDPR	General Data Protection Regulation

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ICT	Information and Communication Technologies
IPR	Intellectual Property Rights
IoT	Internet of Things
IVDs	In Vitro Diagnostic medical devices
IVDR	Vitro Diagnostic Medical Devices Regulation
MDR	Medical Devices Regulation
MSP	European multi-stakeholder platform on ICT standardisation
OIPs	Online Intermediary Services Providers
R&D	Research and development
SEM	Single European Market
SMEs	Small and medium sized-enterprises
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
WAD	Web Accessibility Directive

Keywords

Legislative frameworks, new technologies, emerging technologies, new health technologies, artificial intelligence, digital policies.

Disclaimer

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Executive Summary

Work Package (WP) 8 focuses on the SHAPES Action's ethical and legal dimensions, tackling the cross-cutting legal issues encompassed by SHAPES. Issues addressed by the WP relate to data privacy, data ownership, technology providers' responsibilities, ethics of citizen participation in health and care delivery policies, the potential misuse, abuse and non-intended impact of the SHAPES digital solutions.

As part of WP8,this annex (D8.3.1) constitutes an annex to D 8.3 and focuses on the European Union (EU) regulatory framework for the SHAPES Integrated Platform. This annex discusses the various legal dimensions (excluding privacy which is analysed in deliverable D8.5) associated with features of the SHAPES platform, and the SHAPES digital solutions, and complements the overall discussion of the regulatory framework applicable to the SHAPES ecosystem and marketplace. It also builds on and complements the ethical analysis conducted in deliverables D8.4 and D8.14. In particular, when it comes to the Integrated Platform and the Digital Solutions, this annex focuses on legislation that was deemed relevant by the European Commission in recent policy documents, in the field of digital policy, specifically, albeit not exclusively, the White Paper on Artificial Intelligence (European Commission, 2020b).

It must be noted that it is beyond the scope of this research to discuss any issues concerning Intellectual Property Rights (IPRs) and product liability, which were dealt with in other projects and studies. In that regard, this annex refers to the work performed by other scholars, and by the EU institutions, which is properly cited where appropriate.

Further to an introductory section, the annex is divided into four distinct sections. Section 1 begins by outlining the aims and structure of the study. A primary aim of this annex is to locate the SHAPES Platform and SHAPES Digital Solutions in the EU legal and policy framework. The first section draws the research boundaries, pinpointing the legal and policy frameworks that are relevant and appropriate to the SHAPES Platform. Section 2 explores the various legal and policy definitions of technologies, digital solutions and AI. This section seeks to trace the legal developments to identify up-to-date and appropriate terminology to be used within this annex, and defines the scope of the application of EU law to the SHAPES Platform and digital solutions. Section 3 considers the development of EU policies on Digital Services. A vast body of EU policies have been introduced over the last two decades to support the development of an innovative, inclusive and competitive economy. Section 4 identifies the legal requirements for the SHAPES Platform and Digital Solutions. Section 5 closes by summarising the relevance and importance of the identified legal framework for the SHAPES Platform and Digital Solutions.

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1. Introduction

1.1. Aims

The aims of this annex (D8.3.1), which complement and support deliverable D8.3, are:

1) To locate the SHAPES Platform and SHAPES Digital Solutions in the EU legal and policy framework
2) To identify relevant European Union (EU) legislation and legal requirements to be complied with
3) To identify additional national legal sources that implement EU legislation. In that connection, however, this annex does not analyse national legal sourcesas these fall outside the remit of Task 8.2.

1.2. Objectives and Focus

The SHAPES Innovation Action (IA) is a pan-European project seeking to build, pilot and deploy a large-scale, EU-standardised open platform. The integration of a broad range of technological, organisational, clinical, educational and societal solutions seeks to facilitate long-term healthy and active ageing and the maintenance of a high-quality standard of life (SHAPES 2019).

This annex focuses on the legal requirements relevant to the platform and digital solutions, which are briefly described below:

- ✓ SHAPES Integrated Care Platform is based on four dimensions: home, behaviour, market and governance. Big data analytics and artificial intelligence (AI) analyse information pertaining to health, environment and lifestyle and individual needs, and create user profiles and deliver personalised solutions. Adherence to EU data protection rules ensures user privacy, safety, security, trust and acceptance.

- ✓ SHAPES Digital Solutions include assistive robots, eHealth sensors and wearables, Internet of Things (IoT) devices and mobile applications (apps).

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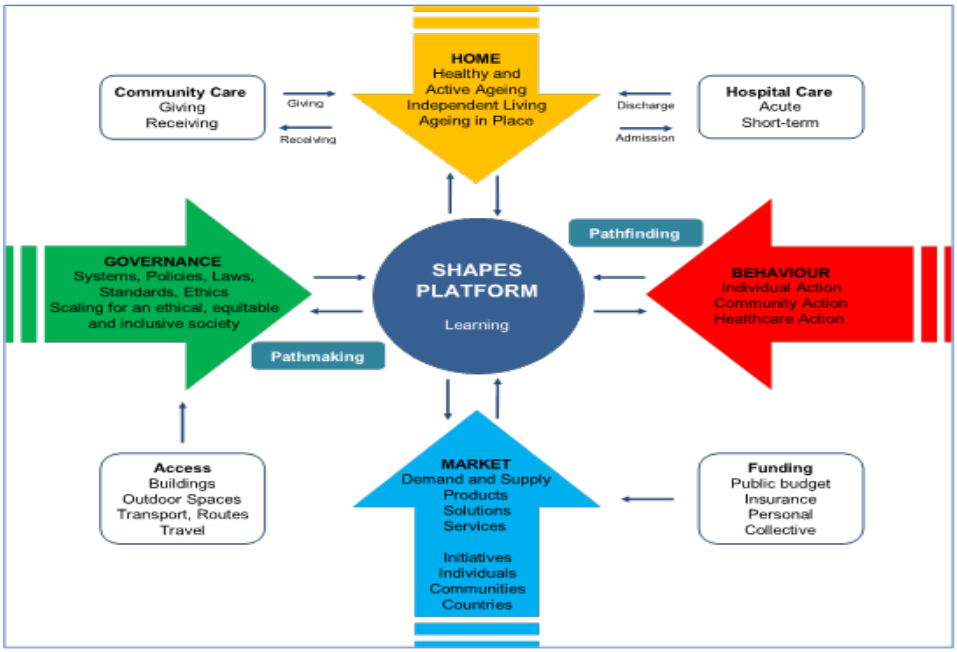

Figure 1 The SHAPES Integrated Care Platform (Adopted SHAPES 2019, 85)

1.3. Scope and Structure of the Deliverable

Annex D8.3.1 focuses on the legal requirements of the SHAPES Integrated Care Platform and Digital Technologies within the EU legal framework. It does not discuss national law, which falls outside the remit of the legal analysis envisaged in WP8- Task 8.2. Notably, the key legal framework includes data protection legislation. However, this is considered separately within the remit of WP8, and is not included in this annex, nor in D8.3. This deliverable takes into account legal developments up to 01 March 2023.

The annex considers that the **EU legal landscape on digital technologies is constantly evolving**, and presents an overview of ongoing policies as well as recent legal developments, which are relevant to the project. It does not endeavour to be exhaustive, but aims to give an overview of the legal landscape in which the SHAPES technologies are situated. SHAPES is at the forefront of period of digital transformation and aims to capture digital advancements with a view of fostering the rights of older people and supporting heathy ageing. In that connection, it aligns with **the objectives of the the EU Digital Decade** policy programme, which lists concrete targets and objectives for 2030. The **Decision (EU) 2022/2481 establishing the Digital Decade Policy Programme 2030** (European Parliament and Council, 2022a) lists among its many objectives that of:

> "promoting a human-centred, fundamental-rights-based, inclusive, transparent and open digital environment where secure and interoperable digital technologies and services observe and enhance Union principles, rights and values and are accessible to all, everywhere in the Union" (Art. 3(1)a)

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The **forthcoming regulatory framework on artificial intelligence** (AI) will be discussed, paying attention to that fact that, when approved, it will introduce accountability, documentation and testing requirements to ensure the compatibility of AI with fundamental rights (European Commission, 2020b). In October 2020, the European Parliament also put forward recommendations on what AI rules should include with regards to ethics, liability and IPRs (European Parliament, 2020). These recommendations place an emphasis on a human-centric and human-made AI, on safety, transparency and accountability; as well as safeguards against bias and discrimination; a right to redress; social and environmental responsibility; and respect for privacy and data protection (European Parliament, 2020).

This annex complements the ethical requirements identified in D8.4. The specific D8.2 activity 'Baselining for Project Ethics' was completed in collaboration with WP8 in M6. This involved designing guidelines and templates for research integrity and for the ethics management of the SHAPES project.

It must be noted that it is beyond the scope of Task 8.2 (and of deliverable D8.3 and its annex D8.3.1) to discuss any issues relating to IPRs. It is also beyond the scope of this annex to address product liability, which have been dealt with in other projects. In that regard, D8.3.1 refers to the work done by other scholars and by the EU institutions, which is properly cited where appropriate.[1] We refer, in particular, to the paper on "Liability for Artificial Intelligence and Other Emerging Technologies" authored by the Expert Group on Liability and New Technologies[2] for the European Commission (Expert Group on Liability and New Technologies, 2020). In 2020, the European Law Institute published an Innovation Paper entitled 'Guiding Principles for Updating the Product Liability Directive for the Digital Age', prepared by Christian Twigg-Flesner. The legislative initiative by the MEP Axel Voss (EPP, DE) calls for a future-oriented civil liability framework, making those operating high-risk AI strictly liable for any resulting damage. The European Parliament suggests that a legal framework on liability would stimulate innovation by providing legal certainty. This resolution follows the European Parliament resolution with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)). In that regard, the Product Liability Directive does not seem suited to deal with goods having a digital component.

On 28 September 2022, the European Commission published a proposal for a new directive on liability of defective products (European Commission 2022c). This would revise the existing Product Liability Directive (Council of European Union, 1985),

[1] There is very limited harmonisation in terms of EU private law. However, a lot of research in relation to a common approach to liability for robotical/AI products has been done. See also the research will rely on the research that has been already done in other EU projects (Robololaw and now INrobotics by SSSA).

[2] This Expert Group provide the European Commission with expertise on the applicability of the Product Liability Directive to new technologies and assist the Commission in developing principles relating to new technologies. See https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3592

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adopted almost 40 years ago in 1985. This proposal confirms that AI systems and AI-enabled goods are 'products' and thus, fall within the scope of the directive. This entails that compensation must be provided in case of defective AI that causes damage without the injured person having to prove the manufacturer's fault, just like for any other product. The proposal provides that both hardware manufacturers and software providers, and providers of digital services can be held liable. Importantly, as it stands, the proposal lessens the burden of proof in complex cases, which could include cases on AI systems. As a complement to these changes, the parallel proposal for a directive on fault-based liability for AI seeks to ensure that, where an injured person has to prove that it was somebody's fault that an AI system caused damage in order to obtain compensation under national law, the burden of proof can be alleviated if certain conditions are met.

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2. Technology, digital solutions and Artificial Intelligence: Normative Definitions

2.1. Defining and Tracing Boundaries

Concepts relating to technology, big data analytics, AI and digital solutions are vast and continuously expanding. In order to trace the material scope of the legal analysis and to understand the extent to which certain rules are applicable, this section briefly discusses the meaning of 'technology' in the relevant SHAPES regulatory framework, before moving onto specific definitions of digital technologies including AI, big data and the IoT.

2.1.1. Technology

Despite its common usage, the definition of 'technology' has given rise to historical debate in the academic community, with some contending that technology is 'poorly understood' and 'ill-defined' (Bleed, 2008, p.98). Without attempting to individually view the definition of technology through either a sociological or scientific lens, this annex will accept the multi-disciplinary definition proposed by Carroll. Carroll (2017, p. 18) presents a tripartite definition recognising that technology is "(a) something that is always inherently intelligent enough either to function, to be used to function; (b) something devised, designed, or discovered that serves a particular purpose from a purely secular standpoint; (c) a significant beneficiary of rationally-derived knowledge that is "used for" a purpose". The EU has avoided providing a legal definition of technology, with the promotion of technology remaining solely in the remit of economic policy. Historical incentives to the creation of the Single European Market (SEM) focussed on the advancement of EU technologies to combat the economic threat to Europe posed by the high technology developments in the US and Japan and newly industrialising states in assembly industries (European Commission, 1992). The formation of the SEM focused on removing the formal and informal barriers to cross-border trade in the region, including the removal of physical barriers associated with state frontier inspections and the removal of the technical obstacles to ease the harmonisation of legal and regulatory measures (European Commission, 1997).

2.1.2. New Technologies and New health Technologies

As it will be discussed in section 3, the EU's digital policy continues to evolve, and often policy documents refer to new forms of technologies in a general fashion (European Commission, 2018). Numerous terms are used in European policy and academia to describe 'new technologies', including: advanced technologies, emerging

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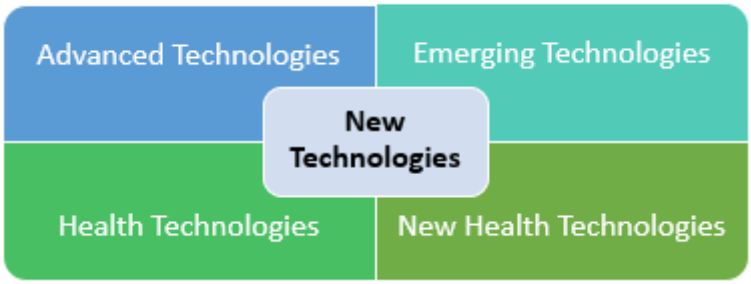
technologies, health technologies, and new health technologies. These terms are often used interchangeably and without precision (Rotolo, *et al*. 2015).



Building on Carrol's definition, new technologies can be defined as newly created technologies, which improve upon existing technologies or create a new product or service. This overly far-reaching and straightforward definition can act as an umbrella term for all forms of new technologies. A flexible and fluid definition reduces the 'risk of running behind the pace of scientific and social' developments (Flear *et al*. 2013). To date, there has been little agreement on what constitutes the precise nature of new technologies. Warren-Jones argues that a precise definition will remain elusive, as researchers from different disciplines will interpret the term 'new' differently. The example relied on to illustrate this point, explains that a medical researcher might interpret the term 'new' to mean something that has not been tested, whereas a medical practitioner might interpret the term to mean something untried (Warren-Jones, 2013). Subtle and minor differences in interpretations like this can result in the misapplication or avoidance of new technologies. EU law does not offer any prescriptive definition of new technologies and for the most part, avoids the terms new technologies, advanced technologies, emerging technologies, health technologies, and new health technologies. However, it should be noted that the General Data Protection Regulation (GDPR) makes a minor reference to the term new technologies. While the GDPR does not offer a definition of the term, when discussing the processing of personal data to the supervisory authorities, it provides that "types of processing operations may be those which, in particular, involve using new technologies, or are of a new kind." (European parliament and Council of the European Union, 2016).

Policy and guidance documents have been equally elusive in defining new technologies. The European Commission's Advancing the Internet of Things in Europe Staff Working Paper (2016a, p. 18) comes closest to explaining the term:

> "'The scale provided by a Digital Single Market (DSM) is also important for the deployment of high-speed infrastructure to enable advanced digital services and the development and adoption of *new technologies* in Europe, such as the Internet of Things, big data analytics or cloud computing."

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The Decision establishing the Digital Decade Policy Programme 2030 mentions digital technologies and new digital technologies.

This inclusion reinforces the legitimacy of using **new technologies as an umbrella term** for various terminologies to describe advances in technologies. Furthermore, policy and guidance documents have additionally outlined the characteristics of new technologies. The Artificial Intelligence for Europe Communication (European Commission, 2018) states that new technologies are 'based on values', concluding that EU policies should promote innovation while respecting the Union's values and fundamental rights as well as ethical principles such as accountability and transparency. The White Paper on Artificial Intelligence a European approach to excellence and trust further displays the Commission's commitment to "ensuring that new technologies are at the service of all Europeans" (European Commission, 2020b, p. 2).

While it might be useful for policy and legislation to avoid offering a precise definition to avoid the risk of falling behind on technological developments, a harmonised understanding of new health technologies is needed to support the creation, piloting and deploying of a large-scale, EU-standardised open platform.

Several definitions of new health technologies have been proposed. O'Rourke *et al*. (2020, p. 825) rely on a pragmatic definition, recognising that a health technology:

> "…is an intervention developed to prevent, diagnose, or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system."

While, Flear *et al*.(2013) warn that the scientific and social interpretations of the terminology depends on human perceptions of 'new' and 'health'. (2013, p. 390). It might be useful as the project progresses to assess what is considered a new health technology, whether they comprise health services, medical equipment or medicines. However, at this point, it is appropriate to adopt the universal definition of health technologies proposed by the World Health Organisation (WHO), which acknowledges that:

> "A health technology is the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life" (WHO, Resolution of Health Technologies, 2007).

We will accept this definition and will work to identify how EU law is facilitating the use of new health technologies. Flear *et al*.'s (2013) seminal work defines a new field of scholarship, 'European law of new health technologies' (Flear *et al*., 2013). Building on these foundations, this deliverable will further explore this new field of scholarship

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by assessing if the legislative framework has the potential to facilitate pan-European smart and healthy ageing. In particular, D8.3.1 will focus on identifying the role EU law plays in regulating new health technologies, and highlight how regulating digital inclusion and new technologies can provide benefits and limit challenges for people with disabilities, including older people with disabilities (Waddington and Broderick, 2020).Upon discussing the limitations and nuances of this new field of scholarship, the research will rely on the features already identified by Flear *et al*.(2013) Four 'frames' shape the study of the scholarship; markets, risk, human rights and ethics. In relation to markets, the established research focuses on the theoretical relationship between EU law and the Internal Market. The risks feature focuses on the legitimacy of risk-management and governance structures. The third feature questions the human rights dimension of the EU law of new health technologies. The final feature focuses on the ethical issues of the European policy landscape (Flear *et al*., 2013). This research extends on the theoretical basis by focusing on specific elements of the relevant legislative framework and referencing appropriate cases of the Court of Justice of the European Union (CJEU). It will focus on identifying the obstacles facing the free movement of health providers, services, goods and persons and any potential distortion of competition.

2.1.3. Artificial Intelligence

While EU law deliberately steers away from offering precise definitions of new technologies and new health technologies, pragmatic definitions of some forms of these technologies, such as AI, big data, and the Internet of Things have been outlined in soft law and policies. McCarthy first coined the term artificial intelligence in 1956, defining AI as "the science and engineering of making intelligent machines, especially intelligent computer programs" (Buiten, 2019). For the purpose of regulation, such a circular definition of AI is of little functional use.

We must turn to policy to find an updated and specific definition of AI. The Communication on Artificial Intelligence for Europe (European Commission, 2018) offers the following definition of AI:

> "Artificial intelligence (AI) refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals. AI-based systems can be purely software-based, acting in the virtual world (e.g. voice assistants, image analysis software, search engines, speech and face recognition systems) or AI can be embedded in hardware devices (e.g. advanced robots, autonomous cars, drones or Internet of Things applications)." (European Commission, 2018)

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> "Artificial intelligence (AI) systems are software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analysing how the environment is affected by their previous actions.
>
> As a scientific discipline, AI includes several approaches and techniques, such as machine learning (of which deep learning and reinforcement learning are specific examples), machine reasoning (which includes planning, scheduling, knowledge representation and reasoning, search, and optimization), and robotics (which includes control, perception, sensors and actuators, as well as the integration of all other techniques into cyber-physical systems)." (p. 6)

While this comprehensive definition considers the different categories of AI, such as specialised AI, general AI and superintelligence, it fails to acknowledge the importance of the human-centred perspective (Carrico, 2018). In 2019, the European Commission adopted a refined definition of AI proposed by the High-Level Expert Group on Artificial Intelligence (AI HLEG). The adopted definition explored in the 2019, A definition of AI: main capabilities and disciplines report aims to avoid misunderstanding and clarify different aspects of AI as a scientific discipline and as a technology (European Commission, 2018). It proposes the following definition:

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Additionally, the document refers to AI systems as meaning 'any AI-based component, software and/or hardware. Indeed, usually AI systems are 'embedded as components of larger systems, rather than stand-alone systems' (p 3). It is envisioned that this definition will be harmoniously used by AI experts, providers and non-AI experts and relied on to develop future AI ethics guidelines and policy. Furthermore, in a more recent resolution of the European Parliament, it is stated that 'the notion of AI-systems comprises a large group of different technologies, including simple statistics, machine learning and deep learning', and it suggests that

> "using the term "automated decision-making" could avoid the possible ambiguity of the term AI; whereas "automated decision-making" involves a user delegating initially a decision, partly or completely, to an entity by way of using software or a service; whereas that entity then in turn uses automatically executed decision-making models to perform an action on behalf of a user, or to inform the user's decisions in performing an action" (European Parliament, 2020 recital G)

Veale (2020, p. 4), however, contends that the definition proposed by the AI HLEG and supporting policies, "suffer from a deficit in recognising the importance of problem structuring and framing more broadly" . Veale's argument centres on the capability, or lack thereof, of AI systems to achieve the broad social and sustainability goals attached to the adopted definition. Although, Smuha (2019) suggests that an ambitious human-centred approach to AI is required to harness all of the ethical benefits of AI systems, and to reduce any (un)intentional harm caused by the digital solutions (2019, p.19). In spite of these drawbacks, this annex accepts and uses the European Commission's policy definition.

2.1.4. Big Data and the Internet of Things

Data has received considerable policy and legislative attention over the last 20 years, with data now considered an important asset for the economy and society (European Commission, 2020). Kitchin (2014) suggests that a data revolution is underway, which is shaping knowledge, business and regulation production. The acceleration in the production and use of data-driven technologies has led to the generation of 'big data'. De Mauro *et al*.(2016) list information, technology, methods and impact as the four main themes of big data and proposes that big data should be defined as "the Information asset characterized by such a High Volume, Velocity and Variety to require specific Technology and Analytical Methods for its transformation into Value." (De Mauro, Greco, and Grimaldi, 2016).

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The European Commission (2020) further offers the following broad and overarching definition:

> Big data refers to large amounts of data produced very quickly by a high number of diverse sources. Data can either be created by people or generated by machines, such as sensors gathering climate information, satellite imagery, digital pictures and videos, purchase transaction records, GPS signals, etc. (European Commission, 2020)

Most distinctly, IoT is described as “a network of interconnected devices or systems (‘things’) that can be remotely controlled over the Internet” (European Commission, 2020). This definition suggests that IoT has the potential to create smart environments by merging physical and digital systems. Atzori *et al*.(2010) contend that IoT systems have the potential to have a high impact on everyday living, in particular for this project, through the development of assisted living systems, supporting e-health operations, and enhanced learning for all members of society (Atzori, Iera and Morabito, 2010).

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3. EU Digital Policies: Setting the Scene

3.1. Europe's Digital Decade – An Introduction

Since the SHAPES project began, a plethora of innovative and human-centred European policies have been introduced. Further, a number of legislative proposals have been put forward to regulate the digital landscape. In a similar manner to the other WP8 Deliverables, this annex has been a 'living document' since its inception. It has been updated regularly until 01 March 2023 which represents the cut off date after which the deliverable D8.3 and its annex D8.3.1 will have been finalised.

In spite of regular updates to incorporate EU legislative and policy proposals, D8.3.1. does not aim to be exhaustive. The complexity of the SHAPES Integrated Platform makes an array of regulary frameworks relevant. Hence, this annex identifies the EU legal requirements that are most relevant to the SHAPES Integrated Platform and Digital Solutions in the broader EU digital policies that have significantly accrued over time. It is useful at this stage to recall recent developments and identify the core policies relevant to the SHAPES Platform and Digital Solutions.

In 2020, the European Commission introduced a digital strategy titled "Shaping Europe's digital future" outlining broad plans to utilise digital technology to transform work for people and businesses, and ensuring fair access to digital solutions by all members of society (European Commission, 2020c). Building on these foundational plans, in 2021, the Commission adopted the Communication on 2030 Digital Compass: the European way for the Digital Decade ('Digital Compass Communication') (European Commission, 2021a). The Digital Compass Communication focuses on establishing the EU's digital sovereignty by setting legislative boundaries on the use of digital data, technology and infrastructure. In 2022, the Decision (EU) 2022/2481 establishing the Digital Decade Policy Programme 2030 was adopted (European Parliament and Council of the European Union, 2022a).

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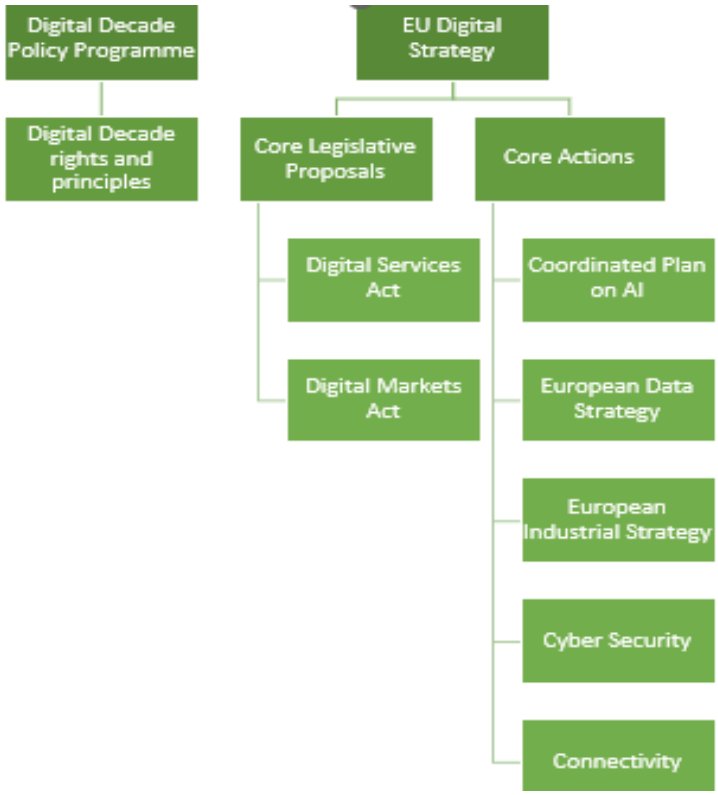

Figure 2 EU's Digital Policies and accompanying policies

EU policies aim to achieve a balance between the need to uphold digital users' fundamental rights and the promotion of an innovative and competitive digital Internal Market (Roberts et al., 2021, Kyvik et al., 2021,Cabral et al., 2021). All proposed digital actions must respect the rights set out under the Charter of Fundamental Rights of the European Union, to ensure each person's rights to privacy, data protection, free expression and assembly and non-discrimination. Additionally, alignment with the European Pillar of Social Rights must be ensured.

Other initiatives introduced under the Lisbon Declaration – Digital Democracy with a Purpose are relevant (European Commission, 2022). The Declaration on digital rights and principles was signed at the highest level by the European Commission, the Parliament and the Council at the end of 2022. The rights and principles revolve around 6 themes:

1. Putting people and their rights at the centre of the digital transformation
2. Supporting solidarity and inclusion
3. Ensuring freedom of choice online
4. Fostering participation in the digital public space
5. Increasing safety, security and empowerment of individuals
6. Promoting the sustainability of the digital future

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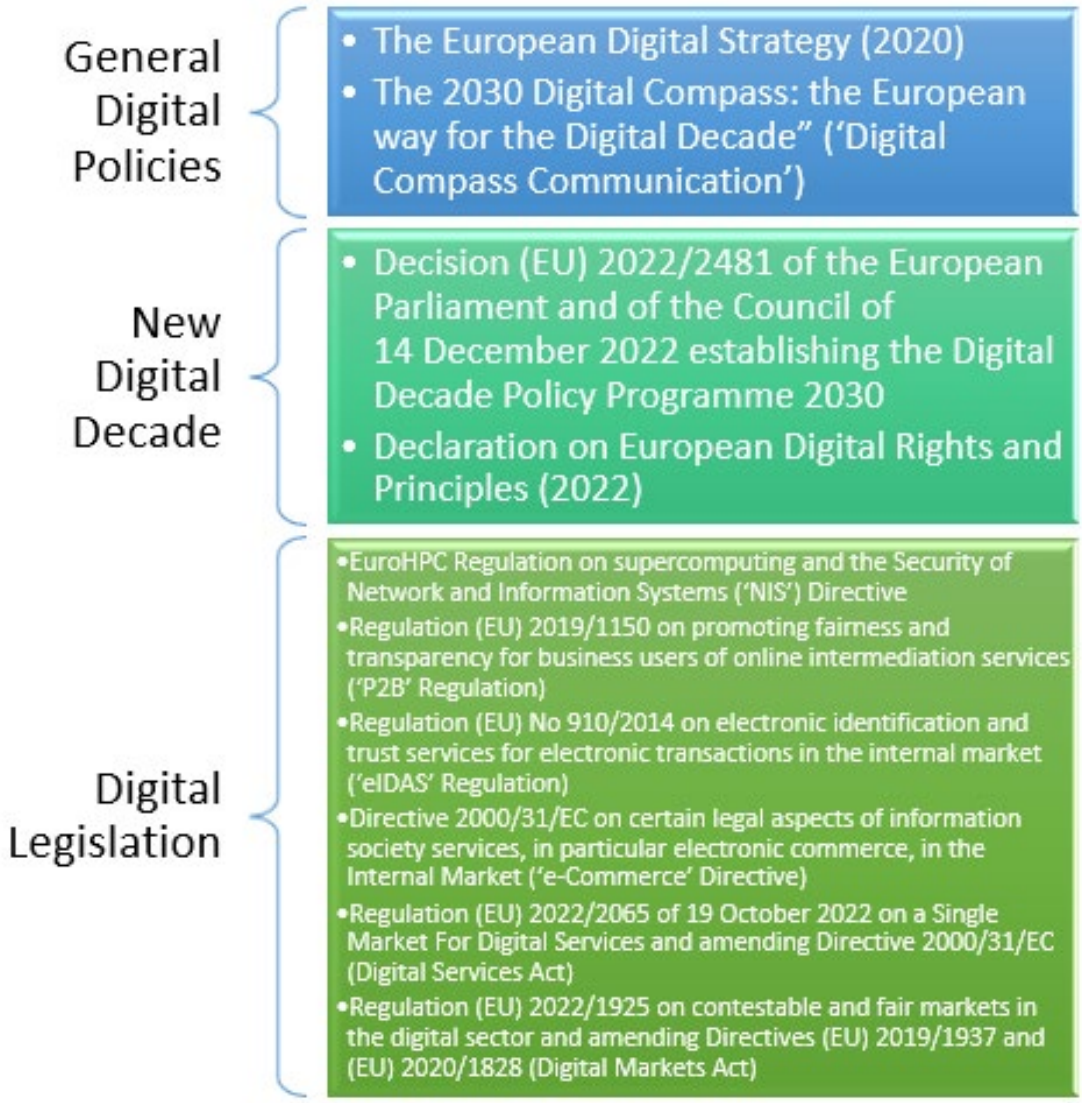
In protecting individuals rights, adherence with the UN Convention of the Rights of Persons with Disabilities (CRPD) is required to ensure the accessibility of digital services for all digital users.

As the consortium partners are at the forefront of creating and distributing digital supplies and services for the benefit of older persons, including persons experiencing neurodegenerative diseases and persons with disabilities, the partners are exceptionally well placed to contribute to ongoing legislative and policy discussions and consultations, but they are also bound to keep track of the evolving and multifacted policy and legal framework(s): 1) Digital Framework; 2) Data Governance; and 3) AI Framework;

1) *Digital Framework*



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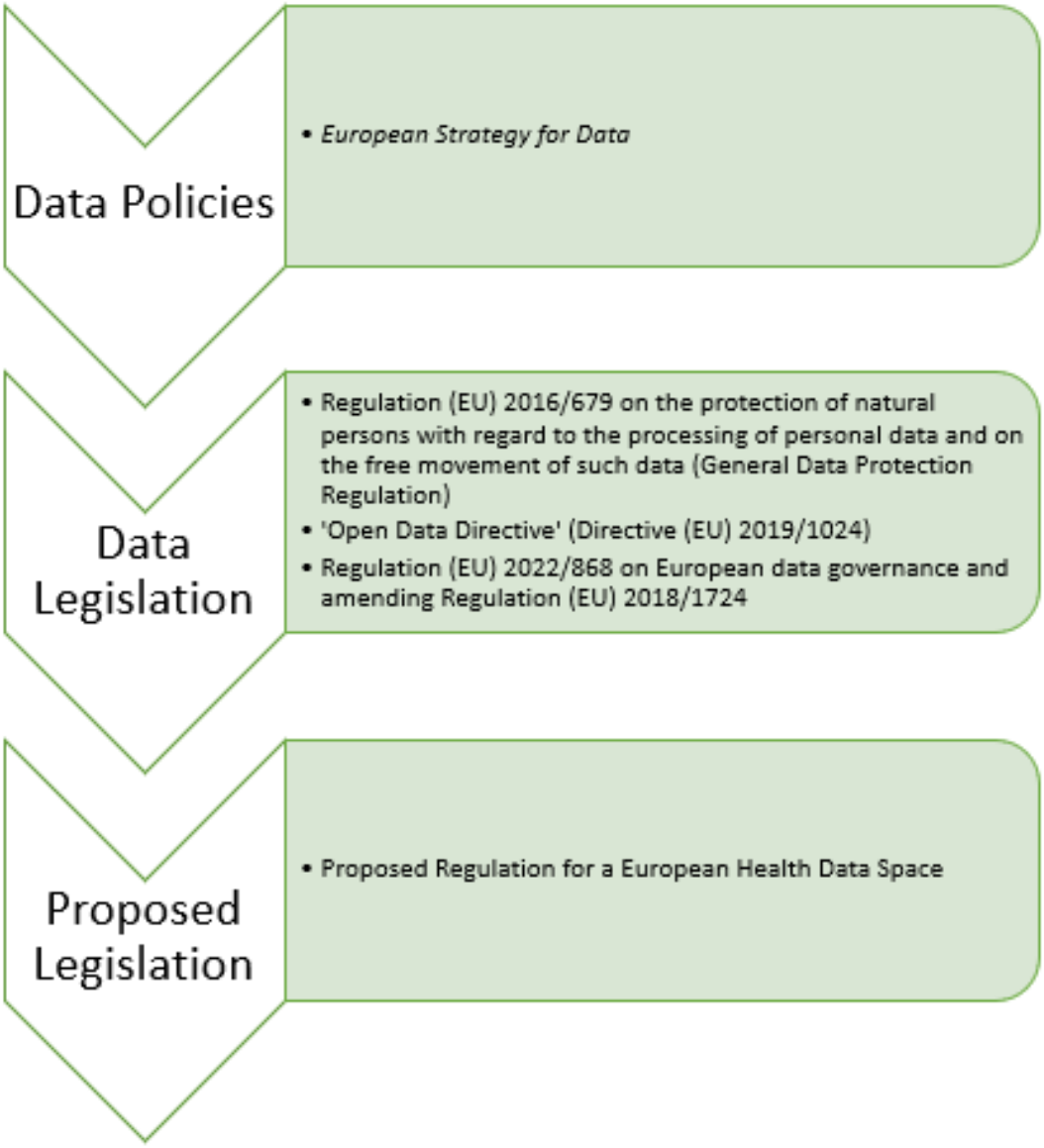
Potential Implications for the SHAPES Partners arising from the Digital Framework
✓ Compliance with the DSA and DMA ✓ Project partners should also assess if the platform's operation protects the fundamental rights of all users of the digital services, including the right to an effective remedy, non-discrimination, and the protection of personal data and privacy online. These considerations are currently included in D8.4 ethics framework.

2) Data Governance



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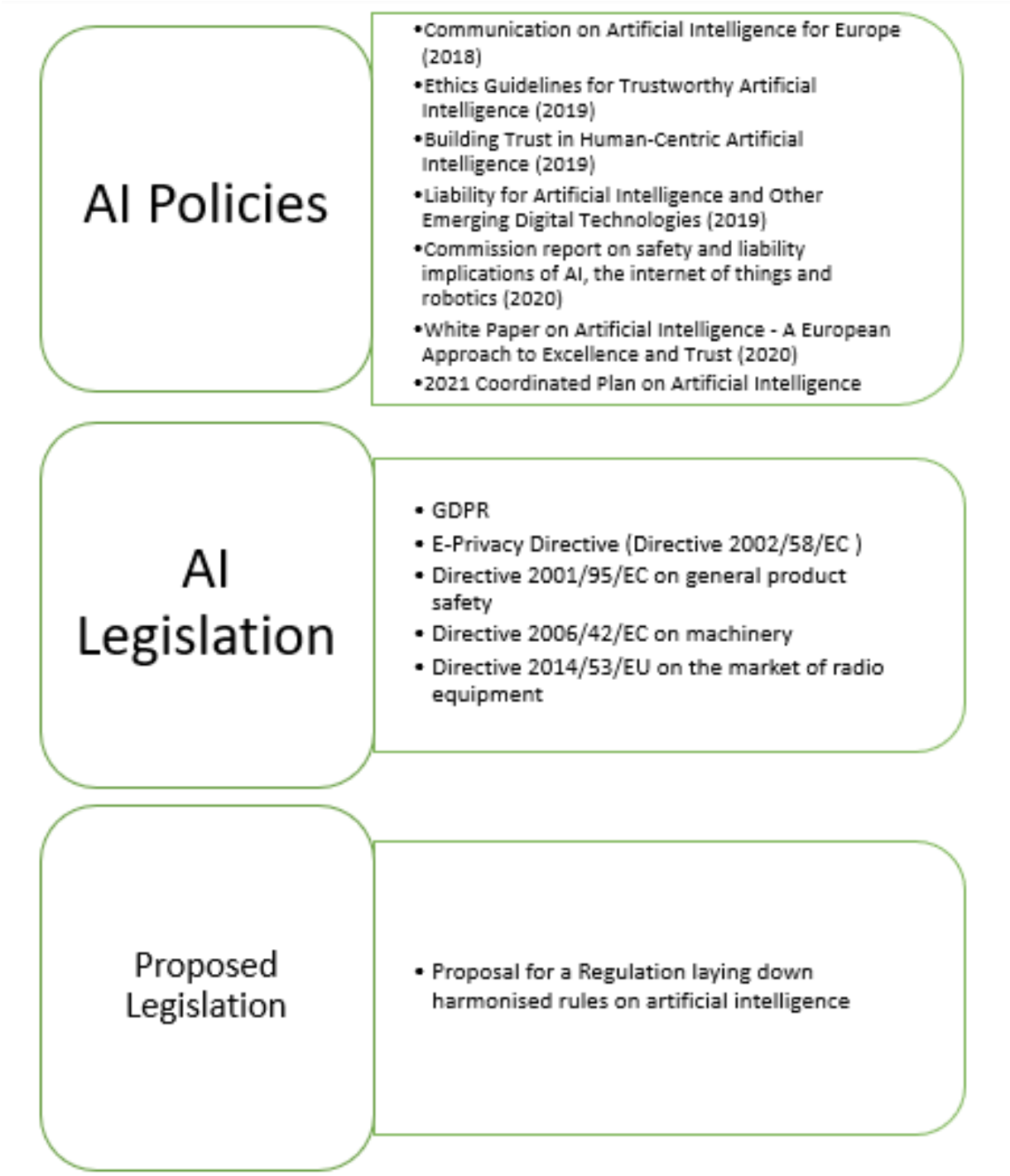
Potential Implications for the SHAPES Partners arising from the Data Governance Framework
✓ Compliance with relevant rules (GDPR, Open Data) ✓ Compliance with future health data rules rules

3) AI Framework



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Potential Implications for the SHAPES Partners arising from the AI Framework
✓ Compliance with relevant rules (Product Liability, Machinery, Radio) ✓ Compliance with future rules (AI Act)

This chapter continues by discussing the developments of these frameworks in more detail.

3.2. Building the Digital Single Market: From "An Information Society for All" to the 2020 Digital Strategy

The European Commission, which according to Article 17 of the Treaty on Functioning of the European Union (TFEU) is tasked with promoting "the general interest of the Union and take appropriate initiatives to that end", has been the engine that prompted the advancement of EU digital policies at various junctures. Since the 1990s, the Commission put forward the political intention to make Europe the most dynamic 'knowledge-based economy in the world' by 2010. Since then and long after 2010, this ambition has remained a blueprint of the EU digital policies (Carlsson and Rönnblom, 2022). In line with that ambition, the creation of a Digital Single Market (DSM) became a main goal. Marcut (2017) suggests that the DSM has become a specific and somewhat different dimension of the Internal Market. Marcut argues that the DSM is based on the application of information and communication technologies (ICTs), while the Internal Market is the result of concerted actions by Member States. In fact, the DSM is not just a free market without internal borders for digital services, but it became a goal in its own right.

The 2010 Digital Agenda for Europe outlines the core tenets of EU current digital policy and identified steps to avoid the EU falling behind other developed economies. Early critiques of the Digital Agenda commented that the policy placed an emphasis on competition, entrepreneurship and property rights, and failed to recognise the importance of social impacts and stakeholder involvement (Giannone and Santaniello, 2019). In 2015, the Commission launched the Digital Single Market Strategy for Europe (DSM Strategy) (European Commission, 2015). Acknowledging that the DSM had not been achieved yet, the Commission identified priorities and a number of actions to ensure the digital transformation. The DSM Strategy defines the DSM as a market:

> "…in which the free movement of goods, persons, services and capital is ensured and where individuals and businesses can seamlessly access and exercise online activities under conditions of fair competition, and a high level

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of consumer and personal data protection, irrespective of their nationality or place of residence."

The DSM Strategy states that "[a]chieving a Digital Single Market will ensure that Europe maintains its position as a world leader in the digital economy, helping European companies to grow globally" (European Commission, 2015). The DSM Strategy was built on three pillars; increasing accessibility to online goods and services, investing in digital infrastructure and maximising the growth potential of the European Digital Economy.

Figure 3- Objectives DSM Strategy

In 2020, the Commission led by Von Der Leyen published a new digital strategy (European Commission, 2020c). One of the primary challenges stressed by Von Der Leyen is the need to develop both a green and digital EU. Any plans introduced to create the digital society must also respect the European Green Deal (European Commission, 2019), which requires future EU actions to work 'towards more sustainable solutions which are resource-efficient, circular and climate-neutral'. In particular, the 2020 strategy emphasises the need for digital solutions to have an equally positive impact on society, ensuring fair access to digital solutions by all members of society. Furthermore, the strategy outlines the need to develop critical

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infrastructures to mitigate against the risks of malicious cybersecurity threats (European Commission, 2020c).

The 2020 Digital Strategy is based on the following four objectives:

1. ***Technology that works for People***

This objective cements the EU's commitment to investing in developing digital infrastructures to scale interoperable digital solutions. Firstly, the Strategy calls for the follow-up on the White Paper on Artificial Intelligence. In particular, requiring the review of safety, liability, fundamental rights, and data legislation relating to AI systems.

Separately, the Strategy sets out plans to invest in Europe's Gigabit connectivity and introduce a European cybersecurity strategy and enact relevant legislation. In support of developing a suitable and available workforce, a Digital Education Action plan and a revised Skills Agenda will be introduced to enable digital learning and strengthen digital skills in society.

2. ***A Fair and Competitive Society***

The objective of A Fair and Competitive Society requires the increased accessibility and ease of use of digital goods and services. Anagnostopoulou (2020) cautions that the success of the digital market pivots on the EU's ability to strike the right balance between growth through new business models and fair competition. (2020, p. 43). New rules were introduced in 2019 to assist with balancing these two often competing objectives. Legislation is now in place to promote a fair and competitive digital market, the most recent and progressive piece of adopted legislation to date is Regulation (EU) 2019/1150 on promoting fairness and transparency for business users of online intermediation services' (European Parliament and Council of the European Union, 2019). The Regulation, referred to as the 'P2B Regulation' aims to address 'frictions' between online intermediary services and consumers by regulating contracts between suppliers and the online intermediary, in order to promote fair terms and to prevent unfair practices (Anagnostopoulou, 2020). Additionally, the current EU competition rules are being evaluated to assess if there are any challenges relating to the operation of digital markets. The promotion of a fairer and more competitive society simultaneously requires the equitable use and storage of data, and the need for effective data protection regulation.

3. ***An open, democratic and sustainable society***

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The third key goal of developing an open, democratic and sustainable society requires the production of trustworthy and ethical digital solutions. In order to develop a digital society, which is inclusive, fair and accessible for all, certain legislation applicable to digital services must be revised and modernised. In this context, the Strategy calls for the deepening of the Internal Market for Digital Services, the revision of the eIDAS Regulation and the implementation of a European Democracy Action Plan. Specific actions identified include the operation of climate-neutral and energy-efficient data centres by 2030 and the development of a European health data space. Such a health data space would require secure access and exchange of electronic health records between Member States (European Commission, 2020).

4. The international dimension – Europe as a Global Player

The Strategy's final objective is to reinforce Europe's position as a global player in supporting global, sustainable, inclusive, equitable and fair digital interactions. This cannot be completed in isolation, and international agreements will need to be concluded by the United Nations, the OECD, ISO, and the G20. Additionally, the EU will proceed with developments to support the EU-African Union Digital Economy Task Force, which is supporting and funding the creation of a single African Digital Market. (European Commission, 2020c). However, in order for Europe to develop their role as a global player, it must reassess the data localisation and intellectual property restrictions placed on European companies based in third countries (Calboli, 2019).

3.3. The Digital Decade policy programme 2030

The COVID pandemic has shown both the potential and the drawbacks of the new technologies, and in March 2021 the European Commission launched the 2030 Digital Compass: the European way for the Digital Decade to pave the way to more equitable digitalised economy and society (European Commission 2021a). With the objective of achieving "digital transformation" in Europe by 2030, the Commission endeavours "to pursue digital policies that empower people and businesses to seize a human centred, sustainable and more prosperous digital future". (European Commission, 2021a, p. 1). In this regard, the Communication notes the disparity in digitalisation amongst both citizens and businesses that has been exposed by the Covid-19 pandemic. (European Commission, 2021a, p. 2). The Compass represents the four cardinal points under which the Commission has set the targets to be achieved over the 'digital decade':

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- ***A digitally skilled population and highly skilled digital professionals***

  In addition to the European Pillar of Social Rights' projection that 80% of adults will have basic digital skills by 2030, the Commission sets the goal of 20 million ICT specialists employed in the EU, with improved gender balance.

- ***Secure and performant sustainable digital infrastructures***

  By 2030, all households within the EU should be covered by a Gigabit network, with all populated areas covered by 5G; as well as concrete goals as to production and implementation of cutting-edge and sustainable digital infrastructures to improve the EU's computing capacity and international engagement.

- ***Digital transformation of businesses***

  The Communication sets the target of 75% of companies should use cloud computing, big data, and artificial intelligence, while at least 90% of SMEs (small and medium sized-enterprises) are to reach at least a basic level of digital intensity.

- ***Digitalisation of public services***

  The provision of key public services should be fully available online, with all EU citizens having access to their medical records online and 80% using a digital ID solution.

  The Commission proposes a monitoring system to track and analyse progress, which shall be published in an annual report.

On foot of that initiative the Digital Decade Policy Programme 2030 was adopted in December 2022 (European Parliamen and Council 2022a). The general objectives of the Digital Decade Policy Programme 2030 as laid out in Article 3 are relevant to and align with the SHAPES' ethos. The most relevant objectives in the SHAPES perspective are highlighted in the figure (Figure 4) below.

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Figure 4- Objectives Digital Decade Policy Programme 2030

3.4. The New Regulatory Framework: DSA and DMA

The urgent and pressing need to regulate the digital services market has led the EU to enact a new comprehensive regulatory framework.

Increased use in online shopping, the prevalence of social media platforms and the rapid advancement of online services have showcased the e-Commerce Directive's inadequacy to protect online consumers (Stalla-Bourdillon, 2017). The e-Commerce Directive, adopted in 2000, established the main legal framework for the provision of digital services in the Internal Market. While, at the time of its adoption, the horizontal

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legal framework created by the Directive was described as 'the cornerstone for regulating digital services in the European single market', nowadays the Directive fails to protect against the disseminating of illegal content, or selling of illegal goods or services online. (European Commission, 2020c). Wendehorst (2016, p 30) further comments on the Directive's shortcomings in relation to protecting customers ordering goods and services via online intermediary platforms and the liability issues attached to the services providers..

On the 15th December 2020, the EU unveiled proposals for a Digital Services Act (DSA) and a Digital Markets Act (DMA) (European Commission, 2020e, 2020f). The legal basis for the two proposals was Article 114 TFEU, which allows for the introduction of legislative measures to ensure the effective functioning of the Internal Market. The European Parliament debated its position of the DMA on 14 December 2021 and the DSA on 20th Jan 2022, and overwhelming voted in favour of the proposed package. One criticism of the initial legislative proposal was that the rules were tilted in favour of large technology companies, namely, the large platform hosts or intermediaries. (Buiten, (2021), Turillazzi et. al, (2021)). Amendments proposed by the European Parliament sought to counter-act this imbalance by providing greater protection for digital users, and in particular, for minors. Notably, and arguably, most importantly, the Parliament voted to prohibit the use of targeting or 'amplification' techniques involving the data of minors for the purpose of displaying ads (European Parliament, 2022). This essentially means a ban on targeted ads for minors and certain vulnerable groups. Separately, the changes introduced aim to enhance transparency and informed choice for the recipient of digital services in terms of targeted advertising. Digital users will have access to additional information on how their data will be monetised and processes to refuse consent to track advertised will be eased (European Parliament, 2022).

Subsequently, the European Parliament and Council reached a rapid political agreement on the two proposals on 22 March 2022. The Digital Services Act (DSA) and the Digital Market Act (DMA) were approved in July 2022 and published in the Official Journal in October and November 2022 respectively (European Parliament and Council of the European Union, 2022a and 2022b). They form a single set of rules that apply across the whole EU and will be *in toto* effective from 2024. They aim to create a safer digital space and to protect fundamental rights of all users of digital services but also to build a more cohesive EU digital market and establish a level playing field to foster innovation, growth, and competitiveness.

The DSA applies to Online Intermediary Services Providers (OIPs), which will include amongst others; collaborative economy platforms, social media platforms, online marketplaces, app stores, internet access providers and cloud and web hosting services.

All online intermediaries providing services in the EU will be subject to the DSA. Again, this means that businesses established outside but operating within the EU will

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have to comply with the DSA when implemented. As highlighted in Article 1(2) of the DSA, this regulation "lays down harmonised rules on the provision of intermediary services in the internal market" and establishes:

(a) a framework for the conditional exemption from liability of providers of intermediary services;
(b) rules on specific due diligence obligations tailored to certain specific categories of providers of intermediary services;
(c) rules on the implementation and enforcement of this Regulation, including as regards the cooperation of and coordination between the competent authorities.

The DSA applies to 'intermediary service' including: (i) a 'mere conduit' service, consisting of the transmission in a communication network of information provided by a recipient of the service, or the provision of access to a communication network; (ii) a 'caching' service, consisting of the transmission in a communication network of information provided by a recipient of the service, involving the automatic, intermediate and temporary storage of that information, performed for the sole purpose of making more efficient the information's onward transmission to other recipients upon their request; (iii) a 'hosting' service, consisting of the storage of information provided by, and at the request of, a recipient of the service.

The DSA extablishes clear liability rules (and exemptions from such liability) as well as due diligence rules. Notably, the obligations set out in the DSA must respect the rights set out under the Charter of Fundamental Rights of the European Union. Separately, the DSA places obligations on intermediary providers to give platform users 'immediate' information on advertisements' sources. Specifically, the DSA provides users with the right to access the information as to why the user has been targeted with a specific advertisement. Additional transparency obligations are placed on the platform hosts, including the possibility to allow users to challenge platforms' content moderation decisions (Cunningham, 2020).

To understand the scope of their obligations under the DSA, SHAPES will need to verify the extent to which it entails an intermediary service, and which type of service is. As the new rules will impose greater moderating and reporting obligations, it is advisable for the SHAPES partners to adopt a robust governance structure for the maintenance and monitoring of the platform during the project life cycle and post the completion of the project. Project partners should also assess if the platform's operation protects the fundamental rights of all users of the digital services, including the right to an effective remedy, non-discrimination, and the protection of personal data and privacy online. These considerations are currently included in D8.4 ethics framework.

The Digital Markets Act (DMA) sets out new rules for gatekeeper platforms in the digital sector. The DMA focuses on imposing responsibilities on platforms that have 'a significant impact on the internal market', namely by prohibiting gatekeepers from

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preventing businesses operating on the platform in accessing their own data. The DMA aims to prevent large gatekeepers from imposing unfair conditions on end-users, thus requiring the platforms to engage in a fair digital economy. New obligations relating to the use of data, interoperability and self-preferencing will be placed on gatekeepers. In particular, the gatekeepers will be required to allow third parties to inter-operate with the gatekeeper's services in specific circumstances. This extends to providing access to performance measuring tools to advertisers using the platform so that the advertising companies can verify the effectiveness of their services (Andrews and Treacy, 2021). Similarly, business users will have the right to access data that is generated by the use of their services.

Studies over the past year conducted on potential impact of the DMA, have widely welcomed this legislation, acknowledging its potential to increase market contestability and fairness in the digital economy (Larouche and de Streel 2021, Petit 2021, Van Cleynenbreugel 2021). However, questions have been raised regarding the broad scope of the rules. Larouche and de Streel (2021), in particular, have argued that the DMA is a 'lost child of competition law and sits in a difficult epistemological position' as the proposed rules are not built on established policy goals as with sector-specific regulation. In contrast with this view, Petit (2021) contends that the DMA should be interpreted as imposing restrictions on unilateral conduct engaged in and by the largest digital technology companies, compared to the traditional prohibitions established by the Treaty competition rules.

To understand the scope of their obligations under the DMA, SHAPES will need to verify the extent to which it falls within the material scope of the DMA. As the DMA entered into force in late 2022 no specific guidance can be provided as this is outside of the planned scope of the project at this time.

The European Commission, in its Digital Markets Act – Impact Assessment support study, suggests the rules will have several socio-economic spill-over benefits. Specifically, the report indicates that the legislative package when implemented will support the growth of innovative digital Small and Medium-Sized Enterprises and will facilitate greater cross-border trade. Increasing cross-border trade and making it easier for new competitors to enter the market will have a positive impact on GDP growth, consumer surplus and encourage greater investment in research and development (R&D) in the ICT sector. The study optimistically estimates that the R&D investments alone will generate between 136,387 and 294,236 new jobs. The new rules, by lowering online harm and consumer fraud and increasing competition in the marketplace, will ultimately enhance consumer welfare. However, these socio-economic benefits may not be realised for quite some time.

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3.5. Situating Digital Policies and Legislation

As with the other digital developments, the proposed policies and legislations do not operate in isolation and the SHAPES consortium partners should be mindful of the broad and changing landscape. Notably, additional support for digital reforms and investments is found in the Recovery and Resilience Facility Regulation, which has the long-term objective of preparing economies and societies for the challenges and opportunities associated with the green and digital transitions (European Parliament and Council of the European Union, 2021). Further, Union budget instruments (e.g. Cohesion programmes, the Technical Support Instrument, the Digital Europe Programme (European Parliament and Council of the EU, 2021a), Horizon Europe and InvestEU) are extremely relevant. As they may support a follow-up of SHAPES.

An array of other instruments are also worth mentioning such as the Security Union Strategy, the Skills Agenda of the EU, the Digital Education Action Plan, the 2021 Strategic Foresight Report, and the Green deal package. However, mostly relevant is the recently approved Declaration on Digital rights and principles, proposed in January 2022 by the European Commission (European Commission, 2022).

3.5.1. The Declaration on Digital Rights and Principles

In a move that is critically important for the SHAPES project, a European Declaration on Digital rights and principles was proposed in January 2022. In December 2022, the Declaration was endorsed by the Parlaiment and the Council, and was signed jointly by the presidents of these institutions.

Such Declaration aims to introduce a set of principles for a human-centred digital transformation (European Commission, 2022). It complements existing data protection and ePrivacy rules, and the Charter of Fundamental Rights (European Commission, 2022). As mentioned above the principles are built around the following six general themes:

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Under the Supporting solidarity and inclusion, theme, the Declaration on Digital Rights and principles calls for a digital transformation that leaves nobody behind. Specifically, it refers to the digital inclusion of older people, persons with disabilities, marginalised, or vulnerable people and those who act on their behalf. Despite its non-binding nature, the Declaration on Digital rights and principles has enormous potential to improve safe and seamless access to the internet, and in particular, to online public services.

A genuine buy-in from Member States will be required to support and promote businesses to adopt inclusive, accessible and human-centred digital services. By 2030, Member States should ensure that public services are available online, in a fully accessible and easy-to-use format, and employing the highest security and privacy standards.

3.6. The 2020 White Paper on AI

The White Paper on AI is described in a detailed manner in deliverable D8.14. However, for the purpose of this analysis it might be worthwhile to briefly review the recent policy developments that led to the adoption of the White Paper (European Commission, 2020b).

The 'Declaration of cooperation on artificial intelligence (AI)' sought to harmonise national AI initiatives and formalise the EU's approach to regulating and governing AI

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operations.[3] The Declaration is underpinned by three objectives. The first objective is to enhance the EU's competitiveness by investing in the research and creation of AI solutions and technology. Secondly, the Declaration is underpinned by the desire to invest in education and upskilling for employees who are at risk or have been replaced by advancements in AI. Thirdly, the Declaration calls for the adoption of adequate ethical and legal frameworks to guarantee sufficient levels of transparency in the management and use of AI solutions.

Most of the guidelines and White Papers introduced in the last three years are based on the objectives set out in the Declaration of Cooperation. The 2018 'European Commission Communication on Artificial Intelligence for Europe' (European Commission, 2018) builds on the Declaration of Cooperation by setting out the EU's AI initiative. It sets out to enhance the EU's technological and industrial capacity and promote the use of AI solutions in both the private and public sector. Notably, the Communication re-emphasises the need to introduce counter-measures to ease any socio-economic challenges created by AI developments, namely, the need to support labour market transitions. Similarly, to the Declaration of Cooperation, the Communication calls for the introduction of an appropriate ethical and legal framework (European Commission, 2018).

The Joint Research Centre published a separate report "Artificial Intelligence: A European perspective" in 2018 (Annoni et al, 2018). This report differed from the Declaration and the Communication by furthering the debate on the challenges and opportunities facing machine learning AI technology developments. The report acknowledges that AI developments in the EU can flourish and compete with the global leaders in the US and China if AI is supported by a 'robust computing infrastructure and good quality data' (Annoni et al, 2018, p. 120). Specifically, the report calls for the EU to invest in the 'emerging new paradigm of computing distributed towards the edges of networks' to support the availability and use of 5G and IoT. The report comes with a stark warning in relation to the use and management of data, calling for the EU to support the development of a person-driven socially-centred IT framework guided by an ecosystem of public administrations, civil society, and the private sector.

An array of policy documents were released beween 2019 and 2021 (see eg European Commission, 2021d). The European Commission adopted a definition of AI proposed by the High-Level Expert Group on Artificial Intelligence (AI HLEG). The document extends the previous definition of AI proposed the year before in the 2018 Communication. As previously mentioned, the revised definition aims to avoid misunderstanding and to clarify different aspects of AI as a scientific discipline and as a technology (AI HLEG, 2019 p.6). Additionally, the document refers to AI systems to mean any AI-based component, software and/or hardware. It is envisioned that this

[3] The Declaration and its signatories are visble at https://digital-strategy.ec.europa.eu/en/news/eu-member-states-sign-cooperate-artificial-intelligence.

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definition will be harmoniously used by AI experts, providers and non-AI experts and relied on to develop future AI ethics guidelines and policy.

Supporting the previously introduced documents and communications, the AI HLEG presented a detailed 'Ethics Guidelines for Trustworthy Artificial Intelligence' (AI HLEG, 2019a). AI systems will be deemed trustworthy if they are considered 'lawful', 'ethical' and 'robust'. In order to demonstrate that the system is lawful, it must respect all applicable laws and regulations. The system must respect ethical principles and values, and it must demonstrate its robustness from a technical perspective while also taking into consideration its social and environmental impact. Specifically, the Guidelines set out seven essential requirements that AI systems are required to meet. The requirements range from the inclusion of appropriate human agency and oversight, technical robustness and safety, privacy and data governance, to transparency and accountability (AI HLEG, 2019a).[4] This Guidelines make several noteworthy contributions to establishing an ethical framework for AI systems. However, the Guidelines fail to discuss whether a specific regulatory framework is required to enforce 'ethical' and 'robust' trustworthy AI systems.

The European Commission's Communication 'Building Trust in Human-Centric Artificial Intelligence' pays further attention to the need to develop a rigorous legal framework that will set the 'global standard for human-centric AI' (European Commission, 2019a p. 2) This is a task led Communication, which requires the Commission to develop the suite of AI policies, documents and Communications in close cooperation with all interested stakeholders, including Member States, industry, societal actors and citizens. The Communication reiterates the EU's stance that AI systems and supporting frameworks must mutually enhance economic competitiveness while respecting fundamental values and building societal trust.

A study published by the Commission on 'Liability for Artificial Intelligence and Other Emerging Digital Technologies' Communication (European Commission, 2019b) outlines how EU liability regimes should be revised to competently deal with potential challenges arising from the production and use of new technologies. In 2020, the Commission published the complimentary report, which recognises the complex product safety and liability issues arising from data autonomy, software updates, the complexity of systems and safety management. Scholars have aidentified drawbacks and gaps in the approach taken by the Commission (Bertolini and Episcopo, 2021).

After a wide consultation (European Commission, 2020a), the European Commission published the "White Paper on Artificial Intelligence - A European Approach to Excellence and Trust" in 2020 (European Commission, 2020b). The White Paper states that any new regulatory framework for AI consisting of legal obligations and

[4] Additional requirements refer to diversity, non-discrimination and fairness, and societal and environmental well-being. In order for AI systems to be deemed trustworthy, AI providers must avoid unfair bias or engage in any activities that have the potential to marginalise vulnerable groups.

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ethical principles for the development, deployment and use of artificial intelligence, robotics and related technologies should fully respect the Charter of Fundamental Rights, and those rights protected in secondary legislation. In that connection, the White Paper on AI states that an extensive body of existing legislation protects fundamental rights and consumer rights, and sets out the rules relating to EU product safety and liability.

The Commission has also clarified that "economic actors remain fully responsible for the compliance of AI to existing rules that protects consumers, any algorithmic exploitation of consumer behaviour in violation of existing rules shall be not permitted and violations shall be accordingly punished" (European Commission, 2020b, p. 14). AI service or supply providers must comply with the following pieces of relevant EU legislation:

- ✓ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety
- ✓ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products
- ✓ Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin
- ✓ Council Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation
- ✓ Council Directive 2004/113/EC of 13 December 2004 implementing the principle of equal treatment between men and women in the access to and supply of goods and services
- ✓ Directive 2006/54/EC of the European Parliament and of the Council of 5 July 2006 on the implementation of the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation
- ✓ Directive (EU) 2016/680 on the protection of natural persons 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 on the free movement of such data.
- ✓ Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services
- ✓ Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity)

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and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act)

- ✓ Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive')
- ✓ Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council
- ✓ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Subsequent to the 2020 White Paper, the Commission published its Coordinated Plan on Artificial Intelligence and a Proposal for a Regulation laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) on 21 April 2021 (European Commission, 2021e) .

The Proposal aims to establish a legal framework for AI ensuring the protection of fundamental rights and user safety, while providing legal certainty to producers which will foster investment and innovation across the EU single market.

The Commission proposes a "single future-proof" definition of AI as "software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with" (Article 3(1)). The proposed Regulation should apply to all providers of AI systems irrespective of whether they are established within the EU or a third country, to all users of AI systems within the EU, and to providers and users of AI systems established in a third country where the output produced by the system is used within the EU.

The Proposal adopts a risk-based approach to classification of AI systems according to the potential impact on fundamental rights and safety. The Regulation would prohibit the use of AI systems that are considered 'unacceptable', including where there is

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significant potential to manipulate human behaviour or exploit vulnerabilities of specific groups, 'social scoring' by public authorities, and 'real time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement (subject to limited exceptions). Systems are classified as being 'high risk' according to the probability and severity of potential harm in areas pre-defined by the Regulation: critical infrastructure, education and or vocational training, employment, access to and enjoyment of essential public and private services, law enforcement, and migration, asylum and border control management. The proposed Regulation places a number of obligations on providers of "high risk" AI systems before they can be placed on the market, including a "conformity assessment procedure". In respect of "low or minimal risk" systems, the Act imposes specific transparency requirements, including making users aware where their interaction or content is generated or manipulated by AI, thus allowing individuals to make informed choices as to whether to proceed.

It is also proposed that enforcement will take place at Member State level by one or more designated national competent authorities, including a national supervisory authority charged with surveillance of the market and supervision of application of the Regulation. Member states will be responsible for laying down effective, proportionate and dissuasive penalties for infringement. In addition, the Regulation proposes establishment of a European Artificial Intelligence Board, composed of the Member States' national supervisory authorities and the Commission, to oversee the harmonised implementation of the Regulation.

While the proposed Regulation is still in the early stages of the legislative process, and will likely be subject to amendments before agreement is reached on a final version, it provides strong indication to AI providers and users as to the future framework of AI regulation in the EU.

3.7. The European Strategy for Data

Several key data-related policies and legislation have been introduced since 2002 to establish a common European data space. In 2002, an expert group on Public Sector Information scrutinised the benefits of supporting the re-use of public sector information which led to the adoption of Directive 2003/98/EC on the re-use of public sector information (European Commission, 2003). Following on from the introduction of the Directive, the European Commission Decision 2011/833/EU on the re-use of Commission documents was introduced in 2011 (European Commission, 2011). The adoption of the open access Directive and Decision paved the way for the introduction of the EU Open Data Portal, which provides free access to open data published by EU institutions and agencies. The data is available for use and re-use for commercial and non-commercial purposes (Davies and Perini, 2016). Building on the creation of the portal, the European Commission funded a European Data Portal to act a repository of public sector open access data.

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Policy and legislative measures accelerated from 2018 onwards with the publication of an updated European Commission Communication, a new Directive on open data and the re-use of public sector information, a new EU Data Strategy and a proposed regulation on data governance (European Commission, 2018). A new Directive on open data and the re-use of public sector information was introduced replacing the PSI Directive, to address lingering barriers to the exchange of EU publicly funded information (European Parliament and Council of the European Union, 2019b) . Notably, the new Directive established minimum open data requirements for all EU Member States.

The White Paper on Artificial Intelligence and, the European Strategy for Data are considered the two pillars of the newly implemented digital strategy of the Commission. The Data Strategy sets out ambitious objectives for the EU, requiring the European institutions and bodies to invest in the tools and infrastructures necessary to store and process data, setting relevant standards, establishing EU-wide common and interoperable data spaces and protecting the data rights of system users. (European Commission, 2020d). The European Strategy for Data and the new regulation on data governance jointly aim to 'ensure Europe's global competitiveness and data sovereignty' to support job creation and societal progress. (European Commission, 2020d). These have been explored in D8.4 and other related deliverables. Furthermore, the Cybersecurity Act has been introduced to strengthen the EU Agency for cybersecurity (ENISA). Such act establishes a cybersecurity certification framework for products and services (European Parliament and Council of the European Union, 2019a).

Importantly for the SHAPES project, the creation of a European Health Data Space is one of the European Commission's key 2019 – 2025 priorities. The development of the data space will promote greater access to health data for health related research, while protecting citizen's access to their data as set out in article 20 of the GDPR. In preparation for the operation of the data space, an overview of the legal modalities application to the sharing of health data is underway (European Commission, 2021c). On 3 May 2022, the Commission published its proposal for a Regulation for the European Health Data Space ('EHDS'), which identifies a legal framework for the use of health data mainly through the medium of AI (European Commission, 2022a). Together with the Data Act and Data Governance Act (European Parliament and Council of the EU, 2022c), the proposed EHDS rules aim to support the creation of a single European market for data. The combined rules are instrumental to the construction of a regulatory framework that empowers people to access their own health data in any Member State and facilitates the use of secondary health data for research, innovation, and policy-making (Article 34, Proposed EHDS Regulation).

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3.7.1. The EU Data Governance Regulation

With a view to "shaping the EU's Digital future", in 2020 the Commission also released a proposal for a regulation on European data governance, which tallied with the current regulatory framework on data protection (European Commission, 2020d). Data governance refers to

> "a set of rules and means to use data, for example through sharing mechanisms, agreements and technical standards. It implies structures and processes to share data in a secure manner, including through trusted third parties" (European Commission, 2020)

The Regulation (EU) 2022/868 on European data governance (Data Governance Act) was approved and published in the Official Jounal in June 2022 (European Parliament and Council of the European Union, 2022c).

For the SHAPES platform is important to note that this Regulation supports the sharing of big data in the health sector, which has the potential to improve general healthcare services and assist with the treatment of rare or chronic diseases. The data governance model is based on the principles of neutrality and transparency. The emerging principle of 'neutrality' requires data-sharing intermediaries to comply with strict-data management provisions, prohibiting the intermediary from selling the data on its platform to other companies or using it directly to increase their market ownership.

A detailed in its Article 1, this Regulation lays down:

a) conditions for the re-use, within the Union, of certain categories of data held by public sector bodies;
b) a notification and supervisory framework for the provision of data intermediation services:
c) a framework for voluntary registration of entities which collect and process data made available for altruistic purposes; and
d) a framework for the establishment of a European Data Innovation Board.

Building on the principles of neutrality and trust, data intermediaries and platform hosts are required to 'function as trustworthy organisers of data sharing'. A new European Data Innovation Board will be established in the form of an expert group to support the Commission to steer data governance and standards.

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3.8. The EU Standardisation Policies

EU Standardisation rules are longstanding. Back in 1983, the Mutual Information Directive set out a process to boost coordination among national standardisation bodies and the European Commission and CEN/CENELEC of their standardisation workplans for the following year and for the exchange of draft standards (Schepel, 2005). The Committee on Standards, set out in that Directive, was required to review the application of the information exchange process and make proposals to the Commission regarding requests for European standards and actions, to avoid 'the risk of barriers to trade'. This Directive was replaced in 1998 by what is termed as the Transparency Directive, which required Member States to notify the Commission and each other of draft standards and their annual standardisation programmes.

After a range of policies to support standardisation as a tool to remove technical barriers to market integration was released between 1980s and 1990s, a new regulatory approach to standardisation commenced in 2012 (Schepel 2013). The 2012 Standardisation Regulation (European Parliament and Council of the European Union, 2012) based on Article 114 TFEU, deals with the relationship between the European Standardisation Organizations (ESOs) and the EU, and the development of European standards and standardisation deliverables for products and services, which support EU legislation and policies, as well as the funding of ESOs and stakeholder participation.The ESOs follows the World Trade Organisation's 'founding principles' for standardisation: coherence, transparency, openness, consensus, voluntary application, independence from special interests and efficiency (Schepel, 2013).

According to the regulation the objective of standardisation is the "definition of voluntary technical or quality specifications with which current or future products, production processes or services may comply […] where compatibility and interoperability with other products or systems are essential". For the purposes of the 2012 Standardisation Regulation, a 'standard' means a 'technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory'. It can be:

- ✓ an 'international standard' which has been adopted by an international standardization body;
- ✓ a 'European standard' which has been adopted by an ESO;
- ✓ a 'harmonised standard' which has been adopted on the basis of a request made by the European Commission for the application of Union harmonisation legislation;
- ✓ a 'national standard' which has been adopted by one of the Member States' standardisation bodies.

A 'European standardisation deliverable' is a technical specification other than a European standard which is adopted by an ESO. A 'technical specification' prescribes

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technical requirements to be fulfilled by a product, process or service, setting out various parameters including quality, performance, interoperability, environmental protection, health, safety and labelling.

The 2012 Standardisation Regulation confirms that CEN, CENELEC, and ETSI as the European standardisation organisations.

In order to promote transparency of standards development and stakeholder participation, Article 3 of the 2012 Standardisation Regulation requires the ESOs and the national standardisation bodies to make available annual work programmes which set out the standards which they expect to prepare or amend. National standardisation bodies must not undertake actions which may undermine the work that an ESO plans to do. Once a European or harmonised standard is adopted, national standards on the same subject matter must be withdrawn. Article 5 provides that the ESOs:

> shall encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders, including SMEs, consumer organisations and environmental and social stakeholders […] [and] shall in particular encourage and facilitate such representation and participation through the European stakeholder organisations receiving Union financing in accordance with this Regulation […].

Article 8 of the 2012 Standardisation Regulation requires the European Commission to devise an annual Union work programme for standardisation to set out strategic priorities and the standards it intends to request from the ESOs. In developing the annual programme, the Commission must conduct 'a broad consultation of relevant stakeholders'.

The Regulation includes provisions that enable the Commission to 'decide to identify ICT technical specifications that are not national, European or international standards, but meet the requirements set out in Annex II', and which may be used in public procurement. This allows the EU to adopt standards produced by various consortia and for a dealing with the ICT sector.

How a harmonized standard relates to EU law was discussed *inter alia* by the CJEU in the *Elliott* case.[5] Irish Asphalt sold James Elliott Construction some rock aggregate, subject to a harmonized standard pursuant to EU law. The Irish High Court had found that the aggregate did not meet the requirements of the harmonised standard, which had been transposed as an Irish standard, due to its sulphur content. The CJEU stated that in substance standards "are by their nature measures implementing or applying an act of EU law". The Court held that harmonised standards form part of EU law, as they are:

[5] Case C-613/14 *James Elliott Construction Limited v Irish Asphalt Limited* EU:C:2016:821.

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> a necessary implementation measure which is strictly governed by the essential requirements defined by that directive, initiated, managed and monitored by the Commission, and its legal effects are subject to prior publication by the Commission of its references […].

In a similar vein, the General Court in *Global Garden Products Italy SpA v Commission*, stated that Commission decisions relating to the publication of harmonised standards 'are legal acts against which an action for annulment may be brought'.[6]

The Commission adopted its Communication on ICT Standardisation Priorities for the Digital Single Market in 2016, recognising the role of common standards in ensuring interoperability of digital technologies and an effective Digital Single Market (European Commission, 2016b). It presents a two-pillar action plan based firstly, on identifying the ICT priorities in respect of the Digital Single Market and, secondly, a political process to validate, monitor and adapt the list of priorities, where necessary, on an ongoing basis. In this regard, the Commission has identified five priority areas in which standardisation should increase competitiveness and access to the global market: 5G communication, cloud computing, the internet of things (IoT), and big data technologies and cybersecurity. In so doing, it is noted that, as technologies converge, standardisation in these priority areas will also significantly benefit other technology areas, such as eHealth, smart energy, intelligent transport systems and connected automated vehicles, advanced manufacturing, smart homes and cities and smart farming (European Commission, 2016b, p. 5).

The priorities under the Communication are intended to complement and to build upon standardisation instruments through a high-level commitment to standardisation from a broad stakeholder base, including industry, standardisation organisations, the research community, as well as the EU institutions and national administrations (European Commission, 2016b, p. 12).

The Commission publishes annually a Rolling plan for ICT standardisation which identifies EU policies in which standardisation, standards or ICT technical specifications are involved or could be employed. It is noted that "[t]his allows for increased convergence of standardisation makers' efforts towards achieving EU policy goals" (European Commission, 2021b). Rolling plans are produced in collaboration with the European multi-stakeholder platform on ICT standardisation (MSP); an expert advisory group representing a range of interested parties and Member State national authorities. Under the thematic categories of key enablers and security, societal changes, innovation for the digital single market, and sustainable growth, the 2021 plan detailed around 180 actions including introducing new chapters on "COVID-19", "Safety, transparency and due process online", "Circular economy", and "U-space".

[6] Case T-474/15 *Global Garden Products Italy SpA v Commission* EU:T:2017:36, para. 60.

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The plan emphasises the essential role that ICT standardisation has to play in tackling the challenges that arise with digitalisation.

In alignment with the EU's proposals to modernise and regulate digital markets and develop a climate neutral, resilient and circular economy, the Commission recently published a new Standardisation Strategy (European Commission, 2022b). The Strategy aims to support promote global competition, protect the EU's technological sovereignty and uphold democratic values in technology application through the means of standardisation. A proposal for an amendment to the Regulation on standardisation sits alongside the Standardisation Strategy. The Strategy acknowledges the need to improve the governance and integrity of the European standardisation system and proposes the amendment to the Regulation to modernise the governance structure (European Commission, 2022d). Specifically, the proposal outlines plans to reform the governance structure of the ESOs to enable the bodies to respond swiftly to standardisations urgencies as well as making the processes more SME and civil-society friendly.

The amendment itself aims to address the issues of the uneven distribution of votes in some decision-making bodies by prescribing that the delegates with decision-making power of the NSBs must be included at every stage of the production of new harmonised European standards. Separately, the Commission has indicated its plan to launch an evaluation on the Regulation. In further support of the Strategy objectives the Commission announced that standardisation priorities will be identified in the 2022 annual Union work programme for European standardisation, a new High-level Forum will be established to inform future standardisation priorities and a Chief Standardisation Officer will be appointed and will be supported by a new EU excellence hub on standards (European Commission, 2022b). Importantly for the SHAPES project, the Commission plans to engage with EU-funded research projects further to identify early and innovative standardisations needs, and to this end, a 'standardisation booster' will be launched to support researchers under Horizon 2020 and Horizon Europe to test the relevance of their results for standardisation.

3.9. Summary

This section of the report offered an overview of recent developments in EU digital legislation and policies. It provides the SHAPES Consortium a clear reference point to the EU rules underpinning the SHAPES digital solutions and platform. Additionally, it provides a broad policy guide for the SHAPES partners. A summary of the adopted policies and legislation is listed in the figure below.

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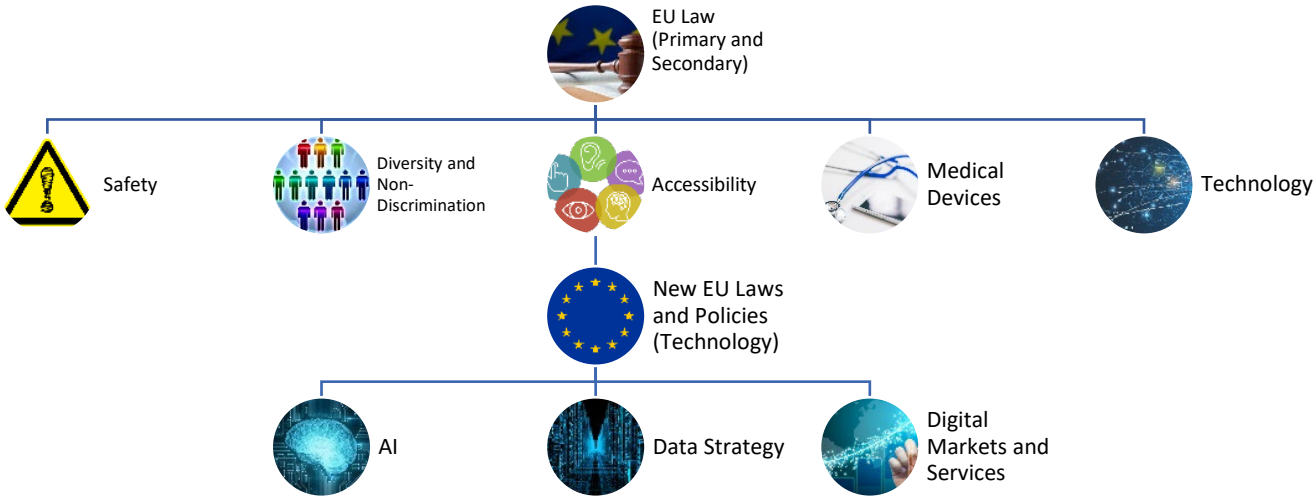

Figure 5- Policy frameworks relevant for SHAPES

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4. Legal Requirements Relevant to the SHAPES Platform and Digital Solutions

4.1. Overview

Taking into account that the SHAPES Platform falls with the scope of what is considered AI for the purpose of EU law, the legislation listed in the White paper is of relevance and is directly connected to the seven key requirements identified in the Guidelines of the High-Level Expert Group: Human agency and oversight, Technical robustness and safety, Privacy and data governance, Transparency, Diversity, non-discrimination and fairness, Societal and environmental wellbeing, and Accountability.

Leaving aside privacy and data governance dealt with in D8.4 and cybersecurity (also dealt in deliverable D8.14), the following table summarises the legislative framework which will underpin the SHAPES Platform and digital solutions.

Title of Legislation	Details
	SAFETY
The General Product Safety Directive (Directive 2001/95/EC)	The purpose of this Directive is to ensure that products placed on the market are safe. "Product" within the remit of the Directive means any product that is intended for consumers and is supplied, in the course of a commercial activity, and whether new, used or reconditioned.
Directive 85/374/EEC on liability for defective products	The Council Directive focuses on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.
	DIVERSITY AND NON-DISCRIMINATION
Race Equality Directive (Directive 2000/43/EC)	The Council Directive focuses on implementing the principle of equal treatment between persons irrespective of racial or ethnic origin.
Directive on equal treatment in employment and occupation (Directive 2000/78/EC)	The Council Directive establishes a general framework for equal treatment in employment and occupation.
Council Directive 2004/113/EC implementing the principle	The Council Directives further implements the principle of equal opportunities and equal treatment of

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of equal treatment between men and women in the access to and supply of goods and services	men and women in the access to and supply of goods and services.
Directive 2006/54/EC on the implementation of the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation	The Council Directives further implements the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation.
	ACCESSIBILITY
European Accessibility Act Directive (EU) 2019/882	The Act sets out the accessibility requirements for products and services.
Directive (EU) 2016/2102 on the accessibility of the websites and mobile applications of public sector bodies	The Directive provides people with disabilities with better access to the websites and mobile apps of public services.
	MEDICAL DEVICES
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, and; Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing	The purpose of these rules is to create an environment that supports the development of innovative companies, thus improving access to high-technological healthcare services and medical devices. The Regulations have a staggered transitional period, with the full application of the Regulations been delayed due to the Covid-19 pandemic.

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Directive 98/79/EC and Commission Decision 2010/227/EU.	

4.2. Safety

This section offers a brief overview of the rules relating to product safety and liability. Legislation relating to product safety and liability may be applicable to the SHAPES Partners responsible for developing new digital solutions.

4.2.1. The General Product Safety Directive (Directive 2001/95/EC)

The purpose of the General Product Safety Directive is to ensure that only safe products are placed on the market. The rules do not extend to covering pharmaceuticals, medical devices or food which are regulated separately. Products within the remit of the Directive refer to any product which is 'intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned'.

In order for products to be deemed safe, they must meet specific EU and national safety and health standards. The products whether new, used, or reconditioned must include sufficient information to allow the products to be traced. At a minimum, all products must include the identity of the manufacturers, a product reference, any relevant warnings and sufficient information about any inherent risks attached to the product.

The implementing decision (EU) 2019/417 sets out the procedures and governance of the EU Rapid Information System (RAPEX), the product safety notification system, as established by Directive 2001/95/EC. The Directive introduced a 'rapid alert system' for dangerous non-food products, allowing Member States to promptly share information on the withdrawal of dangerous products from the market. Member States may delegate responsibility to national enforcement agencies or authorities to monitor, audit, and review product safety. National bodies can impose sanctions for any breach of product safety rules. Importantly, the national bodies are required to share information with the EU rapid alert system as soon they become aware of any product posing a serious health and safety risk.

Importance for SHAPES Integrated Care Platform (and future Marketplace)

All product developers must ensure that products created are safe to sell on the Internal Market. In the unfortunate circumstance where products are found to be unsafe, the producer must take appropriate corrective action.

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If SHAPES partners successfully develop a product that cannot be assessed against existing safety standards, then a bespoke safety assessment must be completed. Such safety assessments must be based on; best practice in the relevant sector, relevant Commission guidelines, state of the art and technology and 'reasonable' consumer safety expectations.

Again, it is important to reiterate that this Directive and the Implementing decision (EU) 2019/417 do not apply to pharmaceuticals and medical devices. Separate directives and arrangements are in place for these sectors.

4.2.2. EU Product Liability Directive 85/374/EC

Medicines and medical devices are subject to the general product liability rules of the Member States which implement the EU Product Liability Directive 85/374/EC. Directive 85/374/EEC establishes the principle of liability for defective products, which applies to products that have been industrially produced. Producers of defective products may be liable in circumstances where a defective product causes 'damage' to a consumer, this extends to including circumstances where there is no negligence or fault on the part of the producers. 'Damage' to consumers includes death or personal injuries or damage to private property caused by the defective product. A product will be considered defective if it fails to provide the safety that consumers reasonably expect, taking into account that the product was used for its intended purpose.

A broad definition of 'producer' is offered by the Directive, and includes; the producer of a raw material, the manufacturer of a finished product or a component of a part, a person putting their name, trade mark or any other distinguishing feature on the product. In certain circumstances where the producer cannot be identified, a supplier may be held liable for the damage caused by a defective product.

The onus of proof is placed on the injured party to prove that the product was defective and to demonstrate a causal link between the damage suffered and the defect. Producers can be declared exempt from liability in circumstances; where the producer did not put the product into circulation or the defect occurred after the product was put into circulation or the defect was caused during the manufacture of a final part of the product. Furthermore, the producer will not be held liable if the state of scientific and technical knowledge at the time the product was put into circulation was not capable of identifying the defect.

Importance for SHAPES Integrated Care Platform (and future Marketplace)

SHAPES partners who produce or manufacture a product, including medical devices, for sale or use in the Internal Market, may be liable for all damages arising from a defect in the product. A broad definition of 'products' is offered by the Directive which includes medicines and medical devices, although the definition does not extend to

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custom medicines or devices.[7] During the pilot stages, SHAPES partners will not fall within the scope of the Directive, once the products have not been industrially produced.

Partners cannot include any contractual clauses to limit their liability in relation to defective products. Injured parties have three years to seek compensation for damage incurred from a defective product. Producers will not be held liable for any defectiveness ten years after the product has been put into circulation on the market. It is important to be aware that the Directive does not preclude additional protections for injured persons under Member States' national laws, which may include contractual, non-contractual or other types of civil liability. Although, it should be noted that Germany, and to a lesser extent Spain, have established separate strict liability rules for defective medicines.

4.3. Diversity and Non-Discrimination

There is a vast body of EU legislation that bans discrimination on various grounds, and promotes diversity. All SHAPES Partners should make themselves aware of the following relevant pieces of legislation.

4.3.1. Race Equality Directive (Directive 2000/43/EC)

Directive 2000/43/EC implements the rules on equal treatment irrespective of racial or ethnic origin. The Directive's primary purpose is to combat discrimination on the grounds of racial or ethnic origin and establish the minimum requirements for implementing the principle of equal treatment between persons in the EU. The Treaty of Lisbon (Article 19 of the Treaty on the Functioning of the EU) provides the EU with a legal basis to combat all forms of discrimination based on sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation.

Importantly for the SHAPES project, the Directive aims to increase an individual's participation in economic and social life and reduce social exclusion. The Directive applies to the SHAPES project, as it applies to all sectors of activities, including access to healthcare, social advantages and access to and supply of goods and services, including housing.

Importance for SHAPES Integrated Care Platform (and future Marketplace)

SHAPES partners must be mindful not to engage in any acts of discrimination on the grounds of racial or ethnic origin. Partners must ensure the promotion of equal treatment when carrying out activities.

[7] Recently the Court of Justice extended the concept of a "product defect" under the Directive with regard to implantable medical devices, including pacemakers and implantable cardioverter defibrillators.

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The Directive offers the following definitions of direct and indirect discrimination, harassment and victimisation;

Direct discrimination: where one person is treated less favourably than another is, has been or would be treated in a comparable situation on grounds of racial or ethnic origin.

Indirect discrimination: where an apparently neutral rule, criterion or practice would put persons of a racial or ethnic origin at a particular disadvantage compared with other persons, unless that rule, criterion or practice is objectively justified by a legitimate aim and the means of achieving that aim are appropriate and necessary.

Harassment: when an unwanted conduct related to racial or ethnic origin takes place with the purpose or effect of violating the dignity of a person and of creating an intimidating, hostile, degrading, humiliating or offensive environment.

Victimisation: unjust or cruel treatment of someone who complains of discrimination or who assists someone else in a complaint of discrimination.

4.3.2. Directive 2000/78/EC on equal treatment in employment and occupation

Council Directive 2000/78/EC of 27 November 2000 establishes a general framework for equal treatment in employment and occupation. It aims to ensure the equal treatment of EU employees regardless of their religion or belief, disability, age or sexual orientation. The scope of the directive extends to both direct and indirect discrimination. Direct discrimination refers to any differential treatment based on a specific characteristic. Indirect discrimination relates to any practice or criteria which disadvantages certain employees.

Importance for SHAPES Integrated Care Platform (and future Marketplace)

SHAPES partners must ensure that employees of a particular religion or belief, disability, age or sexual orientation do not suffer from discrimination on these grounds. The Directive primarily relates to employment activities, including recruitment activities, employment conditions, and promotion and training opportunities.

4.3.3. Council Directive 2004/113/EC implementing the principle of equal treatment between men and women in the access to and supply of goods and services

Directive 2004/113/EC implements the principle of equal treatment between men and women in the access to and supply of goods and services. The purpose of the Directive is to prevent discrimination in the access to and supply of goods and

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services, in both the public and private sectors. This Directive relates to the selling of goods or provision of services for remuneration. Specifically, the Directive prohibits; the less favourable treatment of men and women by reason of their gender, the less favourable treatment of women due to pregnancy or maternity, or any sexual harassment or attempts to discriminate with regards the provision of supplies or services. Articles 2 and 3 of the Treaty of the EU sets out equality between men and women as a fundamental principle of the EU to support the full integration of all into economic and social life.

The Directive requires Member States to establish judicial or administrative redress actions for victims of gender discrimination. The onus is placed on Member States to enforce sanctions for any infringements of the principle of equal treatment. Furthermore, Member States are responsible for delegating monitoring and promoting the equal treatment of men and women to public bodies.

Importance for SHAPES Integrated Care Platform (and future Marketplace)

The Directive extends the principle of equal treatment between men and women beyond the workplace, and combats all gender discrimination in access and supply of goods and services. If SHAPES partners are selling goods or providing services for remuneration, they must not engage in any actions which create favourable treatment of men or women by reason of their gender. Although, it should be noted that the principle of equal treatment does not preclude the use of affirmative action to combat gender inequalities in the context of access to necessary goods or services.

4.3.4. Directive 2006/54/EC on the implementation of the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation

Directive 2006/54/EC consolidates previous legislation on gender equality to ensure equality between men and women in the workplace. The Directive reiterates the importance of promoting equality in employment and working conditions. In particular, the Directive prohibits discrimination in the recruitment process, dismissals, vocational training and promotion opportunities, and membership of workers' or employers' organisations. Additionally, the Directive promotes equality in social protection, particularly it requires that women and men are equally treated under occupational social security schemes.

Furthermore, the directive places obligations on Member States to put in place remedies and redress systems for employees who have been victims of discrimination. It is important to note that the burden of proof is placed on the party accused of discrimination to prove that there has been no breach of the principle of equal treatment.

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Importance for SHAPES Integrated Care Platform (and future Marketplace)

As previously mentioned, SHAPES partners must ensure that they actively promote the principle of equal treatment in the workplace. It is important for SHAPES partners to understand the different types of discrimination, including direct and indirect discrimination and harassment.

4.4. Accessibility

4.4.1. European Accessibility Act Directive (EU) 2019/882

The European Accessibility Act Directive (EAA) aims to harmonise the accessibility requirements for certain products and services. Importantly, for the SHAPES project, the Directive aims to remove barriers to certain products and services for persons with disabilities and older people. In particular, the Directive clarifies the existing accessibility obligations in public procurement and structural funds activities.

Member States are required to transpose the EAA by June 2022. Although, certain elements of the legislation will not enter into force until 2025. In 2025, the Directive will be applicable to certain products, including computers and operating systems, smartphones and other equipment for accessing telecommunication services and e-readers. At the same time, the Directive will apply to audiovisual media services, telephony services, certain elements of transport services, consumer banking and eBooks.

The Directive will require manufacturers to design and manufacture products in line with the changes set out in the legislation, for example requiring manufacturers to include instructions and safety information which can be easily understood by all. Importers, additionally, must ensure that products meet the revised conformity assessment procedures to ensure that the product meets the necessary technical specifications and includes all relevant CE marks. Separately, service providers must ensure that they make written and oral information easily accessible to persons with disabilities.

The Directive implements the UN Convention on the Rights of Persons with Disabilities to respect the right of persons with disabilities (CRPD). The Directive takes into account the obligations deriving from the Convention and covers products and services which could potentially host inaccessible characteristics. Coverage extends to; computers and operating systems, smartphones, TV equipment related to digital services, services related to air, bus, and rail transport, banking services, e-books and e-commerce.

Importance for SHAPES Integrated Care Platform (and future Marketplace)

When developing new products, the SHAPES Partners should aim to design products, which include functionality design, support services and packaging to maximise their

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use by people with disabilities and older persons. When providing services, the SHAPES partners should ensure that the service is accessible, this extends to making websites and mobile devices accessible to navigate and use.

4.4.2. Web Accessibility Directive Directive (EU) 2016/2102

Additionally, the Web Accessibility Directive (WAD) takes into account the obligations deriving from the CRPD requiring public sector web providers to ensure that persons with disabilities can easily understand, navigate and interact with digital services. Websites and apps provided on the web and through mobile devices should not include any attributes that exclude or partially exclude persons with disabilities. Specifically, the Directive implements Article 9 CRPD, by requiring public sector websites to ensure equal access for persons with disabilities to information on public services. The Directive refers to standards which providers must meet to make websites and apps accessible. This includes requiring providers to publish an accessibility statement on each website and app. Such a statement must acknowledge any section of the website or if live feeds are not accessible.

Importance for the SHAPES Integrated Care Platform (and future Marketplace)

The WAD alongside the EAA promotes digital inclusion. The SHAPES Project should ensure that persons with disabilities can easily access, understand, use, and interact with all digital services used and developed by the project.

4.5. The Medical Device Regulatory Framework

Medical devices and In Vitro Diagnostic medical devices (IVDs) are key instruments used in the development and deployment of innovative healthcare solutions in the Internal Market (European Commission, 2020). Medical devices and IVDs assist in the prevention, monitoring, treatment or alleviation of illnesses. The European Medicines Agency (EMA) defines medical devices as “products or equipment intended generally for a medical use” which must “undergo a conformity assessment to demonstrate that they meet legal requirements to ensure they are safe and perform as intended”. (EMA, 2019). Examples of medical devices include software apps, contact lenses, X-ray machines, pacemakers, sticking plasters and hip replacements. Separately, IVDs are used to perform health-related tests, such as blood tests and blood sugar monitoring systems for people with diabetes. While current literature on the use of medical devices by older people has identified areas of tension between older users and specific medical devices, there is a growing consensus that the use of medical devices and IVDs positively assist older people in managing their healthcare needs at home. (Thomson *et al.*, 2013). WPs 4 and 5 scrutinise in detail the use and ability of medical

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devices to support older people living independently, leaving this deliverable to focus on the regulation of medical devices and IVDs at an EU level.

As noted in D8.3, EU Member States have primary responsibility in regulating, organising and delivering healthcare systems (Greer, *et al*., 2019). However, one of the areas in which the EU does intervene directly in the operation of national healthcare systems is through the harmonisation of safety measures in the area of medical devices. However, Member States continue to 'firmly control the market', in terms of access to products, procurement and price (de Ruijter, 2019, p. 16). Until May 2021, medical devices were governed by Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990), Council Directive 93/42/EEC on Medical Devices (MDD) (1993) and Directive 98/79/EC of the European Parliament and of the Council on in vitro Diagnostic Medical Devices (IVDMD).

Directive 90/385/EC was the first piece of EU legislation implemented to regulate and harmonise safety standards for 'active implantable medical devices', such as cardiac pacemakers. The 1993 'Medical Devices Directive' offered a more comprehensive piece of legislation, covering all other medical devices. However, IVDs were not regulated at an EU level, until the IVD Directive was introduced in 2000. The Medical Devices Directive was described as the 'core of the legislation', establishing three categories of devices that are graded according to the risk assessment. The required level of controls, supervision, and marketing and data content was dependent on the categorisation. For low risk devices, manufacturers can affix and self-certify a CE mark which must be registered and verified with a national competent authority. High-risk devices must be supervised and audited by national 'Notified or Conformity Assessment Bodies.' An underpinning system of standards and guidance documents support the harmonisation of medical devices safety standards.[8]

Despite the comprehensive controls set out in the Directives, there was a multitude of problems associated with medical devices safety alerts and product recalls. Notably, complications with breast implants[9] and metal hips highlighted issues with diverging interpretation of the existing medical devices rules (Heneghan *et al*., 2012). Heneghan and Thompson argue that these two key examples "highlight only a fraction of the burgeoning increase in medical device safety alerts and problems with device recalls" (2012, p.186). Jarman *et al*.'s (2020) comparative study found that the use of the Directive's 'essential requirements' as health standards generated further legal uncertainty by failing to address the successive health scandals. The study further criticised the CE marking system, arguing that the device classification system is vaguely-constructed, which has continuously provided firms with too much discretion when applying for appropriate CE marks.

[8] The European Standardisation Organisations, including the European Standards Group, are officially recognised by Regulation (EU) No 1025/2012 as providers of European standards.
[9] Case C-219/15 *Elisabeth Schmitt v TUÜV Rheinland LGA Products GmbH*

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Additionally, improvements in technology led to the blurring of distinctions between medical devices and medicinal products, leading to confusion over the applicable regulatory scheme (Jefferys, 2001). In order to address these concerns, the European Commission proposed two new Regulations on medical devices and in vitro diagnostic medical devices in 2012. Following a robust and technical assessment of the proposed Regulations, an updated legislative package was adopted in April 2017.

The updated medical device regulatory framework was introduced with the primary aim of guaranteeing the "safety and efficacy of medical devices" and the facilitation of "patients' access to devices" in the Internal Market (European Commission, 2019). An underlying objective of the rules is to create an environment that supports innovative companies' development, thus improving access to high-technological healthcare services. The updated framework comprises of

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, and;

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

A number of important changes have been introduced. Most significantly, the legislation is now in the form of a Regulation, rather than a Directive. Regulations are directly applicable at a national level and do not require transposition through national legislation. The Regulations offer legal clarity and certainty and mitigate the previous problems of diverging interpretation of the existing medical devices rules. Although, Jarman *et al*. point out that the updated legislative framework fails to navigate the current problems of market fragmentation and patient safety. The authors further suggest that the new regime's success is dependent on the harmonised support for the successful implementation of the rules at both a regional and national level (Jarman *et al*., 2020).

To support the harmonised use of the rules, the EMA and national competent authorities have been afforded new responsibilities in conducting conformity assessments of medical devices. Such assessments may include an audit of the technical document, safety and performance of the device. Notably, the national competent authorities are responsible for classifying 'borderline products' as medical devices on a case-by-case basis. Borderline products are defined as "complex healthcare products for which there is uncertainty over which regulatory framework applies". (EMA, 2019). Ritzhaupt *et al*. acknowledge that the new rules will significantly strengthen the pre-marketing assessment and post-marketing surveillance of medical devices, estimating that the majority of existing manufacturer self-assessed IVDs will

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have to be CE marked in 2022 (Ritzhaupt *et al.* 2020). Furthermore, the authors argue that the new rules placed on both the EMA and national competent authorities have the potential to establish "more collaborative working relationships across traditional boundaries in preparation for the future" (Ritzhaupt *et al*. p. 566). It is clear that the new rules will place additional responsibilities onto both the private and public sector. It is important for the SHAPES partners to have an understanding of the key changes that will be implemented over the course of the project.

The Regulations have a staggered transitional period, with the full application of the Regulations been delayed due to the Covid-19 pandemic. The following table lists the timeline and transition to the new Regulations.

Timeline and Transition to the New Regulations	
May 2017	Medical Device Regulation (MDR) and In-Vitro Diagnostic Regulation (IVDR) enter into force, following formal publication in the Official Journal of the European Union (OJ).
From 26th May 2017	Devices that conform with the MDR may be placed on the market.
From 26th May 2017	Devices that conform with the IVDR may be placed on the market.
November 2017	Notified bodies were permitted to submit applications to be designated under the new Regulations to the Medical Device Coordination Group (MDCG).
March 2020	In light of the Covid-19 pandemic, the European Commission proposes the postponement of the application of the MDR.
April 2020	The EU Parliament adopted the proposal to extend the date of full application of the new Regulations.
Until 25th May 2020	All certificates issued under the Medical Devices Directive (MDD) are valid
25th May 2020 – 25th May 2024	Certificates issued under the MDD before the MDR fully applies may remain valid for up to 4 additional years
May 2021	**Full application for the MDR.**
May 2022	**Full application for the IVDR.**

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Until 25th May 2022	All certificates issued under the In Vitro Diagnostic Medical Devices Directive (IVDD) are valid.
25th May 2022 – 25th May 2024	Certificates issued under the IVDD before the IVDR fully applies may remain valid for up to 2 additional years.
From 26th May 2023	Implantable devices and class III devices are required to bear the UDI carrier on the device itself.
From 26th May 2024	All devices placed on the market must be in conformity with the MDR.
From 26th May 2024	All devices placed on the market must be in conformity with the IVDR.
26th May 2024 – 27th May 2025	MDD devices already placed on the market before may continue to be made available.
26th May 2024 – 27th May 2025	IVDD devices already placed on the market before may continue to be made available.
From 26th May 2025	Class IIa and class IIb devices are required to bear the UDI carrier on the device itself.
From 26th May 2027	Class I devices are required to bear the UDI carrier on the device itself.

When the Regulations are fully implemented, economic operators must comply with the supply chain quality obligations imposed by the rules to ensure that any issues are addressed as effectively as possible by suppliers, distributors, and importers. Specifically, economic operators must ensure that each device has a unique identifier to allow for the transparent passing of the product's information between the supply chain, and with the centralised European database. (McHale, 2018). The inclusion of new stringent requirements for the designation of Notified Bodies further aim to promote harmonisation and transparency between the management of health and safety systems between the Member States. These requirements, alongside increased control and monitoring responsibilities by the national competent authorities and the Commission embed a system of centrality in the medical device regulation process (Jarman, *et al.* 2020).

Overall, the new regime attempts to address the problems associated with the old rules. Importantly, for the SHAPES partners, the scope of application of the rules has been significantly broadened. Software developers developing standalone software, including apps, for a medical purpose must ensure that all products are appropriately CE marked. However, Jarman *et al*. (2020, p. 61) suggest that "there is a real chance that some components will not be implemented", in particular, the authors suggest the centralised European database will be difficult to maintain and keep updated. Additionally, their study suggests that the Commission and the national competent bodies do not have the logistical capabilities to fully investigate the actions of notified bodies. Furthermore, it suggests that notified bodies also lack the capabilities to oversee supply chain actors (Jarman *et al.* 2020, p. 61).

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Despite these concerns, the new regulatory framework promotes a harmonised and transparent system for regulating medical devices and IVDs and has the potential to reduce the risks of discrepancies in interpretation across the Internal Market. Adjusted transitional periods will allow for manufacturers to navigate through the Covid-19 pandemic and have sufficient time to comply with all new requirements.

Importance for SHAPES Integrated Care Platform (and future Marketplace)

As a general rule, the MDR requires that medical devices bear the CE marking to indicate their conformity thereunder. However, relevant to the SHAPES pilots, the Regulation provides for an exception in the case of investigational devices, i.e. under clinical investigation. The medical devices within SHAPES seem to fall within class IIa and IIb which, in principle, do not require the full approval process before commencing clinical investigation. However, importantly, this is subject to the varying approval processes across the Member States and provided that a negative opinion has not been issued by an ethics committee within the Member State. Therefore particular requirements regarding CE marking during the pilot stages may differ across the Member States, requiring individual assessment in respect of each pilot site.

The MDR and IVDR entered into force on 25 May 2017. The IVDR will apply from 26 May 2022 however, as noted above, the date for general application of the MDR was postponed until 26 May 2021, in light of the COVID-19 pandemic. Upon their date of application, the new Regulations are/will be binding and directly applicable in all Member States, subject to specific transitional provisions. A transitional period, extending until 26 May 2024, exists in respect of certain class I devices subject to particular safeguards in their approval, continued compliance with the Directives, and there being no significant changes in the design or intended purpose. The Directives will continue to apply in respect of a 'sell-off' period for products lawfully placed on the market prior to the Regulation's application date, lasting until 26 May 2025. This will also apply in respect of class I devices, as above, placed on the market from 26 May 2021.' Single use devices may only be reprocessed where placed on the market in accordance with the Regulation, or prior to 26 May 2021 in accordance with the Directive.

Regarding Clinical investigations that have started in accordance with the Directives prior to 26 May 2021, the Regulation provides that they may continue however, after this date, they will be subject to the requirements under the Regulation concerning the reporting of serious adverse events and device deficiencies.

With a view to ensuring transparency and traceability, the Regulations introduce a requirement to place UDI carriers on the label of the device and on all higher levels of packaging, with the exception of custom-made and investigational devices. This obligation will apply to implantable devices and class III devices from 26 May 2021; class IIa and class IIb from 26 May 2023; and class I devices from 26 May 2025. In respect of reusable devices, the timeline governing UDI carriers was changed by the

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Amending Regulation, now applying to implantable devices and class III devices from 26 May 2023; class IIa and class IIb devices from 26 May 2025; and class I devices from 26 May 2027.

The prolonged transition period under the amended MDR facilitates the sector's adjustment to and compliance with the new framework, encompassing new transparency and traceability requirements, and improved procedures in health and safety, "supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance".

As mentioned above, it is important that the SHAPES partners are aware of the timeline and transitions to the new Regulation and understand its implications in respect of their activities.

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5. Concluding Remarks

As part of WP8, this annex to D8.3 (annex D8.3.1) focuses on identifying the regulatory framework for the SHAPES Integrated Platform and digital solutions. It aims to complement the ethical and privacy analysis conducted in D8.4, D8.5 and D 8.14. In particular, this deliverable focuses on reviewing the legislation and policies that have been deemed relevant and appropriate by the European Commission in recent communications (European Commission, 2020). The EU has accelerated their actions in developing an innovative, inclusive digital union that respects individuals' right to data and access to digital solutions. Legislative and policy revisions reviewed in this deliverable trace the boundaries of the frameworks which will underpin the SHAPES Integrated Platform. While, the legislative reforms for digital solutions is not yet complete nor without flaws, the baselining framework has the potential to facilitate the creation of a Pan-European Smart and Healthy Ageing. Task 8.2 will further critique the design of the legislative frameworks, commenting on the proportionality and appropriateness of the rules.

For the purposes of this deliverable, the SHAPES Platform and SHAPES Digital Solutions have been located in the EU legal and policy frameworks. The deliverable has pinpointed the key frameworks that are connected to the SHAPES project. The deliverable can therefore act as a reference guide for the SHAPES partners. This deliverable provides a succinct overview of the scholarship of EU law of new technologies, traces the development of EU policies on Digital Services, and identifies the legal requirements for the SHAPES Platform and Digital Solutions. The identified legislative framework sets out responsibilities which SHAPES Partners must take into account to ensure that all project activities are carried out in a manner which fosters inclusive digital services.

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