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Regulatory Update
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DATA PROTECTION

23 December 2024 - Italian Data Protection Authority: certificates for absence from work, no to health data.

Certifications attesting to the presence in the hospital, to justify an absence from work or the impossibility of participating in a competition, must not contain the indications of the facility where the health service was provided, the stamp with the doctor's specialization, or information that can trace the state of health.

This is what the Guarantor reiterated by fining a Territorial Health Authority for 17 thousand euros.

The Authority intervened following the complaint of a patient who had asked the health facility for a certificate for absence from work. The certificate issued reported the indication of the department that had provided the health service, violating security obligations and the principle of personal data minimization. The data processed, in fact, must be adequate, relevant and limited to what is necessary with respect to the purposes for which they are processed.

In addition, the Authority ascertained the violation of the principle of *privacy by design* as the Company, the data controller, failed to implement, from the design stage, adequate technical and organizational measures, aimed at effectively implementing the principles of data protection and protecting the rights of data subjects.

The health authority will therefore have to pay a fine of 17 thousand euros because, despite having, following the intervention of the Guarantor, modified the forms and carried out specific training of staff on the protection of personal data, the violation concerned a potentially high number of patients for a long period. In defining the sanction, the Authority also considered that the Company did not respond to the Authority's request for information, committing a further violation of the Code.

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23 December 2024 – Italian Data Protection Authority: FAQ on how to access personal data in the medical record has been published.

The FAQ of the Italian Data Protection Authority on access to the personal data of the medical record, the document that contains the set of health and personal information on the individual hospitalization, has been published.

The Authority's clarifications come following some complaints from users who complained about the lack of free release by health facilities of the first paper copy of their medical records. Denial reported after the ruling of the Court of Justice of the European Union C-307/22 of 26 October 2023.

In the FAQs, the Authority clarifies that the healthcare facility, the data controller, following a request submitted pursuant to art. 15 of the Regulation, is required to provide the applicant with a copy of the personal data subject to processing. The first copy of these data is issued free of charge.

The health facility evaluates whether to provide full copies of all or part of the documentation contained in the medical record. The facility is required to provide the applicant, free of charge, with a full copy of his or her health documentation when this is necessary to enable him or her to verify the accuracy, completeness and intelligibility of the information requested, as established by the CJEU judgment 307/22.

The Authority also reminds data controllers (hospitals, health authorities, etc.) that, in the event of receipt of generic requests for access, the European Commission's Data Protection Guidelines recommend asking data subjects to specify the subject of the request (personal data or documentation).

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20 December 2024 – The Italian Data Protection Authority closes the investigation into OpenAI, which will have to carry out a six-month information campaign and pay a fine of 15 million euros.

The Italian Data Protection Authority has adopted a corrective and sanctioning measure against OpenAI in relation to the management of the ChatGPT service.

The measure, which ascertains the violations alleged at the time against the Californian company, comes at the end of an investigation launched in March 2023 and after the EDPB (European Data Protection Board) published the opinion identifying a common approach to some of the most relevant issues related to the processing of personal data in the context of design, development and distribution of services based on artificial intelligence.

According to the Authority, the US company, which created and manages the generative artificial intelligence chatbot, in addition to failing to notify the Authority of the data breach suffered in March 2023, processed users' personal data to train ChatGPT without first identifying an adequate legal basis and violated the principle of transparency and the related information obligations towards users. Furthermore, OpenAI has not provided mechanisms for age verification, with the consequent risk of exposing children under 13 to unsuitable responses with respect to their degree of development and self-awareness.

The Authority, with the aim of ensuring, first of all, effective transparency of the processing of personal data, has ordered OpenAI, using for the first time the new powers provided for in Article 166, paragraph 7 of the Privacy Code, to carry out a 6-month institutional communication campaign on radio, television, newspapers and the Internet.

The content, to be agreed with the Authority, will have to promote public understanding and awareness of the functioning of ChatGPT, in particular on the collection of user and non-user data for generative artificial intelligence training and the rights exercisable by data subjects, including those of opposition, rectification and deletion.

Thanks to this communication campaign, ChatGPT users and non-users will have to be made aware of how to object to generative AI training with their personal data and, therefore, be effectively put in a position to exercise their rights under the GDPR.

The Authority imposed a fine of fifteen million euros on OpenAI, also calculated taking into account the company's collaborative attitude.

Finally, taking into account that the company, during the investigation, established its European headquarters in Ireland, the Authority, in compliance with the so-called one-stop shop rule, transmitted the documents of the proceedings to the Irish Data Protection Authority (DPC), which has become the lead supervisory authority pursuant to the GDPR, so that it can continue the investigation in relation to any violations of a continuous nature that did not end before the opening of the European plant.

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19 December 2024 – EU Court of Justice: the processing of workers' data within the framework of the more specific national rules that Member States may adopt must in any case be carried out in compliance with the principles of the GDPR.

The judgment of the Court of Justice of the European Union of 19 December 2024 (case C-65/23) concerns the interpretation of Article 88 of Regulation (EU) 2016/679 (GDPR) in relation to the processing of employees' personal data in the context of employment relationships. The main issue concerned precisely the application of Article 88 of the GDPR, which allows Member States to provide for more specific rules to ensure the protection of employees' rights and freedoms in relation to the processing of their personal data in the context of employment.

A German employee of a company belonging to an international group objected to the processing of his personal data carried out by the employer during the transition from the use of SAP software to Workday,

a cloud system introduced in 2017 for human resources management. The transfer of data from SAP software to servers in the United States included personal information that, according to the applicant, exceeded what was agreed in a corporate agreement entered into in 2017.

The employee initiated legal proceedings alleging that the data transfer was unnecessary, violated the General Data Protection Regulation (GDPR), and that fictitious data could be used while testing the new software. It also sought the deletion of that data and compensation for moral damage, alleging that the company had exceeded the bounds of the company agreement by transferring unauthorized data, such as private contact details and pay details.

The company defended its actions by saying that it had complied with the requirements of the GDPR and disputing both the moral damage and the causal link between the treatment and the damage. The German referring court involved the Court of Justice of the EU to clarify the compatibility between national law (Section 26 of the BDSG) and the GDPR, in particular with regard to:

1. **Validity of national rules:** If the collective agreements governing data processing must comply with all the provisions of the GDPR (Articles 5, 6 and 9).
2. **Necessity of processing:** Whether the parties' margin of discretion in collective agreements is to be subject to full or limited judicial review.
3. **Criteria for judicial review:** What parameters to apply to assess the compliance of such contracts with the GDPR.

Finally, the court also assessed the issue of compensation for non-material damage under Article 82 of the GDPR, while withdrawing some preliminary claims in this regard.

The EU Court of Justice has ruled that, although Article 88 of the GDPR allows Member States to adopt more specific rules on data processing in the context of work, these rules must nevertheless comply with the fundamental principles of the Regulation, in particular those relating to the lawfulness, fairness and transparency of processing (Article 5), the conditions for consent (Article 6, paragraph 1) and the processing of special categories of personal data (Article 9(1) and (2)).

In addition, the Court has stated that the parties to a collective agreement do not have an unlimited discretion in determining the necessity of the processing of personal data provided for in that agreement. The processing must be justified and proportionate to the purposes pursued, and must be subject to appropriate judicial review to ensure the protection of employees' rights.

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13 December 2024 – Council of State: the user who opens an online account must immediately understand whether his personal data – protected in their economic value also by the Consumer Code – will be processed for marketing purposes.

With judgment no. 9614 of 2 December 2024, the Council of State clarified that those who open an account on any online platform must be able to immediately understand whether the data provided will be used for marketing purposes, without having to navigate between various screens. Therefore, structures or forms of organization of platforms that make it complicated - or at least not immediate - to acquire such information are not lawful - resulting in a misleading commercial practice. This ruling once again underlines how the principle of transparency in data processing is not only a pillar of data protection, but also part of the commercial fairness of economic operators.

This is because – the Council of State correctly points out – personal data have their own economic value and therefore the Consumer Code (Legislative Decree 206/2005) also applies in addition to the protections provided for by Regulation 679/2016. GDPR and the Consumer Code also contribute – for areas of respective competence – to the other issue addressed by the ruling, namely the pre-setting of marketing consent which - if under the Consumer Code it is not an aggressive commercial practice - from the point of view of the GDPR remains a prohibited practice.

ARTIFICIAL INTELLIGENCE.

19 December 2024 – EU Commission UE: second draft of the Code of Practice for AI Models for General Purposes (GPAI) published.

The European Commission has published the second draft of the "*Code of Conduct for the Use of General Purposes Artificial Intelligence (GPAI) models,* which includes provisions for transparency, copyright, systemic risk assessment and mitigation for GPAI models, in particular those released after 2 August 2025.

The first part of the draft code details transparency and copyright obligations for all providers of general-purpose AI models, with significant exemptions for providers of certain open-source models in line with the AI Act. As for the model for a proper summary of the content of the training data, a proposal by the Office for AI is expected early next year.

The second part of the Code concerns only providers of the most advanced general-purpose AI models that could pose *systemic risks*, in accordance with the classification criteria set out in section 51 of the AI Act (Regulation 2024/1689). This section highlights measures for assessing and mitigating systemic risk, including model assessments, incident reporting, and cybersecurity mandates.

A further purpose of the second draft of the Code of Conduct is to clearly highlight the obligations arising from the AI Act, which the Code aims to further specify through concrete measures that the signatories undertake to take in order to effectively fulfil these obligations.

The public consultation on the second draft of the Code will be open until 15 January 2025, with further discussions planned, and a third draft is scheduled for 17 February 2025.

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18 December 2024 – European Data Protection Board: Opinion 28/2024 on the application of GDPR principles to AI models.

The European Data Protection Board (EDPB) has adopted Opinion 28/2024 on the use of personal data for the development and deployment of AI models. The opinion examines **(1)** when and how AI models can be considered anonymous, **(2)** whether and how legitimate interest can be used as a legal basis for the development or use of AI models, and **(3)** what happens if an AI model is developed using unlawfully processed personal data. Also consider the use of first- and third-party data.

Regarding anonymity, the opinion states that the anonymity of an AI model should be assessed on a case-by-case basis by data protection authorities. For a model to be anonymous, it should be very unlikely to (1) directly or indirectly identify the people whose data was used to create the model and (2) extract that personal data from the model through queries. The opinion provides a non-prescriptive and non-exhaustive list of methods for demonstrating anonymity.

As regards legitimate interest, the opinion provides general considerations that data protection authorities should take into account when assessing whether legitimate interest is an appropriate legal basis for the processing of personal data for the purposes of the development and deployment of AI models.

A three-step test helps to assess the use of legitimate interest as a legal basis. The EDPB provides examples of a conversational agent to assist users and the use of AI to improve cybersecurity. These services can be beneficial to individuals and may rely on legitimate interest as a legal basis, but only if the processing proves to be strictly necessary and the balance of rights is respected.

The opinion also includes a number of criteria to help data protection authorities assess whether individuals can reasonably expect certain uses of their personal data. Those criteria include: whether or not the personal data were publicly accessible, the nature of the relationship between the individual and the controller, the nature of the service, the context in which the personal data was collected, the source from which the data was collected, the potential further uses of the model, and whether individuals are actually aware that their personal data is online.

If the comparative test shows that the treatment should not take place due to the negative impact on individuals, mitigation measures may limit that negative impact. The opinion contains a non-exhaustive list of examples of such mitigation measures, which may be of a technical nature or make it easier for individuals to exercise their rights or increase transparency.

Finally, when an AI model has been developed with unlawfully processed personal data, this could have an impact on the lawfulness of its dissemination, unless the model has been duly anonymized.

DIGITAL MARKETPLACES

17 December 2024 – EU Council: EU directive on enhancing digitalisation in company law adopted.

The EU Council has adopted a new directive that adapts company law to the needs of the digital age. This measure, which expands and updates the use of digital tools and processes, represents a fundamental step to modernize the management of companies within the EU. By exploiting the great potential of digital tools, the aim is to simplify the lives of entrepreneurs, reduce administrative burdens and make cross-border activities faster, easier and more transparent.

Specifically, the directive provides for the *Business Registers Interconnection System* (BRIS), with which it will be easier to share crucial information, such as data relating to company shareholders. In addition, a multilingual digital system (*Digital EU Power of Attorney*) is introduced to simplify cross-border legal formalities, eliminating the need for additional apostilles and translations for business documents.

The new rules also promote the use of the "*once-only principle*", which allows companies to establish subsidiaries and branches in other member states without having to repeat the same legal processes in each country. In this context, a multilingual European company certificate is proposed that could be free of charge for certain categories of companies, such as limited liability companies and partnerships. Finally, it is envisaged that cooperatives can be included in the future scope, further expanding the scope of the reform.

With formal approval by the Council, the Directive was adopted. The signature of the President of the Parliament and the President of the Council is now awaited, after which the act will be published in the Official Journal of the European Union.

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11 December 2024 – EU Council: green light for the electronic VAT exemption certificate.

After the VIDA Package (*VAT in the Digital Age*, which we reported on in the previous Newsletter 16/2024), the EU is taking a further step towards updating VAT systems.

The EU Council has in fact reached political agreement on the new directive that paves the way for the introduction of an electronic tax certificate for VAT exemptions to replace the current paper certificate used when goods must be exempt from VAT, for example because they are imported for embassies, international organizations or armed forces. The exact electronic format, including the necessary IT specifications, will be discussed in expert groups and determined in Commission implementing acts.

During a transitional period (reduced by the EU Council from 4 years to only 1 year) Member States will be able to use both the electronic and paper versions.

Member States have made a number of amendments to the Commission's initial proposal. In particular, they limited the scope of the mandatory use of the electronic VAT exemption certificate to situations where two Member States are involved and the exemption is not granted by way of refund.

INFORMATION TECHNOLOGY

13 December 2024 – Supreme Court of Cassation: online defamation and aggravating circumstance of the means of advertising applicable to the various social media (yes to WhatsApp, no to Facebook).

Judgment no. 42783/2024 issued by the Court of Cassation addressed for the first time the issue of the different harmful potential of social media in the crime of defamation, establishing that not all social media have the same ability to reach a more or less wide audience of recipients.
The Supreme Court, if - on the one hand - confirmed that the defamatory posts published on Facebook integrate the aggravating circumstance of the advertising medium given "*the objective potential that, in this case, the harmful text has to reach an indeterminate or in any case quantitatively appreciable number of people*", on the other hand Laro clarified that - only with regard to the aggravating circumstance - it is necessary to distinguish between social networks / media (Facebook) and a *chat* aimed at a small number of people (WhatsApp Group) since "*what is relevant, indeed, is not the number of subscribers to the chat but the 'technical conformation' of the medium, aimed at creating an exchange of communications that remains - clearly - confidential. The dissemination of the message to several subjects - the members of the chat - takes place, in other words, in an IT context which, if on the one hand allows the rapid dissemination of the text, on the other hand does not determine the loss of an essential connotation of confidentiality of the communication, intended for an identified and previously accepted number of people*"

INTELLECTUAL AND INDUSTRIAL PROPERTY

18 December 2024 – Ministry of Enterprise and Made in Italy: the call for the promotion abroad of collective and certification marks has been adopted.

The call for proposals (directorial decree of 10 December 2024) has been adopted with which the Ministry of Enterprise and Made in Italy makes operational for the year 2024 the facilitation for the promotion abroad of collective and certification marks.

From 18 December 2024 and until 20 January 2025, the associations representing the categories, the protection consortia referred to in art. 53 of Law no. 128 of 24 April 1998, as amended, and other associative or cooperative bodies may submit applications to the managing body Unioncamere for access to the contribution set at 70% of the expenses assessed as eligible and within the limit of 150,000 euros, against initiatives to promote the collective mark abroad or certification to be carried out within 6 months following the granting of the contribution.

Initiatives such as:

- participation in international fairs and exhibitions;
- collateral events to international trade fairs;
- bilateral meetings with foreign associations;
- seminars in Italy with foreign operators and abroad;
- communication actions on the foreign market, including through large-scale distribution and online channels; 2024/
- creation of virtual communities to support the brand.
- The criteria and methods of application are reported in the announcement.

The annual allocation provided for by law amounts to 2.5 million euros.

The forms are available at the link www.marchicollettivi2024.it

16 December 2024 – Ministry of Enterprise and Made in Italy: adopted the Treaty on the Law on Design promoted by WIPO member states.

After about 20 years of work at the multilateral level, the diplomatic conference hosted in Riyadh (Saudi Arabia) adopted the Design *Law Treaty*, promoted by the member states of the World Intellectual Property Organization (WIPO), the United Nations agency at the service of innovators and creators.

Italy participated in the work to reach the agreement, which represents a significant step forward in international collaboration in the field of design.

The new treaty, in particular, aims to simplify and harmonise the procedures for registering industrial designs, providing greater legal certainty and facilitating access to the protection of the work of designers, especially smaller designers and micro, small and medium-sized enterprises (SMEs).
It will be easier, faster and more convenient for designers around the world to protect their designs both domestically and abroad.

The new Treaty, once ratified, will enter into force in at least 15 countries.
