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Malta: Law & Practice

Paul Micallef Grimaud,
Stuart Firman and Michela Galea
Ganado Advocates

MALTA

Law and Practice

Contributed by:
Paul Micallef Grimaud, Stuart Firman and Michela Galea
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Contents

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Authors

Paul Micallef Grimaud is a partner at Ganado Advocates and heads the firm's intellectual property, TMT and data protection practice groups. He is a warranted advocate with over 20 years' experience advising clients in the media, technology and entertainment space and representing them in court and arbitration proceedings. Paul has a keen interest in AI and innovative technology and is regularly involved in the drafting of laws, strategy and policies surrounding this area. He occupies the post of Vice President for the Professional Advancement of the Chamber of Advocates, is President of the Malta Institute of Privacy Law (MIPL) and is a member of ECTA's Law Committee.

Stuart Firman is a senior associate within Ganado Advocates' corporate finance team, regularly assisting clients in the areas of corporate and commercial law, with an emphasis on domestic and cross-border mergers and acquisitions, corporate reorganisations and cross-border transactions. Stuart also provides advice to clients on foreign direct investment (FDI) law and assists them with FDI notifications.

Michela Galea is an advocate within Ganado Advocates' intellectual property, TMT and data protection practice group. She provides support to clients on a wide range of IP matters, including securing IP protection, enforcing IP rights, and defending IP-based claims. Her work involves drafting of critical agreements within the IP realm such as assignment agreements, licensing, and franchise agreements, ensuring her clients' IP assets are effectively managed and protected. Michela also supports clients in data protection and privacy matters, ensuring compliance with data protection legislation.

Ganado Advocates

171, Old Bakery Street
Valletta VLT 145
Malta

Tel: +356 2123 5406
Email: lawfirm@ganado.com
Web: www.ganado.com

1. General Legal Framework

1.1 General Legal Background

Whilst recognising the impact that AI is having on a range of economic sectors and establishing the Malta Digital Innovation Authority (MDIA) to spearhead initiatives and drive necessary changes around AI, Malta generally continues to rely on its existing legal frameworks – including civil, commercial and criminal laws – and harmonised EU legislation to manage AI-related matters.

Malta's legal system is *"mixed"* one, where its civil, commercial and criminal laws are principally based on civil law, whilst the main source of its public and administrative laws is common law. These legal systems are still influential on the interpretation of Malta's laws and it is expected that any decisions of the Italian, French and English courts in relation to AI will have an influence on the interpretation of Malta's civil, commercial and public laws.

Contractual and Tortious Lability

General principles of contract and tort law would continue to apply to the use of artificial intelligence in Malta. These are covered by the Civil and Commercial Codes (Chapters 16 and 13, respectively) of the Laws of Malta.

Acting in good faith (in the manner of a bonus paterfamilias) is one of the underpinning principles of both contract law and tort law. The use of AI would be generally deemed to be a tool and the user of such *"tool"* remains ultimately responsible for damage caused by it or through its use. The principle of culpable negligence under Article 1033 of the Civil Code, whereby *"any person who with or without intent to injure, voluntarily or through negligence, imprudence, or want of attention, is guilty of any act or omission constituting a breach of the duty imposed by law, shall be liable for any damage resulting therefrom"*, is particularly relevant to damages resulting from the use of AI. As with any technology, the use of AI brings with it the duty of care towards others. This applies both where the use of the technology is a private one, as well as where it is used in a professional context. The user is not able to rely on ignorance of the effects of the use of the technology or the *"black box"* phenomenon.

IP, Data Protection and Consumer Affairs

Apart from its domestic laws, as an EU member state, Malta's laws adopt harmonised EU legislation in most of the areas that are relevant to AI, be they copyright and IP, data protection, use of medical devices, product safety or consumer protection law. The domestic laws that

have transposed the EU Directives or support EU Regulations in these fields, most notably the Copyright Act (Chapter 415 of the Laws of Malta), the Data Protection Act (Chapter 586 of the Laws of Malta), the Consumer Affairs Act (Chapter 378 of the Laws of Malta) and the Medical Devices Regulations (Subsidiary Legislation 427.44) have not been modified to cater for AI specificities. Neither has Transport Malta (the authority for transport in Malta) updated its Highway Code or introduced any specific provisions related to the use of automated vehicles in Malta. The use of personal data for AI in the health sector has been dealt with in the Processing of Personal Data (Secondary Processing) (Health Sector) Regulations (Subsidiary Legislation 528.10), which is discussed in further detail in **8.2 Data Protection and Generative AI** and **14.3 Healthcare**.

In summary, all relevant public authorities and bodies are keeping a watchful eye on developments in their areas of interest whilst, at the same time, waiting for more concrete signs of the need to change the status quo of the legal frameworks they are responsible for. Naturally, the discussions being held at pan-European level and at inter-supervisory authority level, will determine how the responsible authorities and the legislature will behave going forward.

Maltese Regulators

The MDIA was set up as a public authority in 2018 to lead and advise the government on developments and initiatives in the innovative technology space, including AI. It has developed and is revising a national AI strategy for Malta (the *"Malta AI Strategy and Vision 2030"*) and is also spearheading legislative change that will allow for proper regulation, in accordance with the EU's AI Act.

In 2019 the MDIA launched what it described as *"the world's first national AI certification programme aiming for AI solutions to be developed in an ethically aligned, transparent and socially responsible manner"*. The AI Innovative Technology Arrangement (AI ITA) scheme laid out a certification programme similar to that found in today's EU AI Act through which, according to the risks envisaged in the use of the technology, developers and deployers could attain certification through a technology systems auditor licensed by the MDIA who would certify that the technology met pre-set objectives and criteria. In 2022, the MDIA also issued programme guidelines for a Technology Assurance Sandbox.

Inevitably, Malta's regulators, in particular the Malta Financial Services Authority (MFSA) and Malta Gaming Authority (MGA), have been following and commenting on developments in the use of technology, including AI, within their sectors of focus. Other legislation that is being harmonised at EU level will have an impact on the use of AI in certain sectors. In this vein, the MFSA has issued Guidelines on DORA (the EU's Digital Operational Resilience Act), which update its Guidelines on Technology Arrangements, ICT and Security Risk Management, and Outsourcing Arrangements, for public consultation. Similarly, the Network and Information Security 2 (NIS 2) Directive has been recently transposed into Maltese law. These are the key aspects of Maltese regulation that impact the use of AI within financial services and other sectors deemed to be essential or important.

EU Regulators

The Guidance of the European Central Bank (ECB) and the European supervisory authorities – the European Banking Authority (EBA), the European Insurance and Occupational Pensions Authority (EIOPA) and the European Securities

and Markets Authority (ESMA) – on the use of AI, cyber-risk and digital resilience, will continue to be key to developments in Malta regulating the use of technology, including AI, in the financial sector, where, save for harmonised standards at EU level, one would expect regulation to come in the form of directives issued by sectoral regulators. This approach is likely to be followed in other sectors, including transport, health and education.

2. Commercial Use of AI

2.1 Industry Use

AI is pervasive in the industries that form the basis of Malta's economic activity. In particular, large-scale use of AI is known to take place in the financial services (banking, insurance and investments), gaming (both i-gaming and video gaming) and health sectors, amongst others. The uses range from predictive AI (for instance in risk and credit worthiness checks, as well as in medical prognosis) to generative AI (in content and software development, as well as customer support and compliance).

Transport

In the public sector, the government has expressed the need to revert to AI to solve Malta's traffic problems. From press releases that were published it seems that the government and relevant authorities are in fact investing in intelligent management systems. A pilot project was launched, under the leadership of Transport Malta, with the following goals:

- to reduce congestion and emissions;
- to identify patterns in transport behaviours;
- to deliver insights to enable intelligent journey-planning and scheduling of public transport;
- to create intelligent private journey routing (in conjunction with third-party applications); and
- to assist with monitoring, policing, and enforcement.

Health and Education

The health sector is also relying on AI to assist with the procurement and effective management of medicines. The Central Procurement and Supplies Unit (CPSU) has launched a pilot project for a forecasting application that will be a decision-making tool used by the CPSU to help in budgeting, planning the procurement process (tendering, quotations, etc) and planning the ordering process. This application would attempt to predict future outcomes based on past events and management insight. It is intended to provide CPSU management and procurement personnel with an insight and the baseline tools and techniques to help better manage and react to fluctuations in demand.

Additionally, in February 2025, Malta secured funding from the EU4Health programme to participate in the four-year *"BreastScan"* project. This initiative aims to integrate AI into radiology, enhancing the accuracy and efficiency of breast cancer screenings.

In education, in May 2024, the Ministry for Education, Sport, Youth, Research, and Innovation adopted the Digital Education Strategy 2024–2030. This strategy emphasises the importance of digital literacy as a fundamental 21st-century skill and outlines a clear path to drive excellence in digital transformation within the education sector. The strategy is structured around four key pillars.

- Nurturing Digital Global Citizens: Introducing ICT and digital literacy in primary schools, ensuring that learners achieve digital com-

petencies as a core entitlement through ICT in secondary schools, and promoting digital citizenship empowerment and eSafety awareness.
- Empowering Educators for the 21st Century: Fostering a digital school culture that integrates technologies and 21st-century skills, consolidating and promoting professional development opportunities for all educators in digital literacy and technology-enhanced learning, and developing digital competencies of prospective educators before entry into the profession.
- Community Engagement and Collaboration: Empowering guardians and carers to support learners' digital competencies and effective learning, and creating strong relationships and strategic alliances with experts to enrich digital education through their expertise and knowledge.
- Enriching Digital Resources: Unleashing the potential of every learner through digital integration with the provision of tablets in primary classrooms and laptops in secondary classrooms, providing resources and space for the development and strengthening of digital skills and competencies, and promoting the online corporate presence of the Ministry for Education, Youth, Research, and Innovation (MEYR) and sustainability in the procurement of digital software.

Tourism and Utilities

The Malta Tourism Authority is also reported to be launching a Digital Tourism Platform to allow for more meaningful use of tourist data.

In a pilot project owned by the Ministry for Energy, Enterprise and Sustainable Development, AI algorithms will be used to collect, organise, and analyse current data to discover patterns and other useful information relating to water and energy usage. The solution will deploy large-scale analytics and machine learning on customer data to help the utility companies to maximise resources and subsequently provide responsive real-time customer service management. Concurrently, they can make real-time adjustments to attain optimised generation efficiency.

Predictive maintenance models and scenarios will also be developed.

This project is expected to drive better efficiency, resilience and stability across Malta's energy and water networks, and lay the foundation for the next evolution of its smart grid network.

2.2 Involvement of Governments in AI Innovation

The Malta AI Strategy and Vision 2030

The Malta AI Strategy and Vision 2030 contains 22 action points in its education and workforce section, six dealing with legal and ethical issues, and 11 in the part focussing on ecosystem infrastructure. These are being rolled out by the MDIA in conjunction with other public entities.

The objectives in the education and workforce space are:

- understand and plan for the impact of technology and automation on the Maltese labour market;
- equip the workforce with stronger digital competencies and new skills;
- build awareness amongst the general population of what AI is and why it is important;
- build awareness of AI amongst students and parents;
- foster and embrace the adoption of AI in education;
- develop teachers' knowledge and awareness of AI in education;

- equip all students enrolled in higher education programmes in Malta with AI skills; and
- increase the number of graduates and post-graduates with AI-related degrees.

The legal and ethical objectives are:

- establish an ethical AI framework towards trustworthy AI;
- launch the world's first national AI certification framework;
- appoint a technology regulation advisory committee to advise on legal matters; and
- set up a regulatory sandbox for AI and a data sandbox for AI.

The objectives related to ecosystem infrastructure are:

- investment in Maltese language resources;
- incentivise further investment in data centres;
- establish a digital innovation hub (DIH) with a focus on AI;
- increase the extent of the open data availability to support AI use cases;
- provide cost-effective access to compute capacity;
- expand Malta's data economy through 5g and the *"internet of things"* (IoT); and
- identify best practices for securing national AI solutions.

The MDIA is currently leading efforts to revise Malta's national AI strategy, with a realignment process scheduled for completion in 2025. This has been prompted by various factors including:

- 80% of the objectives outlined in the 2019 Strategy having been established, and partially or fully executed;
- new areas having gained relevance, while others have become obsolete since the strategy's inception, necessitating a reassessment;
- Malta adapting its regulations to align with international frameworks in the field of AI including the EU's AI Act; and
- the emergence of new challenges and opportunities has prompted a need to adjust the strategy to address evolving societal dynamics.

Other Initiatives

In addition to that mentioned above, the MDIA, together with the Ministry for the Economy and other constituted bodies, such as TechMT (an industry/public partnership), have been playing a central role in the promotion of AI initiatives. From the launch of sandboxes (such as MDIA's technology assurance sandbox), to the setting up of business incubators (such as the Digital Innovation Hub – DIH) and the making available of grants for digital innovation and grants for AI research, as well as seed funds, this network of bodies has been supporting technology development and innovation, including the development and adoption of AI.

Moreover, under a project to be funded by the EU, the MDIA, Malta Council for Economic and Social Development (MCESD) and University of Malta have created a hub (the Malta – EDIH) wherein the complete set of services of a European Digital Innovation Hub are provided on an open, transparent, and non-discriminatory basis and targeted towards SMEs, small mid-caps, and public sector organisations. Within the Hub public workshops are organised to facilitate two-way dialogue between AI experts and industry.

3. AI-Specific Legislation and Directives

3.1 General Approach to AI-Specific Legislation

The MDIA was established in 2018 through the Malta Digital Innovation Authority Act (Chapter 591 of the Laws of Malta) with the aim of regulating innovative technology through the issuing of compliance certificates (both mandatory and voluntary). Originally focused mainly on the regulation of distributed ledger technology (DLT), its remit was quickly expanded to other forms of innovative technology, including AI, through amendments that came into force in 2024. The MDIA has been designated as Malta's cybersecurity certification authority and as the competent authority for data intermediation services and for the registration of data altruism organisations under the Data Governance Act.

Initially, Malta took a proactive and innovative approach to the regulation of AI within its jurisdiction. In October 2019, Malta issued the Malta AI Strategy and Vision 2030. This strategy outlined the policy that the country set out to adopt within the following years in order to *"gain a strategic competitive advantage in the global economy as a leader in the AI field"*. The basis of the strategy's overall vision is three-fold. Firstly, it focuses on building an infrastructure that promotes the investment in AI applications and R&D. Secondly, it explores how these AI applications can be deployed in the private sector. And, thirdly, it promotes adoption of AI in the public sector so as to maximise the overall benefit that can be derived from this innovative technology. This strategy is constantly being updated and a revision, taking into account the various recent developments, is expected to be issued soon.

From a regulatory perspective, the strategy included an ethical AI framework as well as a national AI certification programme. A Technology Regulation Advisory Committee was also founded to act as a point of reference for matters relating to the laws and regulation of AI, as well as assisting on the creation of regulatory and data sandboxes.

The AI Sandbox programme, which ensures that AI systems are developed in line with technology-driven control objectives, is one of the cornerstones of the 2030 vision.

The laws regulating the functions and scope of the MDIA are also currently being revised to better equip the Authority to meet its obligations and aims, going forward. In particular, the revisions make way for the introduction of local legislation required to complement the AI Act.

To date, the regulatory approach remains an optional one where developers are encouraged to make use of regulatory sandboxes to test whether their technology will live up to the scrutiny of mandatory regulation once this comes into force, in the shape and form of harmonised EU laws and standards.

Apart from those legislative developments mentioned elsewhere in this chapter, to date, no specific, local AI laws have been drafted, nor have laws relating to intellectual property, data protection or other areas that are central to AI been amended to cater for the challenges posed by the technology. This said, regulatory authorities are expected to spearhead developments in this space, in particular in the field of financial services and insurance.

3.2 Jurisdictional Law

No AI-specific legislation has been enacted in Malta. Preparatory legislative work is underway to allow for the introduction of the AI Act, which will have direct effect in Malta.

3.3 Jurisdictional Directives

Back in October 2019, an ethical AI framework for the development of safe and trustworthy AI was published as part of the Malta AI Strategy and Vision 2030. This non-binding AI framework was essentially a set of AI governance and control practices which were based on four guiding principles. Firstly, AI systems must allow humans to maintain full autonomy whilst using them. Secondly, AI systems must not harm humans, the natural environment, or any other living beings. Thirdly, the development, deployment and use of AI systems must always be in alignment with the principle of fairness. Finally, one must be able to understand and challenge the operations and outputs of AI systems.

This AI framework reflected the Maltese policymakers' aspirations to strike a balance between endorsing the uptake of AI technology, whilst also ensuring its safe deployment within the relevant industries.

3.4 EU Law

3.4.1 Jurisdictional Commonalities

Even though the AI Act has been directly applicable across all EU member states (including Malta) from June 2024, Malta enacted the Malta Digital Innovation Authority (Amendment) Act (Act No XIX of 2024) to cater for broader powers of the MDIA, whilst removing restrictions that previously hindered its functioning. The MDIA is leading Malta's implementation of the EU AI Act and is working with key stakeholders to ensure an effective and supportive regulatory framework.

3.4.2 Jurisdictional Conflicts

Malta is currently in the process of aligning its national framework with the requirements of the EU's AI Act, with the MDIA playing a pivotal role in this alignment. The MDIA's voluntary certification frameworks and sandboxes apply to AI-based solutions, aiming to promote ethical and transparent AI development in line with the EU AI Act. These efforts are part of Malta's broader strategy to integrate the EU AI Act's provisions into its national regulatory environment. In line with Malta's wider strategy, any process which is inconsistent with these harmonised rules will be disapplied.

3.5 US State Law

This is not applicable in Malta.

3.6 Data, Information or Content Laws

As outlined in **3.4.2 Jurisdictional Conflicts**), any processes that would be inconsistent with the EU's harmonised rules will be disapplied.

3.7 Proposed AI-Specific Legislation and Regulations

Following the amendments to the Malta Digital Innovation Authority Act mentioned in **3.4.1 Jurisdictional Commonalities**, subsidiary legislation is expected to be introduced to iron out any legislative inconsistencies that may hinder the proper operation of the AI Act and any other EU technology-specific legislation. As an EU member state Malta will adopt all other EU laws that may impact the take up of AI.

With the increasing relevance of generative AI, it is also possible that IP laws could be modified to allow for the creation of certain ownership rights in AI-generated works. This would be particularly relevant to the i-gaming and e-gaming development sectors that are relevant to Malta's economy. Although there have been discussions

and proposals in this regard, it is too early to say what position might be adopted by the government.

4. Judicial Decisions

4.1 Judicial Decisions

The Maltese courts have not had the opportunity to address the legal challenges being posited by AI, particularly in relation to intellectual property rights and damages resulting from the use of AI solutions. Decisions of foreign courts in those jurisdictions on whose laws Maltese law is modelled would be of significant importance and would offer guidance to Maltese courts when deciding these unexplored issues. Thus, EU and UK court judgments on intellectual property rights and Italian and French court judgments in relation to tort and contractual damages resulting from the use of AI would be of interest to the courts in Malta.

5. AI Regulatory Oversight

5.1 Regulatory Agencies

MDIA

The MDIA leads the initiatives and policies surrounding AI and acts as advisor to the government on all matters relating to AI.

The MDIA has formulated Malta's AI strategy (see **2.2 Involvement of Governments in AI Innovation** for further detail) and is currently implementing the various action points in co-operation with other stakeholders.

MFSA and MGA

The MFSA and MGA are expected to also play a lead role in shaping the use of AI in the financial and gaming sectors, which are key industries in Malta. The Ministry of Health and Active Ageing, acting through various units that are tasked with co-ordinating and leading projects for the said Ministry, will also have an important role to play. Transport Malta will likewise be instrumental in regulating the use of autonomous vehicles and AI-enabled means of transport, including drones.

IDPC

The Office of the Information and Data Protection Commissioner (IDPC) will continue to monitor developments relating to the use of personal data in and by AI and will regulate these matters in accordance with co-ordinated positions at the European Data Protection Board (EDPB) level.

In March 2025, the IDPC published a statement announcing that it had been designated as the Fundamental Rights Authority (FRA) for the purposes of the AI Act, insofar as the monitoring of the protection of personal data is concerned and that by 2 August 2025 it would be designated as Market Surveillance Authority (MSA) for AI systems used for law enforcement purposes, border management and justice and democracy, and possibly for other high-risk AI systems listed in Annex III to the AI Act.

Other

On a broader level, where a non-EU person intends on investing in an AI related activity in Malta – whether by way of greenfield investment or investment by way of acquisition of interests or assets – such person may be required to seek clearance from Malta's foreign direct investment office prior to effecting such investment.

5.2 Regulatory Directives

The coming into force of the EU AI Act largely harmonises the regulatory approach taken towards the uses of AI throughout the Euro-

pean Union. The positions and guidance notes published by the various pan-European industry regulators serve to provide direction to the national supervisory authorities and regulators. In this vein, in June 2024, the MFSA issued a short explanatory note to ESMA's initial guidance on Markets in Financial Instruments Directive II (MIFID II) requirements to firms using artificial intelligence technologies when offering retail investment services.

The need to consider the interplay of different regulations that come together when using AI, including DORA, NIS 2 and the Cyber Resilience Act (CRA), has led the MDIA to launch a regulatory sandbox through which participants can align with the various regulatory obligations. The MDIA works closely with the other regulatory authorities, principally the MFSA, in view of their *"shared commitment to ensure a secure and trustworthy digital environment."*

As mentioned in **2.2 Involvement of Governments in AI Innovation**, Malta has previously introduced an ethical framework designed to guide the development and deployment of AI systems within the country. This framework emphasises principles such as transparency, accountability, and respect for human autonomy, aiming to foster public trust in AI technologies. Whilst this is not a binding document, it provides an insight into Malta's hopes and expectations for the development of AI.

5.3 Enforcement Actions

Whereas, to date, in view of its remit, the MDIA is not known to have applied fines or taken enforcement action, apart from suspending or cancelling licences, the MFSA, MGA and IDPC have all taken corrective measures and imposed fines for breaches of the frameworks that they are responsible for upholding. It does not, however, seem to be the case that any fines have been imposed or any action taken against any industry players as a result of their deployment of AI solutions.

6. Standard-Setting Bodies

6.1 National Standard-Setting Bodies

Despite the various government authorities discussed in this article setting standards for the sectors they oversee, to date no standards have been imposed specifically in relation to the use of AI. Nor do representative bodies of professionals seem to have set standards for the use of AI in their professions.

6.2 International Standard-Setting Bodies

Until standards are harmonised across jurisdictions, it is expected that any standards that may be in line with what is applied in one jurisdiction will not automatically be accepted by regulatory bodies in other jurisdictions. This said, regulatory authorities within the EU collaborate closely together within their pan-European bodies of regulators, such as the EIOPA, EDPB, ESMA and EBA. It would be expected that standards that are set by these authorities would equally find application in Malta.

7. Government Use of AI

7.1 Government Use of AI

As discussed in **2.1 Industry Use**, the government has embarked on a number of pilot projects where the use of AI for certain deliverables mentioned therein is being tested. Other than these, no further uses of AI by the government have been publicised.

7.2 Judicial Decisions

No decisions related to government use of AI have been given by the Maltese courts.

7.3 National Security

The use of AI in national security matters has not been publicised.

8. Generative AI

8.1 Specific Issues in Generative AI

To date, Maltese law, regulators or the courts have not dealt with the complex legal issues surrounding generative AI. It is expected that under general principles of contract law, the courts would uphold the limitations embedded in the licences and terms and conditions for use of generative AI solutions.

Copyright and Generative AI

In instances where the use of generative AI is not bound by licensing conditions, whether copyright could arise in generated works would depend on the originality of the generated works and the level of human intervention in the generation of the works.

Should the AI-generated work constitute a substantial copy of an original work and this is put in use by the entity that, through its prompts, generated the work using a third-party model, the said entity would be in breach of the copyright of the original work's author, irrespective of the entity's knowledge or intention in creating a copy of the original work. The only exceptions to this are the exhaustive list of exceptions to copyright protection found in Article 9 of the Copyright Act (Chapter 415 of the Laws of Malta) apply. These exceptions include acts of reproduction of literary works by public libraries which are not for economic advantage, the reproduction of works for purposes of teaching or illustration without compensation, the reproduction or translation of works to render them accessible to persons with disability without compensation.

Similarly, if a model is trained on works in which copyright arises, without the authorisation of the copyright owner, the developers are liable for breach of copyright. This may result in the copyright owner prohibiting the commercial use and/or deployment of the AI model.

Where a work that would ordinarily qualify for copyright protection is created wholly by an autonomous process without meaningful intervention in the creation of the work, copyright would not arise. This is because copyright arises where the author or any of the joint authors of the artistic, literary or audiovisual work that qualifies for copyright protection is a citizen of, or is domiciled or permanently resident in, or in the case of a body of persons, is established in, Malta or a state in which copyright is protected under an international agreement to which Malta is also a party. The term *"author"* is defined as *"the natural person or group of natural persons who created the work eligible for copyright"*. The creation of a work by an autonomous process would therefore do away with the *"author"* and, consequently, copyright could not arise in it.

Personal Data and Generative AI

Another risk posed by generative AI relates to the use of personal data in both the training of the model and the interaction with it at prompt stage. The use of personal data in training a model must necessarily comply with one of the legitimate grounds under Article 6 of the GDPR. This is often not the case. The situation is compounded even further if special categories of data are used in the training of the model. It is with this in mind that the Processing of Per-

sonal Data (Secondary Processing) (Health Sector) Regulations (Subsidiary Legislation 528.10) was enacted. Under this law, where the use of health data by the public health providers for purposes other than the original intended use, which purposes are listed in the law, can lead to benefits for the health system in Malta, this use can be deemed permitted subject to the use of anonymisation techniques or clearance from an established ethics committee.

It is also important to note that there are no Maltese law exceptions to Article 22 of the GDPR. Under this provision of the law, a data subject may object to the fully automated processing of his or her data, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her. Maltese law also allows no exceptions to the data subject rights of access to, rectification of and deletion of his or her personal data which is used in the training of AI models.

The risks of using personal data – and, even more so, data that is covered by professional secrecy or legal privilege – in prompts when using generative AI, cannot be overlooked. No guidance has yet been issued in this respect by Maltese regulators or professional representative bodies, although it remains the responsibility of professionals to ensure that the protected or privileged information is not disclosed or breached through the use of the technology.

8.2 Data Protection and Generative AI

The Maltese Data Protection Act (Chapter 586 of the Laws of Malta) and subsidiary legislation made thereunder does not weigh in on the rights of data subjects in an AI context. Neither do they create any noteworthy exceptions to the position under the GDPR. The principles of data minimisation, purpose limitation, legitimate grounds for processing under Article 6 and 9 of the GDPR, as well as the rights of the data subjects under Articles 12–22 of the GDPR all need to be considered carefully by developers involved in the training of models and deployers of AI systems, alike. Human oversight and the ability to fulfil the controller obligations in relation to data subject requests are principles that would need to be followed at all stages of AI development and deployment. Anonymisation techniques are equally important measures to consider, as promoted in, amongst others, the single piece of Maltese legislation that deals with the use of personal data (medical records) for, amongst other things, training AI models: the Processing of Personal Data (Secondary Processing) (Health Sector) Regulations (Subsidiary Legislation 528.10).

9. Legal Tech

9.1 AI in the Legal Profession and Ethical Considerations

Legal tech is high on the agenda of legal professionals. This brings with it ethical considerations, including the effect on professional secrecy and legal privilege of interacting with generative AI. The UK Bar Council's guidance on generative AI captures these issues well. Neither the Maltese regulator for lawyers (the Committee for Advocates and Legal Procurators within the Commission for the Administration of Justice), nor the representative body of the legal profession (the Chamber of Advocates), have issued any guidance. This said, it is expected that they soon will. Until then, AI is to be considered as a useful tool that comes with its dangers and challenges and does not change the level of responsibility of lawyers to act ethically in accordance with the Code of Ethics that regulates the profession and their legal obligations resulting from, amongst other pieces of legislation, the Profes-

sional Secrecy Act (Chapter 377 of the Laws of Malta) and the Code of Organisation and Civil Procedure (Chapter 12 of the Laws of Malta).

10. Liability for AI

10.1 Theories of Liability

As mentioned in **1.1 General Legal Background**, liability in relation to the use of AI will continue to be governed by the principles of tort and contract law under the Civil Code and Commercial Code. The notion of acting in good faith as a bonus paterfamilias and of culpable negligence under Article 1033 of the Civil Code will apply to the deployment of AI.

Under Maltese law the technology itself would not have legal personality. It would therefore be the deployer or developer that would be ultimately responsible for harm caused by the use of AI. The determining factor would be the cause of the damage suffered by the injured party, whether this was a result of the wrongful use of the technology or a defect in the technology itself. In any event where damage is suffered by a third party, the latter may opt to act against the deployer of the technology who directly caused the harm or even against the developer of the technology. Unless the developer is sued by the claimant, it would be up to the deployer to turn to the developer to recover the damages that the deployer may be made to pay the injured party.

Moreover, the Product Liability Directive (85/374/EEC) was transposed into the Maltese Consumer Affairs Act. The *"new"* Product Liability Directive (2024/2853), which extends the notion of strict liability to AI and software, has not yet been transposed into Maltese law. The European Commission had been working on an AI Liability Directive; however, at the time of writing (May 2025) this has been withdrawn.

10.2 Regulatory

Currently there are no proposed amendments to the liability regime for AI development and deployment. However, we would expect the necessary legal provisions to bring into effect the amendments to the Product Liability Directive to be drafted and discussed in Parliament over the coming months.

11. Specific Legal Issues With Predictive and Generative AI

11.1 Algorithmic Bias

Algorithmic bias is one of the identified and well-documented risks of AI. Although no standards have been mandated by Maltese regulators and/or law to avoid the risk of algorithmic bias, developers of AI are guided by best industry practice. The obligations of explainability, transparency and auditability of solutions being imposed through the AI Act will act to minimise these risks in a harmonised fashion.

Prejudice caused as a result of algorithmic bias could be particularly relevant in the areas of employment, credit worthiness and insurability evaluations, amongst others. Where bias in the algorithm creates prejudice and damages are suffered, the liability principles mentioned in **10. Liability for AI** will apply.

11.2 Facial Recognition and Biometrics

The use of AI for facial recognition and biometrics is known to be one of the more sensitive uses of this technology and brings with it inherent risks to the privacy of the individuals. Article 9 of the GDPR provides a high level of care that needs to be applied to the use of biometric

data, which is treated as a special category of personal data.

The AI Act has also largely tackled the use of facial recognition including a number of uses of such techniques, including real-time facial recognition in public places (save for certain exceptions), predictive policing, internet scraping of facial images to create databases and emotion inferencing at work or school as prohibited uses. When not forbidden, facial recognition and biometrics are considered high-risk uses under Annex III.

Given the jurisdictional scope of the AI Act, similar to that of the GDPR, together with the level of fines that may be imposed in cases of breach, it is expected that the regulation of biometrics and facial recognition will be regulated and harmonised to a large degree.

In addition to these specific laws, the use of facial recognition and biometrics is central to the fundamental human right of respect for one's private and family life (Article 8 of the European Convention on Human Rights). The State has an obligation to ensure that this human right is safeguarded and should the police or any other State institution breach this human right, the State would be found liable in damages to the individual whose rights were breached.

11.3 Automated Decision-Making

As mentioned in **8.1 Specific Issues in Generative AI**, the use of fully automated decision-making, including profiling, needs to be clearly explained to data subjects and they would have the right to object to it under Article 22 of the GDPR where this could lead to legal effects concerning them or similarly significantly affect them. The ECJ's 2023 decision in the *"Schufa case"* sets out clear guidance to be followed by the courts and data protection regulatory bodies.

Risks related to automated decision-making arise not only where personal data is involved. Automated algorithmic trading, creditworthiness or insurability decisions are equally risk prone and may lead to the deployer of the AI bearing the responsibility for the wrong decisions taken by the AI system. As mentioned in **10. Liability for AI**, the culpable fault principle of tort and negligence in fulfilling one's contractual obligations, may apply.

Contradictorily, it is in riskier areas such as health, education, finance and mobility, that the greatest benefits of automation are likely to be seen. Until such time as the technology becomes completely dependable with in-built auditable checks and balances that cannot be overwritten and that control the use of the technology itself, human oversight remains of paramount importance and the technology should not be allowed to replace the professional. It is this human oversight and the ability for the human professional to take the final decisions that aligns automation in AI with the professional ethics and regulatory requirements of regulated professions.

11.4 Transparency

A data subject has the right to know how the data was used and the results produced. The *"black box"* risk associated with full automation is therefore one that cannot be underestimated by the deployers of AI who remain liable for the results produced by the system and damages that may result therefrom.

Transparency obligations underlie the professional use of AI in all sectors. This results from the patchwork of laws that regulate the industrial use of technology, be it the AI Act, GDPR, or

sector-specific regulation. The use of chatbots and other technologies that render services that are generally provided by natural persons, is no different. Users are to be made aware that they are interacting with an AI technology and must be given the opportunity to stop this communication or request that they interact directly with a natural person.

12. AI Procurement

12.1 Procurement of AI Technology

Deployers of AI are ultimately responsible for using the technology within their business practice. They should therefore ensure that the various obligations to which they are subject are reflected in a back-to-back manner in the procurement agreement with the AI supplier. In this manner they will ensure that they will be able to turn to the supplier in if they are obliged to pay damages resulting from their use of the technology. Furthermore, certain sector-specific laws and regulatory directives may impose obligations on licensed entities in relation to the outsourcing agreements they have with third parties, including AI suppliers. This is the case, for instance, with DORA and the *"Guidance on Technology Arrangements, ICT and Security Risk Management and Outsourcing Arrangements"* issued by the MFSA (which are based on the EBA Guidelines) in relation to licensed financial service providers, where certain obligations would need to be inserted in the outsourcing agreements.

13. AI in Employment

13.1 Hiring and Termination Practices

Automation in the field of employment is one of those areas where Article 22 of the GDPR, relating to automated decision-making, is of critical importance. Fully automated processes that lead to the selection of candidates for a job, are legally risky and could give rise to discrimination, challenge and ultimately damages being borne by the employer.

13.2 Employee Evaluation and Monitoring

The same concerns that arise with regard to hiring and termination practice may also apply to employment performance analysis and monitoring. Moreover, using AI tools to draw inferences about an employee's emotions when at work is forbidden under the AI Act.

14. AI in Industry Sectors

14.1 Digital Platform Companies

The use of AI in digital platforms is a given in today's world. Digital platforms thrive on data they obtain from their users. Consequently, data protection legislation and enforcement remain key to curbing abuse. Other EU instruments of note that will help shape the future of this industry are the Digital Markets Act and the Data Act, which, in their own ways and from their own angle, seek to mitigate the conglomeration and control of data by gatekeepers.

14.2 Financial Services

The financial services industry is one of the greatest net beneficiaries of AI, and use of the technology is widespread in the sector, whether in the provision of services, for purposes of marketing or internally for risk management.

This highly regulated industry is modelled through a patchwork of laws and regulations that tackle and curb the risks of the use of technology, including AI, from different angles. The main risks identified by the MFSA in its *"Artificial*

Intelligence" edition of its *"FinSights: Enabling Technologies"* series on awareness information are accountability, black box algorithms and lack of transparency, data quality, (restricted) competition, (inconsistency in and fragmentation of) regulation and discrimination.

The AI Act itself tackles a number of these issues, mandating transparency, explainability and auditability in different degrees depending on the levels of risk posed by the use of the technology and also classifying credit worthiness and life insurance as high-risk uses to which greater scrutiny and more onerous obligations apply.

Moreover, DORA obligations that include proper risk management, incident response preparedness, including resilience testing, incident reporting obligations and management of ICT third-party risk, would apply, as will the MFSA Guidance on Technology Arrangements, ICT and Security Risk Management (subject to modification in order to supplement DORA obligations.)

Likewise, GDPR obligations of transparency, explainability, data minimisation and purpose limitation, along with the data subject rights, including the right to object to the use of one's data by fully automated systems that may produce legal effects or significantly affect the data subject, also apply to the use of AI.

Confidentiality and professional secrecy considerations impact the licensed providers' interaction with generative AI and large language models, whilst the Data Act obligations relating to the data owner's control rights, where the IoT is being deployed, may also apply.

It is for this purpose, given the complexity of regulation in this industry, that sector players are advised to take a 360° view of the regulatory implications resulting from their use of AI.

14.3 Healthcare

Healthcare is known to be another high-risk scenario for the use of AI.

One piece of legislation that was enacted and that could have a considerable impact on the development of AI solutions in the health sector is the Processing of Personal Data (Secondary Processing) (Health Sector) Regulations (Subsidiary Legislation 528.10), Under this law, where the use of health data by the health providers for purposes other than the original intended use, which purposes are listed in the law, can lead to benefits for the health system in Malta, this use can be deemed permitted subject to the use of anonymisation techniques or clearance from an established Ethics Committee. This permitted secondary use of health data could lead to AI advances in the Maltese health sector.

Patient rights, professional responsibility, coupled with the risks of culpable negligence, ethical considerations, professional secrecy and the use of highly sensitive health data are all matters that need to be considered carefully when healthcare professionals are interacting with AI. In this regard, in 2019 Malta has enacted the Processing of Personal Data (Secondary Processing) (Health Sector) Regulations (Subsidiary Legislation 528.10) to allow for the exploitation of health data by technology in a controlled environment. See **3.6 Data, Information or Content Laws**.

14.4 Autonomous Vehicles

It is still early in the process of autonomous vehicles being tested on Maltese roads, despite there having been reports of intended tests in the public transport field and an AI-driven traffic management system. Transport Malta does

not seem to have proposed any changes to the highway code or laws that require vehicles to be driven by persons that have a licence issued in accordance with the law.

14.5 Manufacturing

Product safety requirements in manufacturing apply irrespective of the use of AI made by the manufacturer.

14.6 Professional Services

As mentioned in **9.1 AI in the Legal Profession and Ethical Considerations**, issues of professional secrecy, confidentiality and, in case of lawyers, legal privilege, are amongst the legal and ethical challenges that would need to be considered carefully by professionals when interacting with and using AI. It is expected that professional representative bodies will set standards to be followed.

15. Intellectual Property

15.1 IP and Generative AI

AI systems, being computer programs and algorithms, are afforded copyright protection. Under Article 2 of the Copyright Act, a computer program is defined as a literary work and, subject to it having an original character, is afforded copyright up to 70 years after the end of the year in which its author dies.

The data compiled for the purpose of training an AI model may also enjoy sui generis protection rights relating to databases. Under Article 25 of the Copyright Act *"the maker of a database who can show that there has been qualitatively or quantitatively a substantial investment in either the obtaining, verification or presentation of the contents of the database shall have, irrespective of the eligibility of that database or its contents for protection by copyright or by other rights, the right to authorise or prohibit acts of extraction or re-utilization of its contents, in whole or in substantial part, evaluated qualitatively or quantitatively"*.

As generative AI models become more precise, the manner in which a user prompts the model becomes a valuable element that the user may wish to protect. This protection may be achieved by treating the prompts as trade secrets under the Trade Secrets Act (Chapter 589 of the Laws of Malta). A trade secret is defined as information that:

- is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- has commercial value because it is secret; and
- has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

15.2 Applicability of Patent and Copyright Law

As mentioned in **8.1 Emerging Issues in Generative AI**, under the Maltese Copyright Act, in order for copyright protection to arise an *"author"* would need to be a natural person. Consequently, AI-generated works would not qualify for copyright protection unless a natural person can evidence, if challenged, that he or she did substantively participate in the creation process. Currently there are no Maltese court judgments to go by on this matter.

A similar interpretation would apply to the notion of inventor under the Patents and Designs Act

(Chapter 417 of the Laws of Malta) whereby the right to a patent will apply to the *"inventor"* and only *"natural person or legal entity may file an application for a patent"* (Article 9).

15.3 Applicability of Trade Secrecy and Similar Protection

As mentioned in **15.1 IP and Generative AI**, prompts in generating a work through AI may be protected through trade secrets.

15.4 AI-Generated Works of Art and Works of Authorship

Although there are ongoing discussions about the need to provide protection to AI-generated works that do not infringe third-party rights, to date no legislative steps have been taken in this direction by Maltese legislators.

There is no local case law or current litigation which addresses this scenario in Malta.

15.5 OpenAI

The use of OpenAI to create works and products brings with it the unknown of whether the created work infringes third-party rights over works that were used in the machine learning process. The use of such infringing work would expose the user to potential liability for breaches of third-party rights despite his or her ignorance of the fact. Additionally, the use of the generated work must comply with any licence conditions attached to the use of OpenAI.

16. Antitrust

16.1 Emerging Antitrust Issues in AI

While there is no dedicated Maltese legislation specifically addressing AI-related antitrust issues, Malta operates under EU and local competition laws, which are applicable to AI technologies and practices. We expect the Maltese regulators to adopt a similar approach to that which the EU takes on such matters.

Emerging antitrust issues may fall under the responsibility of one or various sector regulators. Primarily, the Office for Competition within the MCCAA will continue to be tasked with addressing anti-competitive behaviour, including collusion, even when this results from the use of AI, such as AI-driven pricing strategies. Other sectoral regulators, namely the MFSA (for licensed entities within the financial services sector, such as banks, payment service providers and insurers) and the MCA (for telecommunications and postal services providers), will also have a remit to ensure that their licensed entities will not adopt abusive and market-distorting behaviour.

17. Cybersecurity

17.1 Applicability of Cybersecurity Legislation to AI

Malta's cybersecurity legislation is fully aligned with the EU's package of laws in this area. DORA is today the standard being followed by all entities falling within its scope, with the MFSA having issued Guidelines and *"Minimum Expectations"* on the subject in 2024. The various Delegated Regulations and pan-European sector regulator positions are today followed rigorously by stakeholders in the affected financial sectors.

Malta has recently (April 2024) transposed the NIS 2 Directive, expanding cyber-resilience obligations to all those entities to be defined as *"essential"* or *"important"* under the same Directive. Additional guidelines by the regulator (CIPD) are expected to be published over the coming weeks.

The cybersecurity risks associated with the use of AI are well documented and the September 2024 OECD report places this as the highest ranked risk amongst respondents in the financial services field.

Malta will apply the body of legislation, mainly composed of the AI Act, DORA, NIS 2 and GDPR to counter these cybersecurity risks by placing onerous obligations on the operators adopting AI tools when providing their services.

18. ESG

18.1 ESG Dimensions of AI

Malta's approach to integrating AI within its ESG framework reflects a commitment to sustainable and ethical technological advancement. In particular, Malta's 2030 AI strategy is structured around three core pillars, each reinforcing ESG dimensions.

- Investment, start-ups, and innovation: By fostering a vibrant start-up ecosystem, Malta encourages innovations that address environmental challenges and promote social responsibility.
- Public sector adoption: As discussed in **2.1 Industry Use**, the government is making efforts to implement AI pilot projects in sectors such as traffic management, healthcare, and education to enhance public services. These initiatives demonstrate a commitment to social well-being and equitable access to technology, aligning with the social aspect of ESG.
- Private sector adoption: By supporting businesses in integrating AI, Malta promotes corporate governance practices that are transparent and accountable. This approach ensures that AI applications adhere to ethical standards, mitigating risks associated with bias and discrimination.

Malta's participation in international initiatives, such as the AI for Good Innovation Factory, a global start-up competition led by the United Nations to find the most promising AI solutions that support the UN Sustainable Development Goals (SDGs), highlights Malta's dedication to leveraging AI for sustainable development goals. These collaborations facilitate the exchange of best practices and reinforce Malta's commitment to global ESG standards.

Additionally, the MFSA has been guiding listed entities on the transition from the Non-Financial Reporting Directive (NFRD) to the Corporate Sustainability Reporting Directive (CSRD). This shift mandates more comprehensive sustainability disclosures, enhancing transparency for investors. Large companies are expected to apply these new rules starting from the 2024 financial year, with reports published in 2025, as reported in a circular by the same entity in July 2024.

19. AI Governance and Compliance

19.1 AI Governance and Best Practice Compliance Strategies

A holistic legal and regulatory due diligence/impact assessment that is regularly revisited in view of changes in operations and/or law is a must in the complex world of interaction with AI. This will lead to full knowledge of the obligations expected from the deployer of the technology and will help put in place processes and procedures to ensure that the obligations are honoured. A culture of proper compliance will then need to be nurtured in the organisation through training and awareness programmes.

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