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InsurTech in Italy: opportunities, risks and applicable regulation

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Abstract

InsurTech is an economic and legal phenomenon concerning the application of new technologies and, in particular, Artificial Intelligence, to the insurance sector. The phenomenon is emerging not only in the international and European panorama but also in the Italian one.

In this regard, the paper describes the development of InsurTech in the Italian Legal system and analyse the state of the art of its regulation.

The focus of the paper is on the relationship between Artificial Intelligence and the insurance sector, in specific concrete areas of application: firstly, the change of the insurance sector thanks to the spread of new technologies, as Internet of Things (IoT), and, secondly, the insurance sector applied to Artificial Intelligence devices, such as the case of driverless cars and that of software as a medical device (SaMD).

Finally, the paper discusses the perspective of the insurance sector in the light of the AI evolution.

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Keywords: AI systems; IoT; Big Data; InsurTech;

Summary: 1. Outlines of InsurTech in the Italian legal system. – 1.1. InsurTech development in Italy. – 1.2. The Italian legal regulation applicable to InsurTech. – 2. Some concrete areas of InsurTech application in Italy. – 2.1. Artificial Intelligence applied to insurance field. – 2.2. Insurance field concerning Artificial Intelligence devices. – 3. Perspectives of the insurance sector in the light of AI development.

1. Outlines of InsurTech in the Italian legal system.[1]

1.1. InsurTech development in Italy.

The term InsurTech derives from the union of "insurance" and "technology" and refers to the legal-economic phenomenon that extends the application of digital technologies to the insurance sector. It aims to acquire new potential and more effective allocation of products and services on the market, also proposing new insurance products or reformulating the offer of more traditional insurance services.[2]

At the time of Web 1.0 the businesses digitalisation was considered as the simple opening of a company website. Then, in the era of Web 2.0, the development of social networks, blogs, podcasts, and ecommerce have changed completely the business scenario. With web 3.0 we took part in the transformation of the web into a database and in the development of Information and Communication Technologies (ICT). Currently, with the arrival of new Web 4.0 technologies and, in particular, Artificial Intelligence (AI), there has been an even deeper impact on the business models and the type of services. Industry 4.0 has also involved the insurance sector by imposing a radical change that has overwhelmed cultures, companies, processes, data management and customer relations.

In Italy, InsurTech is currently a quite small sector of the insurance sector but characterised by a sustained growth rate[3]. It is a phenomenon that is emerging not only in the international and European panorama but also in the Italian one and which, in its broadest meaning, identifies the entire process of digitalisation of the insurance sector, from the filling of insurance policies to management of claims, thanks to the use of technologies such as Big Data Analytics, Artificial Intelligence (AI) and Application Programming Interface (API), as well as technologies still in the process of spreading, such as Blockchain and Distributed Ledger Technologies (DLT) in general.

[1] The author of this paragraph is Dr. Maria Cristina Gaeta, Research Fellow in Private Law, Scientific Secretary of the Research Centre of European Private Law (ReCEPL) at Università degli Studi Suor Orsola Benincasa (Naples, Italy).

[2] E. Battelli, 'Le nuove frontiere dell'automatizzazione contrattuale tra codici algoritmici e big data: gli smart contracts in ambito assicurativo, bancario e finanziario' (2020) 4 *Giustizia civile*, 681 ss; C. Tabarrini, A. Luberti, 'InsurTech. Una ricognizione empirica e giuridica', in Consumers' Forum (in collaboration with Università degli Studi Roma Tre), *Consumerism 2018. Il cittadino nell'era dell'algoritmo* [2018], 93

[3] AmCham Italy, 'Working Group Insurance, Subgroup InsurTech, White Paper on the State of the art of InsurTech in Italy', [2021], available at: https://www.amcham.it/it/download/comitato-gruppidilavoro/37

Concerning the relationship between InsurTech and FinTech (Financial Technology), it is necessary to underline that they can be considered as separate or connected phenomena. While InsuTech refers to the insurance sector, FinTech concerns the financial sector. Therefore, the relationship between InsurTech and FinTech is a strict consequence of the relationship between the insurance system and the financial system. There is a close relationship of the two phenomena, even if they require two different legal regulations according to their peculiarities. Indeed, InsurTech is a little bit more complex phenomenon as essentially it is the application to FinTech and RegTech (Regulatory Technology) in new market context: the insurance market.

Concerning the development of the InsurTech phenomenon, currently there are 564 Italian companies active in the FinTech and InsurTech sectors, most of which are based in Northern Italy, according to research conducted by the FinTech & InsurTech Observatory of the School of Management of the Politecnico di Milano, in 2021.[4] These companies are increasingly focused on technological development but are paying particular attention to a sustainable perspective, in compliance with the objectives set at the European level[5] and International level[6]. More specifically, to date, Italian companies in the FinTech and InsurTech sectors have raised 2 billion of euros. This is a relevant figure even though still not competitive enough with respect to the development that these realities have had in other countries, such as the United States of America or in Asia and other European Member States, where startups are progressively increasing.[7]

[4] FinTech & InsurTech Observatory of the School of Management of the Politecnico di Milano, 'Cresce il Fintech in Italia: quali sono le startup e i numeri e della rivoluzione', 15 december 2021 available at: https://blog.osservatori.net/it_it/FinTech-in-italia

[5] Eco-innovation Action Plan (EcoAP), launched by the European Commission in December 2011, that is the logical successor of ETAP, the action plan for environmental technologies of the European Union; Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, *The European Green Deal*, 11.12.2019, COM(2019) 640 final, which was followed by the identification of the first proposals of the Directorate-General for Research and Innovation of the European Commission, to implement the European Green Deal objectives; European Commission Reflection paper - Towards a Sustainable Europe by 2030, 30.01.2019, COM(2019)22; Regulation of the European Parliament and of the Council on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088, 18.06.2020, 2020/852; Proposal for a Council Recommendation on learning for environmental sustainability, 14.1.2022, COM/2022/11 final; Communication from the Commission Guidelines on State aid for climate, environmental protection and energy 2022 ((2022/C 80/01).

[6] United Nations, Sustainable Development Goals (SDGs), *Transforming our world: the 2030 Agenda for Sustainable Development*, 2015, as integrated by the High-level Political Forum (HLPF) established at UN, to in-depth the SDGs see: https://sdgs.un.org/publications/transforming-our-world-2030-agenda-sustainable-development-17981; United Nations Summit on Sustainable Development, New York, 25-27 September 2015, all the details on the Summit are available at: https://sustainabledevelopment.un.org/post2015/summit; World Economic Forum Annual Meeting 2020, Stakeholders for a Cohesive and Sustainable World, 2021, to see the details of the Annual meeting: https://www.weforum.org/events/world-economic-forum-annual-meeting-2020 but, in general, one of the mission of the World Economic Forum is to protect the world from Climate Change https://www.weforum.org/topics/climate-change/; XXVI United Nation Conference on Climate Change (COP 26), Glasgow 31.10.2021-12.11.2021, more details at: https://ukcop26.org/, and the Glasgow Leaders' Declaration on forests and land use, 12.11.2021, signed during the UN Conference, for more information: https://ukcop26.org/glasgow-leaders-declaration-on-forests-and-land-use/.

[7] American Chambers of Commerce in Italy (AmCham Italy), Working Group Insourance, Subgroup InsurTech, White Paper on the State of the art of InsurTech in Italy, 2021

More specifically on the use of technologies in relation to the insurance sector, in Italy there are many companies that have insurance coverage but, from the analysis of the FinTech & InsurTech Observatory it results that 84% have at least active insurance coverage and of these, 42% purchase insurance policies in the traditional way, therefore, through face-to-face meetings with an agent and use of paper documentation, 38% use a hybrid mode, and only 26% use fully digital channels. At the same time, however, the development of the use of technologies in the insurance sector is increasing as a consequence of the COVID-19 pandemic, considering that the digitalisation process caused by the pandemic has also involved the insurance sector, where online contractual relationships through videoconference, or the direct interaction on the online platforms, have been increased. It is, indeed, evident the trend of reliance on technologies also in the insurance sector, which is leading to a growth of the Insurtech in Italy.

Analyzing more in detail the InsurTech sector in Italy, there are 130 innovative companies, and they are divided into two categories: 64% are properly InsurTech companies, that means they offer insurance services, while 36% are Tech Insurance companies, therefore companies that offer technologies for the players in the insurance sector. Overall, these companies were able to raise 120 million euros in funding.[8]

A further area of InsurTech innovation and development, in addition to that relating to the development of new technologies in the insurance sector, is that of connected business ecosystems, which extends collaboration between multiple startups beyond the borders of the insurance sector. The ecosystem is a business model extended to several economic entities with common objectives, aimed at developing a unique value proposition with customer needs at the center. Insurance companies can, therefore, develop new high value-added services in collaboration with startups or companies from other sectors. In this case, technological innovation makes possible a seamless collaboration between actors from different sectors with low transaction costs and high levels of integration, that guarantee univocal management of customer needs and adequate and agreed service levels between the parties. Some typical examples can be seen in services for the domestic sector or in those for transport sector, where insurance coverage (for example for theft and fire risks, as well as for civil liability) can be combined with monitoring and maintenance services, representing an integrated service for the customer, with high added value[9].

Finally, another type of startup that is developing in the InsurTech area is that of peer-to-peer insurance, which can also be implemented through specific platforms. Peer-to-peer insurance, enabled by digital technology, allows the sharing of risk by a small group of people (so-called 'pool'), who share a solidarity fund: if none of the people in the 'social pool' presents a claim to the insurance company to be indemnified, part of the money is returned to them as

[8] FinTech & InsurTech Observatory of the School of Management of the Politecnico di Milano presented at the conference "FinTech & InsurTech: è ora di puntare sullacollaborazione!" held on 14.12.2021, more datails: https://www.osservatori.net/it/eventi/on-demand/convegni/convegno-risultati-ricerca-osservatorio-fintech-insurtech-convegno.

[9] *See* note n. 7.

a dividend. Peer-to-peer insurances are still in the initial phase, but they are expected to spread in Italy thanks to their function[10].

Coming to some concretes examples of the most well-known Italian startups in the InsurTech field, there is Yolo,[11] the first national company for the digital distribution of insurance policies. Yolo is a completely digital insurance broker, which operates in four countries (Italy, Spain, United Kingdom and Ireland). Furthermore, the Claider app of Carpita Servizi Assicurativi[12] is in growing development and has completely rethought the complaint process and management of claims, offering a completely digital customer experience. Finally, an insurance agency specialised in the sale of digital online policies is Prima.[13] Prima is one of the first InsurTech companies mainly involved in the automotive sector, but also in the home and family sector.

As has been highlighted, the InsurTech sector is also growing in Italy. It, therefore, appears necessary from now on to build knowledge and skills in this area, to encourage emerging technologies and their regulation, creating the culture and perspectives necessary to actively participate in the success of new technologies in the insurance sector.

1.2. The Italian legal regulation applicable to InsurTech.

The Italian legislation in the insurance field is particularly complex and not easily open to such technological development. More specifically, insurance contracts are regulated in Italy by the private insurance code.[14] Private insurance code is a well-structured legislation which, however, does not contemplate the development of automated or intelligent systems applicable to insurance contracts.

Therefore, the existing legislation should be suitably updated considering the impact that new technologies have on existing contractual types in the insurance sector. This evident development of InsurTech, as well as the need to regulate it, has been clear in Italian government policy, before relating to FinTehc and then more specifically on InsuTech.

A first initial intervention by the National Institution as concerned the FinTech. In this regard, the Bank of Italy published in 2018 the results of a survey on the adoption of technological innovations applied to financial services.[15] At the same time, to answer to the need to trace an institutional framework of analysis and interpretation of the FinTech phenomenon and of a radical change that is taking place in the banking, financial and insurance

[10] *See* P Marano, 'Navigating InsurTech: The Digital Intermediaries of Insurance Products and Customer Protection in the EU' (2019) 26 2 MJECL, 305 ff.; F. Morello, 'Transparency at any cost? Consumer protection i peer to peer finance', in this EJPLT issue; P Grimaldi, 'Information asymmetries in banking and financial contracts: possible solutions from legal design', in this EJPLT issue.

[11] All the details on Yolo are available on the official website www.yolo-insurance.com.

[12] All the details on Carpita Servizi Assicurativi are available on the official webpage: www.carpita.it/claider.

[13] All the details on Prima are available on the official website: www.prima.it

[14] Italian Legislative decree of 07.09.2005 n. 209, *Italian Private Insurance Code.*

[15] Banca d'Italia, 'FinTech in Italia. Indagine conoscitiva sull'adozione delle innovazioni tecnologiche applicate ai servizi finanziari' [2017] availabe at: https://www.bancaditalia.it/compiti/vigilanza/analisi-sistema/stat-banche-intermediari/Fintech_in_Italia_2017.pdf

market, the Basel Committee on Banking Supervision (BCBS) has published an extensive document.[16]

More focused on InsurTech is the Italian Decree of the Prime Minister (D.P.C.M.) 18.12.2020, no. 179,[17] in which are provided further assets and relationships of strategic importance for the national interest, in addition to those already identified in the decrees that were promulgated pursuant to Italian Legislative Decree 15.03.2012, no. 21,[18] and related to the sector of art. 4, para 1, Reg. 2019/452/UE, [19] included the financial sector as critical infrastructure (letter a), as well as artificial intelligence and robotic as critical technologies (letter b). In this regard, art. 8, D.P.C.M. no. 179/2020, lists the technologies that have strategic relevance and are considered critical in the context of assets and relationships in the financial sector, including the insurance sector. In this list, in art. 8, para. 1, letter b), n. 3, specific reference is made to critical digital technologies applied in the insurance sector (InsurTech).

Furthermore, from 2021 the FinTech and InsurTech Regulatory Sandbox has also entered in force in Italy. The Regulatory Sandbox was foreseen by the Italian legislator already in June 2019, through an amendment to the law converting the Italian Growth Decree.[20] Then it was implemented by the Italian Ministerial Decree (D.M. 30.04.2021, no. 100[21]) in force from 17th July 2021, after the study phase by the Italian Ministry of Economy and Finance and the competent authorities. The D.M. no. 100/2021 governs the operations and powers of the FinTech Committee institutionalised at the Italian Ministry of Economy and Finance, Treasury Department by art. 36, para 2-octies of the Italian Growth Decree [22], as well as the conditions for carrying out the experimentation of FinTech activities which implement the Regulatory Sandbox.

The Regulatory Sandbox on FinTech and InsurTech is a protected space dedicated to experimenting with technological innovation activities in the banking, financial and insurance sectors. This is one of the most innovative projects in the FinTech and InsurTech sector, which represents an important step forward for the digitalisation of the Country. The experimentation will allow FinTech operators to test innovative solutions, benefiting from a simplified, transitional regime, and in constant dialogue with the supervisory authorities: Bank of Italy, the National Commission for society and the stock

[16] Basel Committee on Banking Supervision BCBS, 'Sound Practices: Implications of Fintech developments for Banks and Bank supervisors' [2018], available at: https://www.bis.org/bcbs/publ/d431.htm

[17] D.P.C.M., 18.12.2020, no. 179, *Regulation for the identification of national assets and relationships of interest in the sectors referred to in Article 4, paragraph 1, of Regulation (EU) 2019/452 of the European Parliament and of the Council, of 19 March 2019, pursuant to Article 2, paragraph 1-ter, of the decree-law of 15 March 2012, n. 21, converted, with amendments, by law 11 May 2012, n. 56*.

[18] Italian Legislative Decree 15.03.2012, no. 21, *Rules on special powers on corporate structures in the defense and national security sectors, as well as for activities of strategic importance in the energy, transport and communications sectors*.

[19] Regulation of the European Parliament and of the Council establishing a framework for the screening of foreign direct investments into the Union, 19.03.2019, 2019/452/EU.

[20] Italian Legislative Decree 30.04.2019, n. 34, *Urgent measures for economic growth and for the resolution of specific crisis situations*, converted into L. 28.06.2019, n. 58.

[21] D.M. 30.04.2021, no. 100, *Regulation implementing article 36, paragraphs 2-bis and following, of the legislative decree 30.04.2019, n. 34, converted, with modifications, by the law 28.06.2019, n. 58, on the discipline of the Committee and FinTech experimentation*.

[22] Official webpage of the Italian FinTech Committee see: http://www.dt.mef.gov.it/it/attivita_istituzionali/sistema_bancario_finanziario/fintech/comitato_fin/

exchange (Commissione Nazionale per le Società e la borsa, abbreviated as CONSOB) and the Insurance Supervisory Institute (Istituto per la Vigilanza sulle Assicurazioni, abbreviated as IVASS). In particular, regarding the insurance sector, IVASS is the competent authority that examines the application for operators that carry out significant innovative activities in the insurance sector and analyses the technology development in this sector identifying the appropriate and effective legislative measures to regulate InsurTech.[23]

The mentioned Regulatory Sandbox supports the growth and evolution of the Italian FinTech and InsurTech market and at the same time guarantees adequate levels of consumer protection and stability in financial balances. This is an important regulatory intervention, even if it concerns only the experimentation phase and does not regulate the relationship between private individuals in concrete. Among other things, not all FinTech and InsurTech activities fall within the regulated perimeter. Therefore, the Regulatory Sandbox certainly constitutes the first significant legislative intervention in the FinTech and InsurTech sector, useful for Italian companies that intend to invest in this sector, but an *ad hoc* regulation must be envisaged and with due care. Finally, is evident that the Italian Regulatory Sandbox is provided by the law while in other States it is left to the provision of competent authorities as expressly provided also by the articles 53 and 54 of AI Act Proposal.[24]

What is contestable, of the Italian Regulatory Sandbox is the fact that it is provided only at a national level, when, instead, it would be more appropriate to provide for a Regulatory Sandbox at least at a European level, as indicated also in the AI Act Proposal. Indeed, at EU Level already exist Regulatory Sandboxes even if in partially or completely different areas of application. In this regard, the DLT Pilot regime should be noted[25]. The DLT Pilot Regime Sandbox is part of a digital finance package aimed at increase digital finance. More in details, on 24th September 2020, the European Commission adopted the digital finance package, based on European public consultation[26] entitled 'Digital finance outreach',[27] following the FinTech Action Plan of 2018.[28]

Finally, with particular regard to payment services, on 13th January 2018, in Italy entered in force the Legislative Decree no. 218/2017 [29] which

[23] The Regulatory Sandbox Project on FinTech and InsurTech, with particular regard to role of IVASS, is available at: https://www.ivass.it/operatori/sandbox/index.html?com.dotmarketing.htmlpage.language=3

[24] Proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amend and amending certain union legislative acts

[25] European Parliament and Council Proposal 594/2020 for a Regulation on a pilot regime for market infrastructures based on distributed ledger technology, 21.04.2021, COM (2021) 206 final.

[26] European Commission Consultation (banking and finance) is available at: https://ec.europa.eu/info/business-economy-euro/banking-and-finance/regulatory-process-financial-services/consultations-banking-and-finance_en

[27] The Digital finance outreach, 01.07.2021 (last update 01.04.2022), is available at: https://ec.europa.eu/info/publications/digital-finance-outreach_en

[28] European Commission, FinTech action plan: For a more competitive and innovative European financial sector, 8.03.2018, available at https://ec.europa.eu/info/publications/180308-action-plan-fintech_en

[29] Legislative Decree 15.12.2017, no.218, Implementation of Directive (EU) 2015/2366 relating to payment services in the internal market, amending Directives 2002/65 / EC, 2009/110 / EC and 2013/36 / EU and Regulation (EU) no. 1093/2010, and repeals Directive 2007/64 /EC, as well as adaptation of the internal provisions to Regulation (EU) no. 751/2015 relating to interchange fees on card-based payment transactions. (18G00004)

implemented the second Payment Services Directive.[30] These legislative provisions regulate digital payments, including via API, and can also be applied to the InsurTech area.

It is clear that the Italian government and legislator have understood that the importance and development of InsurTech entail the need to regulate it in compliance with the ethical principles of trustworthy intelligent systems and, in general, the protection of the individuals, as provided by the European and international Institutions.[31] The Institutions pay their attention on avoiding discriminatory treatments in relation to the choice between to grant or not the insurance contract or, in any case, in relation to the terms and conditions of use of the insurance on the base of predictive analysis of insured parties' data or their profiling.[32]

From the point of view of private law, then, it is possible to affirm that there are many advantages connected to the development of new technologies also in the insurance field, considering, however, that, if not properly regulated, they expose individuals to serious risks.[33] These are already existing risks that are amplified by gravity and reduced by frequency.

Among the main risks certainly are included those concerning data protection and cybersecurety.

About data protection, a high amount of insured parties' personal data are processed, through the use of new technologies. Furthermore, with the Information and Communication Technologies (ICT), first of all the Internet of Things (IoT) or cloud computing, the processing of personal data takes place on a large scale, and this involves a real big data flow with serious implications regarding the protection of personal data and, more generally, the protection of the insured parties 'privacy. In this context, another issue is related to the fact that often the insured parties are aware of the processing of their personal data or they do not completely understand the consequences of the data processing, in particular when the data processing is made through automated systems. At the same time, also non-personal data are processed. The relevance (also economic) of non-personal data has been recently considered at the European level and, in particular, the European Commission has published a Regulation Proposal on fair access to and use of data,[34] as part of the European Data strategy.[35]

[30] Directive of the European Parliament and of the Council, On Payment Services In the internal market, amending Directives 2002/65/EC, 2009/110/EC and 2013/36/EU and Regulation (EU) No 1093/2010, and repealing Directive 2007/64/EC, 25.11.2015, 2015/2366/EU, abbreviated as PSD2.

[31] Consultative Expert Group on Digital Ethics operating within the European Insurance and Occupational Pensions Authority (EIOPA), Artificial intelligence governance principles: towards ethical and trustworthy artificial intelligence in the European insurance sector, 2021; National Associations of Insurance Commissioners (NAIC), Principles on Artificial Intelligence, 2020.

[32] E. Battelli, 'Big Data e algoritmi predittivi nel settore assicurativo: vantaggi e nuovi rischi' (2019) 12 *Corriere Giur.*, 1517 ff.; G. d'Ippolito, E.M. Incutti, 'I processi decisionali interamente automatizzati nel settore assicurativo' (2019) 3 *Riv. dir. impr.*, 736 ff..

[33] P Marano, K. Noussia (ed.), *InsurTech. A Legal and Regulatory View* (Springer, 2020).

[34] Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act), 23.2.2022, COM (2022) 68 final.

[35] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A European strategy for data, 19.02.2022, COM (2020)66 final.

In the case of the processing of personal data, a regulation is already in force and is the General Data Protection Regulation,[36] implemented in Italy with Italian Legislative Decree no. 101/2018,[37] which amended Legislative Decree no. 196/2003, so-called Italian Privacy Code.[38] However, the GDPR does not provide for a complete discipline regarding the processing of data using new technologies, providing only for some specific cases, such as automated data processing (Article 22 GDPR). Moreover, GDPR does not go into detail on the risk of discriminatory treatments using personal data.

About the second issue, it is important to stress that privacy can be considered in a broader context, that is that of cybersecurity domain, or that of IT security, which also includes data security (personal and non-personal data). Therefore, a cybersecurity breach can also involve a data breach or in any case can involve discriminatory treatments using personal data or non-personal data.

In 2018, the European regulation of cybersecurity came into force (Network and Information Security Directive, abbreviated as NISS directive), [39] implemented in Italy with Italian Legislative Decree n. 65/2018.[40] However, it is a general framework of rules for the governance and strategy for cybersecurity, but not provides specific rules of private law applicable in the relationship between the parties with regard also to the insurance sector.

In conclusion, in Italy it is currently possible to apply by analogy the mentioned legislation in force also to InsurTech and, in particular, the private insurance code (legislative decree n.209/2005), as well as the data protection and cybersecurity legislation, as implemented by national law (Italian Legislative Decrees no. 196/2003 and no. 65/2018). In addition, concerning the consumer contract, consumer code finds application (legislative decree n. 206/2005).[41] Nevertheless, the importance that InsurTech plays more and more in the Italian legal system is evident and this requires regulatory intervention.

[36] Regulation of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, 27.04.2016, 2016/679/UE (General Data Protection Regulation, abbreviated as GDPR).
[37] Italian Legislative Decree 10.08.2018, no. 101, Provisions for the adaptation of national legislation to the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27.04.2016, relating to the protection of individuals with regard to the processing of personal data, as well as the free circulation of such data and repealing Directive 95/46 / EC (General Data Protection Regulation)
[38] Legislative Decree 30.06.2003, no. 196, so-called Italian Privacy Code.
[39] Directive of the European Parliament and of the Council concerning measures for a high common level of security of network and information systems across the Union, of 6.07.2016, 2016/1148/EU, so-called NIS Directive
[40] Italian Legislative Decree 18.05.2018, n. 65, Implementation of Directive (EU) 2016/1148 of the European Parliament and of the Council of 6.07.2016 concerning measures for a high common level of security of network and information systems in the Union.
[41] Legislative Decree 6.09.2005, n. 206, Consumer Code.

2. Some concrete areas of application of InsurTech in Italy.[42]

2.1. Artificial Intelligence applied to insurance field.

The insurance sector is changing with the development of new technologies.

Until now the insurance was a tool to locate and repair the damage, now the insurance is a tool used to prevent and repair the damage. One wonders, therefore, if these technologies can be useful tools for consumers or represent a new business model for companies.

Artificial Intelligence systems used by insurance companies would allow a more accurate prediction of loss probabilities, reducing asymmetric information; On the other hand, AI could transform some risks from low gravity/high frequency to high gravity/low frequency. Therefore, insurance companies should change traditional insurance coverage and create insurance products in progress, customizing them. Among the AI technologies used by insurance companies, *Internet of Things* (IoT) must be mentioned, because this technology is the basis of the connected insurance and smart contracts, also as the blockchain. The use of IoT would compromise a massive proliferation of user data by reducing costs and making policies more efficient.

In particular, connected insurance is a technology that uses IoT platforms, sensors, and connected devices, to collect data relevant to the monitoring of customer behavior and lifestyle by diversifying the calculation of insurance product prices on the basis of the data collected. Connected insurance follows the logic of the insurance sector: collect, select and store information.

Insurance contracts use smart contracts technology to perform specific actions desired by the parties upon the occurrence of certain conditions, established by an algorithmic code that uses the rule of "if...then", this happens/ is done to cover the cost of air tickets in case of delay or cancellation of the flight. For example, the refund provided for in the ticket purchase contract, if the event occurs, will be automatically credited to the consumer/insured's bank account.

The blockchain represents the real digital transformation of insurance companies, which will make transactive processes more efficient, relating to the management of road accidents and the reduction of timing for the practices management, as evidenced by a study conducted by the Boston Consulting Group[43], which calculates and quantifies the benefits that the entire insurance industry could obtain if the blockchain technology were fully adopted.

The use of the blockchain allows access to Big Data, elaborates predictive analyses, and reduces the margin of error and fraud, to define more precisely the risk profiles for the insured, improving existing insurance processes and allowing the traceability of all data.

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[43] Boston Consulting Group, 'The First Blockchain Insurer', 2018, available at: https://www.bcg.com/it-it/publications/2018/first-all-blockchain-insurer

Insurance coverage will be flexible, customizable, and coherent to the needs of the individual insured, "Usage-based insurance", because of Big Data. However, Big Data and IoT offer undisputed advantages, but present also risks to the person, because his personal data, as an object of legal protection, become an object economically appreciable.

Moreover, predictive algorithms could generate discriminatory evaluation and profiling criteria. In fact, in the matter of "car RC" there are "on-board diagnostics" devices, which, recording the style of driving and the number of braking performed, make the insurance contract "user-centric", in which the insured becomes a decision-making element in the contractual dynamics.

Last but not least, not to be underestimated is the risk of entrusting an algorithm with the decision to offer insurance coverage and, in addition, the risk of being subject to theft of digital identity and all the extortion, including the c.d. "phishing", may be contained or entirely avoided by the use of appropriate technologies.

The use of predictive algorithms is in contrast with the normal contractual uncertainty, typical of the insurance contract, and against the principle of mutuality enshrined in Art. 1895 of the Italian Civil Code ("The contract is null and void if the risk has never existed or has ceased to exist before the conclusion of the contract"), and is accentuated when the algorithm denies compulsory insurance coverage to a person (e.g. care insurance contracts) contrary to the law.

But there is more: after the COVID-19 pandemic, digitalisation has had a strong increase. Physical meetings with consultants have been reduced by 32%, in favor of videoconferences and branch access by 39%.

There is a growing trend of reliance on technology in the insurance industry!

2.2. Insurance field concerning Artificial Intelligence devices.

Having concluded the examination on the AI applied to the insurance field, we wonder, on the contrary, how to adapt the insurance field to the systems of AI, for example, driverless cars and medical devices.

The insurance industry in car sector is going to be radically modified with the development of ADAS systems (Advanced Driver Assistance System) and driverless cars, in fact, it is estimated that by 2030 the traditional car insurance market will be reduced by 60%[44]. The current Italian system of preventive rules and compensation covers three risk profiles: the danger of the driver, the danger of the motor vehicle to third parties, and the danger of the vehicle for the transported.

The advent of driverless cars, leads to a centrality of the "third-part" in the system of civil liability, so as to put in crisis the current system based on the dichotomy between the system of compulsory private insurance and Art. 2054 of the Italian Civil Code (indexed "Circolazione dei veicoli"), according to which

[44]Marketsandmarkets, 'ADAS Market by System (ACC, DMS, IPA, PDS, TJA, FCW, CTA, RSR, LDW, AEB, & BSD), Component (Radar, LiDAR, Ultrasonic, & Camera Unit), Vehicle (PC, LCV, Bus, & Truck), Level of Autonomy (L1, L2&3, L4, L5), Offering, EV, and Region - Global Forecast to 2030', 2019, available at the link: https://www.marketsandmarkets.com/Market-Reports/driver-assistance-systems-market-1201.html

it is the driver who is held liable for a damage caused by the operation of the vehicle.

With the advent of these technologies, there is, therefore, a transition to the centrality of the vehicle and no longer of the driver, so the system provided for in the Civil Code will have to be reformed, foreseeing, in the event of a completely autonomous accident, the liability of the owner and/or its producer.

In this new scenario, defined as "liability for autonomous vehicles", the European system Market Enterprise Responsibility (MER) presupposes the creation of a fund to be financed by the manufacturers of driverless cars on the basis of the market shares achieved by the companies, to create funds to be used for compensation of the damage.

The MER would allow social security cover for all kinds of bystanders, but each European state would have to reformulate its own system of national rules in order to achieve full harmonization with other state disciplines.

Another major player in the insurance industry is the Software as a medical device (SaMD), AI system that can be used autonomously to diagnose, prevent, monitor, or treat a disease. The system assists the operator in the diagnosis, screening, monitoring, prediction, and determination of the disease.

AI and machine learning (ML) technologies have the potential to adapt and optimize SaMD real-time performance to improve health care. SaMD, based on artificial intelligence/machine learning, change and adapt intrinsically as they become available and, through the technologies of Big Data Analytics, deep learning, and robotic automotive process, can collect a large amount of data.

The use of these systems is regulated at the European level by Regulation 2017/745/EU – Medical Device Regulation (MDR) and Regulation 2017/746/EU – In-Vitro Diagnostic Regulation (IVDR). However, the current EU regulatory framework does not directly define a self-learning AI system (in fact, in April 2021 the European Commission presented the Artificial Intelligence Act (AIA) project, that regulates equally all sectors of the AI industry, including medical devices).

Medical device manufacturers, due to the great growth in the industry, must comply with legal requirements, which include reporting and monitoring of the product, reminders, and warnings. In this context, manufacturers of medical devices, responsible for all claims arising from their products, must provide sufficient financial cover (Art. 10, co. 16 MDR).

To protect the producer and distributor of this software from civil actions arising from the exposure of the products to consumers, adequate liability insurance for risk control is needed.

Medical devices AI represents an opportunity to transform and improve patient outcomes and efficiency, as well as accelerate healthcare research.

Future legislative changes will have to focus on transparency of technology and non-discriminatory protection of the policyholder, also with a view to effective protection of personal data, in the case of driverless car insurance and in the case of SaMD.

3. Perspectives of the insurance sector in the light of AI development. [45]

In the light of the analysis conducted so far, it is clear that the insurance world is changing its perspective with the evolution and the development of new technologies. From an insurance system with a compensatory function, we have now moved to an insurance system progressively based on AI, able to predict and quantify damages, also thanks to the use of predictive techniques, as well as able to monitor the performance of the insurance contract and the behaviour of the insured party.

Different are the risks of the insurance industry that can be considered in relation to the application of AI.

Firstly, the issue of more accurate prediction of risk probabilities emerges in relation to the lack of detailed information about the insured party that are necessary to be able to concretely quantify the policy, often profiling the insured parties through connected insurance.[46] In this regards, thanks to AI systems, that elaborate the data processed, the insurance company would be able to profile the insured party and predict his/her behaviour, without guaranteeing the completely awareness of the party or without giving him/her the possibility to modify the results obtained by the algorithms via data analysis.[47]

The imbalance between the parties to the contract is evident. In fact, even if the insured party is willing to consent to the processing of his/her data, in the belief that he/she will get a cheaper insurance premium, on the contrary, he/she runs the risk to give excessive information on himself/herself, which could also lead to discriminatory treatment, because it is too personalised.

The personalisation of insurance products and premiums according to the characteristics of individuals plays a major role. An insurance company, by adopting automated decisions, makes a prediction of the probability of a risk materialising on the basis of information taken from the user's past, thus making a prediction. However, in the application of personalisation techniques, care must be taken not to lead to cases of discrimination against the insured on the basis of subjective elements that discriminate in the identification of insurable persons or in any case in the quantification of the relevant insurance policy. Profiling, if not properly regulated, can perpetuate stereotypes and social segregation; it can also confine a person to a specific category and limit them to the preferences suggested for that category.

Therefore, despite the advantages of these systems, in terms of efficiency and effectiveness, the algorithms underlying their operation can lead to discriminatory results.

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[45] The author of this paragraph is Dr. Maria Cristina Gaeta, Research Fellow in Private Law, Scientific Secretary of the Research Centre of European Private Law (ReCEPL) at Università degli Studi Suor Orsola Benincasa (Naples, Italy).

[46] E. Battelli, Big Data e algoritmi predittivi nel settore assicurativo: vantaggi e nuovi rischi' (no. 22); E. Battelli, 'Le nuove frontiere dell'automatizzazione contrattuale tra codici algoritmici e big data: gli smart contracts in ambito assicurativo, bancario e finanziario' (no. 2); D. Porrini, 'Big Data, Personalization of policies and effects in the insurance market', in V. Sickle-G. Ghidini, G. Olivieri (eds.), *Informazione e big data tra innovazione e concorrenza*, (Giuffré, 2018), 319 ff..

[47] On the contractual balance, see L. Gatt, 'Il contratto nel diritto europeo', in G. Amodio e F. Macario (eds.), *Diritto civie. Norme, questioni concetti* (Mulino, 2nd ed., 2022), 554 -562.

In fact, the same Working Party Article 29 (WP29) and, then, the European Data Protection Board (EDPB), introduced by the GDPR, consider that profiling and automated decision-making may involve significant risks for the rights and freedoms of individuals, who are often unaware of the profiling activity or not fully aware of the consequences.

Another risks that should be considered is related to the typology of the risks, that shifts from low severity and high frequency to high severity and low frequency. Indeed, AI has the ability to transform the nature of insurance risk. For example, with driverless cars the number of claims is reduced and, consequently, the probability of loss for the insurance company will be reduced (low frequency). At the same time, however, a failure or hacking attack on the autonomous driving AI system in driverless cars can lead to serious accidents and, therefore, an increase in the maximum possible loss (high severity).

One potential way to reduce the severity of the risk and ensure sufficient independence of loss events could be to classify the applied AI systems, which would also imply different insurance plans proportionate to the risk. In this sense, the Artificial Intelligence Act Proposal of 2021 divides AI-enabled products into prohibited AI systems, high risk AI systems and low risk AI systems.

Finally, the Big Data revolution associated with the use of predictive algorithms has involved the financial-insurance system, for which it is important to analyse data on a statistical basis, in order to predict the probability of a certain risk. These data are personal data and also non-personal data, which have an increasingly relevant potential, including economic potential, with a consequent impact on the market. In this context, in addition to the GDPR and the NISS Directive, it is hoped that the proposed ePrivacy Regulation and Data Act will enter into force in the short term.

In conclusion, the growth of InsurTech seems to promise further significant developments, involving many of the insurance sectors in terms of growth of the number of start-ups and investments. Therefore, the main recommendations that emerge from this paper are addressed to the Government, the Supervisory Authorities, the Trade Associations, the companies operating in the sector and the individual players involved in the insurance industry, so that they invest consciously in the InsurTech sector. In particular, there is a need to invest in the education system in order to train young people with adequate skills and valuable experiential opportunities in the field of new jobs in the digital world.

In addition, there is a need to set up an artificial intelligence authority (regulated by the AI Act Proposal), which could also be responsible for InsurTech, as suggested by the European Central Bank.

Furthermore, it is necessary to provide stable and ongoing relations with the InsurTech world, including through the active contribution of the associations that are emerging in this field, and to create forms of collaboration useful for the birth and development of ecosystems in which companies from different sectors develop more integrated solutions and services.

At the same time, this work is addressed to the legislator, as it is necessary to integrate the existing legislation and, in an evolutionary way, to introduce a regulatory framework on InsurTech, after having previously explored the

emerging business models, within specific Sandboxes. In this regard, the implementation of an *ad hoc* Regulatory Sandbox for Artificial Intelligence, as envisaged by the AI Act Proposal, appears to be the first step to be taken. It could be integrated for some aspects with the one already started by the Italian FinTech Committee, but autonomous for different profiles. In any case, the implementation of the AI Regulatory Sandbox is still to be defined and will depend on a soft law regulation, or at least a second level of binding law, that will integrate or complement the AI Act Proposal when it comes into force. After the entry into force of the proposed regulation, it is easy to assume that the AI Regulatory Sandbox will constitute the operative benchmark for different sectors, becoming the dominant model able to include different innovations of the relevant sectors, such as for the data driven economy, or to stimulate the creation of new and autonomous Regulatory Sandboxes.

Once the experimentation phase through Regulatory Sandboxes will be completed, in view of regulating InsurTech, a first intervention should concern the identification of principles protecting the individual, in relation to the impact that new technologies have also in the insurance sector.[48] The aim is to envisage an intervention like that initiated by the Project Group 'Restatement of European Insurance Contract Law', which gave rise to the Principles of European Insurance Contract Law - PEICL, principles on the regulation of insurance contracts, envisaged at European level.[49]

Indeed, starting from the PEICL it would be possible to supplement them, regulating the InsurTech phenomenon in a way that protects individuals, who find themselves in a position of vulnerability with respect to the rapid and incessant development of the new technologies. Considering, then, the cross-border impact that new technologies necessarily imply, the introduction of principles applicable at least at the European level, would allow to protect the existing legal cases with clear transnational features, resulting from the removal of geographical barriers for the pervasiveness of ICT.

[48] Explainatory memorandum of the Proposal for a Regulation of the European Parliament and of the Council on a pilot regime for market infrastructures based on distributed ledger technology (DLT); M Lima Rego, B Kuschke (eds.), *Insurance and Human Rights*, Springer 2022.

[49] The Project Group 'Restatement of European Insurance Contract Law, Principles of European Insurance Contract Law (PEICL, is available at https://www.uibk.ac.at/zivilrecht/forschung/evip/restatement/sprachfassungen/peicl-en.pdf, for more details see: A. Th. Müller, 'Vers un droit européen du contrat d'assurance. Le "Project Group Restatement of European Insurance Contract Law"'(2007) 15 (1) European Review of Private Law, 59 – 100. *See* also H Heiss, 'Towards a European Insurance Contract Law: Restatement - Common Frame of Reference - Optional Instrument?', available at http://www.aidahungary.org/wp-content/uploads/2014/02/AIDA2006_11_24_Helmut_Heiss_eloadas.pdf. More in general on the Principles of European Contract Law (PECL), see L. Gatt, 'Il contratto nel diritto europeo' (n 32) 554 -562.