Privacy and personal data - legal authorisation for the processing of personal data under the prescription regulations for psychotropic and narcotic substances in Portugal

Privacidad y datos personales: autorización legal para el procesamiento de datos personales bajo las regulaciones de prescripción de sustancias psicotrópicas y narcóticas en Portugal

Carla Barbosa

Researcher at Centre for Biomedical Law, Faculty of Law University of Coimbra, Portugal
Lawyer

Abstract

We cannot speak of personal data, health data and personal health data without first talking about privacy. Privacy as a fundamental right has only recently come into existence within European legal systems, a result of the contemporary information society, which has put the lack of intimacy and privacy of its citizens onto the agenda. One way to protect privacy is through personal data protection (including health) legislation. This legislation prohibits the processing of personal health data. This is not, however, an absolute principle as there are exceptions. Processing sensitive or very personal data as is the case with personal health data is possible provided that it has the consent of the data subject or there is legal authorisation to do so. The latter eventuality includes the case of the psychotropic and narcotic substance regulations, as will be seen later.

Key Words

Privacy, data protection, processing sensitive data, psychotropic and narcotic substance.

Resumen

No podemos hablar de datos personales, datos de salud y datos de salud personales sin antes hablar de privacidad. La privacidad como un derecho fundamental ha surgido recientemente dentro de los sistemas legales europeos, como resultado de la sociedad de la información contemporánea, que ha puesto en la agenda la falta de intimidad y privacidad de sus ciudadanos. Una forma de proteger la privacidad es a través de la legislación de protección de datos personales (incluida la salud). Esta legislación prohíbe el procesamiento de datos personales de salud. Sin embargo, este no es un principio absoluto, ya que hay excepciones. El procesamiento de datos confidenciales o muy personales, como es el caso con los datos personales de salud, es posible siempre que cuente con el consentimiento del interesado o exista autorización legal para hacerlo. La última eventualidad incluye el caso de las regulaciones de sustancias psicotrópicas y narcóticas, como se verá más adelante.

Correspondencia a:

Carla Barbosa
Email: cbarbosa@fd.uc.pt
Privacy as a fundamental right has existed in the Portuguese legal system since the 1960s, when a general right to the protection of privacy was recognised (Mota Pinto, 2000, p. 153). It was, however, only in 1976 that the right to self-determination in information as an autonomous fundamental right emerged.

The recognition of the right to protect the privacy of personal and family life, as well as its effective consecration in law, is therefore a relatively recent phenomenon, the result of the contemporary information society, which has put the lack of privacy onto the agenda.

Concerns about privacy are, however, much older, dating back to at least the 19th century, when Samuel Warren and Walter Brandeis (Warren and Brandeis, 1890) defined the right to privacy and the famous Right to be let alone. With remarkably innovative vision for the time, the writers asserted that every individual “shall have full protection in person and in property” and that this principle was as old as the common law; “but it has been found necessary from time to time to define anew the exact nature and extent of such protection” (Warren and Brandeis, 1890, p. 193).

In European terms, we also find references to the concept of privacy in the 1970s. In 1970, the Council of Europe, through Resolution 428, stated that the right to privacy consisted essentially in “the right to live one’s own life with the minimum of interference. It concerns private, family and home life, physical and moral integrity, honour and reputation, avoidance of being placed in a false light, non-revelation of irrelevant and embarrassing facts, unauthorised publication of private photographs, protection against misuse of private communications, protection from disclosure of information given or received by the individual confidentially. Those who, by their own actions, have encouraged indiscreet revelations about which they complain later on, cannot avail themselves of the right to privacy”.

In Portugal, the right to protect the privacy of personal and family life has been approached by the law in various ways. The National Ethics Council for the Life Sciences (CNECV), in its report 43/CNECV/04, presents one approach to the concept of individual privacy. It states that “in terms of ethics, what is at stake is the protection of individual liberty, carving out a space for personal life which is virtually inaccessible to any external

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“meddling”. It adds that “the term ‘privacy’ may cover four different dimensions: a) physical privacy i.e. limited physical accessibility, of any kind, without consent of the person; b) mental privacy, i.e. the restriction on any illegitimate interference in the mind or in the will of the person; c) decision-making privacy, which refers to freedom in the area of individual choice; and d) information privacy, achieved by imposing limits on unauthorised access to individual information. 2

Helena Moniz argues that the core of a private life consists of data on parentage, place of residence, telephone number, state of health, marital, love and emotional life, facts arising within the home, the information transmitted by letter or other means of telecommunication, facts that have been forgotten, objects imbued with personal memories, assets and liabilities, meetings with friends, exits and entrances into the home...” (Moniz, 1997). Health data are therefore components of an individual’s private life.

In legislative terms, in 1997, when the Convention on Human Rights and Biomedicine3 (also called the Oviedo Convention) was opened for signature by the Member States of the Council of Europe, one of the subjects on which there was consensus was the protection of private life and access to medical information4.

Article 10 of the Convention declares that ‘everyone has the right to respect for private life in relation to information about his or her health’, thereby reinforcing the idea that health data is a part of private life, is not within the sphere of public life and is therefore not open to the general public5.

2. Open to signature by the Member States in Oviedo on 4 April, 1997, approved for ratification by Resolution of the Assembly of the Republic on 19 October and ratified by Decree of the President of the Republic No. 1/2001 of 3 January. The Portuguese National Ethics Council for the Life Sciences observes that the Convention on Human Rights and Biomedicine is “a very important milestone in the history of universal human rights that for the first time manages to bring together, in a consensual text, the general principles and specific provisions on the protection of the human being faced with the possible misuse of biology and medicine”, and highlights that “for the first time in a text from a Convention, tries to establish the fair but difficult balance between the rights and the interests of the individual, society, science and the human species”. Yet for

4. It should be noted that, while the concepts of privacy and confidentiality are intertwined, they have different meanings. While privacy concerns the right to be left alone and the right to prevent third-party intrusions, confidentiality is the right of everyone to protect their information from unwanted revelations. Enrique Costas defines confidentiality as “the armoured enclosure that envelops and protects the personal secrecy within, the secure chamber where that secret can rest in confidence, confident”, and says that “the limits of what is secret therefore go beyond the secret, they include its periphery: those details, references, methods and instruments that, even while in themselves innocuous, could reveal the secret or lead to its disclosure” (Costas, 1991).

5. The Oviedo Convention specifically addresses the protection of privacy with regard to health data. However, the protection of private life in general results in other international treaties such as the Universal Declaration of Human Rights (Article 12 - “No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks.”), the European Convention on Human Rights (Article 8 - “Everyone has the right to respect
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In the case of Portuguese legal instruments, health data are part of a very restricted sphere of private life which the Constitution of the Portuguese Republic, through Article 26, treats as a fundamental right: the right to protect the privacy of personal and family life. Article 26 of the CRP, among other rights, establishes the fundamental right of privacy of personal and family life. Jorge Miranda and Rui Medeiros claim that "although the law does not have the breadth that it has been given to American jurisprudence, where the right to privacy comes as a paradigmatic expression of all personal rights, the right to the privacy of personal life includes, in all cases, not only the right to object to the disclosure of private affairs (public disclosure of private facts), but also the right to respect for private life, namely the right to oppose investigation into private life (intrusion)."

It is often said that the contents of this basic right relate to very sensitive or very personal data, since these are the last re-doubt of private life.

8 J. Garcia Canotilho and Vital Moreira understand that this right to privacy in personal and family life can be analysed in terms of two other smaller rights: the right to prevent access by strangers to information about personal and family life and the right to prevent anyone from disclosing information they have on the personal and family life of others (Canotilho and Moreira, 1993, p. 181).


10 Romeo-Casabona defines sensitive data as “data in connection with which the data subject is more vulnerable when the data is known or used by a third party because of its potential for causing discrimination and other misuse, especially when accessed, used or illicitly disclosed” (Romeo-Casabona 2004, p. 37).

11 With regard to privacy and the protection of medical confidentiality, many other national and supranational standards could be analysed. We shall not do this formally, however, as we are aware that in examining these standards we would have to study issues such as privacy, personal data and medical confidentiality in greater depth. As mentioned above, it is not possible to analyse the problem of access to the clinical process without touching on these issues; however, our intention is to approach them in a purely reflective way. We shall...
Helena Moniz argues that “as part of the law of privacy there is a core right to privacy in personal life and it is in accordance with these two areas that we shall classify personal or sensitive data; personal when it only covers the domain of private life, and sensitive data, also termed highly personal, when regarding the domain of privacy in personal life” (Moniz, 1997, p. 240). This demarcation leads us to the not always easy determination of these cores or spheres of life. In this respect, one that has been the most talked about is the German theory of the three spheres: the intimate sphere, the private sphere and the social sphere. “The intimate sphere corresponds to the hard core of the right to privacy in personal life; the private sphere balances questions of proportionality; the social sphere falls within the framework of the right to personal image and words and not the right to privacy in personal life” (Miranda and Medeiros, 2010, p. 620).

As for health data, Paulo Mota Pinto argues that “the elements relating to health, such as, for example, a person’s medical history, also undoubtedly include the protection of privacy”, recalling that “in Judgement No. 355/97, (...)” the Constitutional Court stated that “the ring-fenced processing of data relating to oncological diseases includes the sphere of patient privacy, and to this extent interferes with the definition of the content of privacy, respect for rights, freedoms and guarantees”. The conclusion, according to the author, is that “health data including the category of data on private life, such as information regarding ethnic origin, family life, sex life, convictions in criminal proceedings, assets and liabilities and financial situation (...), are part of every person’s private life.” (Mota Pinto, 2000, p. 167)

Article 35 of the Constitution of the Portuguese Republic, under the heading “use of information technology”12, states, in paragraph 1, that “every citizen has the right of access to all computerised data that concern him and which he may require to be corrected and updated, and the right to be informed of the purpose for which they are intended, as laid down by law”. Article 35 contains the fundamental right of informational self-determination, which optimises another fundamental right mentioned above: the right to protect personal and family life (Article 26 CRP). Optimising the protection of privacy presupposes the ability to control (individual autonomy) the flow of information that this legal device contains. Protection of privacy thus requires not only negative or defensive dimensions (prohibitions on intervention or interference), but above all the recognition and imposition of mechanisms of hetero and self-control (it is “a right of defence and a right of freedom with negative content in that it allows the individual to decide who, when and under what conditions they may use or make public information that concerns them” but it is also a right that is “accompanied by decision-making powers and action in respect of personal data, the power to supervise this information, preventing and correcting harm to individual freedom”.

12 Notwithstanding the title of this article, manual files also enjoy equal protection (cf. Article 35(7) of the Constitution of the Portuguese Republic).
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(Miranda and Medeiros, 2010, p. 789)\textsuperscript{13}. However, the material nature of this right is not limited to protecting the \textit{intimate sphere} of an individual’s life. On the contrary, it goes beyond this (Miranda and Medeiros, 2010, p. 784). Helena Moniz writes that “while Article 35(2) guarantees the right to privacy (personal data), Article 35(3) guarantees the right to privacy (sensitive or very personal data). (Moniz, 1997, p. 240)

\textbf{2. THE PROCESSING OF PERSONAL DATA AND THE SPECIFIC CASE OF THE PROCESSING OF PERSONAL HEALTH DATA UNDER THE EUROPEAN GENERAL DATA PROTECTION REGULATION (GDPR)\textsuperscript{14}}

Besides the Oviedo Convention and the Constitution of the Portuguese Republic, there is, however, other legislation dealing with informational self-determination, which regulates the protection of personal data. This is, in fact, an area that has been the subject of several recent legislative changes.

\textsuperscript{13} In 1985, the German Supreme Court, in a ruling of 15 December, defined the right to informational self-determination as “the ability of the individual, based on the idea of self-determination, to basically make decisions about himself when and within which limits he can reveal situations about his life”, adding that it is “a fundamental right which guarantees the individual the power to decide in principle on the use and disclosure of his personal data”.

\textsuperscript{14} In Portugal the General Data Protection Regulation is implemented by Law 58/2019, of 8 August, which replicates several of the principles established in the Regulation and covers various matters that this law determined should be regulated by the various member states through domestic legislation.

A network society with new challenges driven by various aspects such as universal internet access, the multiplication of operators, cultural and economic globalisation, the growing importance of social networking and cloud computing has made it necessary to amend European legislation on personal data protection, in particular the 1995 Directive.

Thus, after a long public debate (which began in 2012 with the release of the first version of what would become the General Data Protection Regulation) this change was finally approved in 2016. On 4 May, the long-awaited Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 was published 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. The regulation applies throughout the European Union from 25 May 2018. However, after publication, authorities should begin the process adapting to the new rules. This new legal instrument will be immediately applicable in all Member States, without the need for transposition.

It maintains the European tradition of privacy and protection of personal data but brings some innovations. The scope for application will be diverse. The new regulation have an extraterritorial application in so far as it applies to organisations that have European citizens as their target market (no need to have their headquarters located in one of the Member States). It also terminates the rule on prior notification of the processing of personal data but requires compulsory notification of violations of personal data. The existing legislation is converging with the rapid technological developments in the sector. It creates a single regulator to assess authorisations and
matters related to the processing of personal data, defined with regard to the organisation’s place of business. The definition of personal data is enlarged to include, in particular, location data and electronic identifiers. It creates a definition of ‘profiling’, ‘pseudonymisation’, ‘genetic data’, ‘biometrics’ and ‘health data’. The rules on transfers of personal data to a third country are enhanced.

With regard to the processing of health data, the new European regulation provides an obligation on Member States, in addition to the conditions applicable to special categories of data, to ensure specific guarantees for the processing of data in the field of health (Article 81). Specific conditions shall be laid down for the processing of personal data for the purposes of historical research, statistics and science (Article 83).

The Regulation gives a definition that we consider to be fairly comprehensive in terms of what we understand as personal health data. These should include in particular all data pertaining to the health status of a data subject; information about the registration of the individual for the provision of health services; information about payments or eligibility for healthcare with respect to the individual; a number, symbol or particular assigned to an individual to uniquely identify the individual for health purposes; any information about the individual collected in the course of the provision of health services to the individual; information derived from the testing or examination of a body part or bodily substance, including genetic data and biological samples; and any information about, for example, an illness, a disability, a risk of disease, medical history, clinical treatment or physiological or biomedical state of the data subject, regardless of its source, such as e.g. from a physician or other health professional, a hospital, a medical device, or an in vitro diagnostic test.

REGULATION (EU) 2016/679, in recital 35, stipulates that all data concerning the state of health of a data subject that reveal information about their physical or mental health in the past, present or future should be regarded as personal health data. The above includes information about an individual collected during registration for the provision of health services, or during this provision itself; any number, symbol or particular assigned to an individual to identify them unambiguously for healthcare purposes; the information obtained from the analysis or examination of a body part or bodily substance, including genetic data and biological samples; and any information about, for example, an illness, a disability, a risk of disease, medical history, clinical treatment or physiological or biomedical state of the data subject, regardless of its source, for example, a doctor or other professional health, a hospital, a medical device or an in vitro diagnostic test.

The Regulation allows, however, for the possibility of processing the data in those situations where there is consent by the personal data subject (I) or if the processing is necessary for the purposes of preventive medicine or work, to assess an employee’s capacity to work, a medical diagnosis, the provision of healthcare or treatments or social project or the management of health systems and services or social project based on EU or Member State law or because of a contract with a healthcare professional, subject to the conditions and guarantees laid down in the regulation itself (II) or if the processing is necessary for reasons of public interest in the field of public health, such as protection against serious cross-border health
threats or to ensure a high level of quality and safety in healthcare and medicines or medical devices, based on EU or Member State law to provide for appropriate measures and that safeguard the rights and freedoms of the data subject, in particular the obligation of professional confidentiality (III).

As regards the processing of personal health data for the purpose of providing healthcare, there are no substantial changes when we compare what was already provided for in the 1995 Directive and what the current Regulation determines. In fact, the principles are the same:

I) Health data are considered sensitive data and are therefore included as a special category of personal data;

II) There is a prohibition on processing special categories of personal data;

III) The processing of spatial categories of personal data, as is the case of health data lato sensu, including genetic data in this way, will always be allowed whenever there is consent by the subject of such data.

3. LEGAL AUTHORISATIONS FOR THE PROCESSING OF PERSONAL (HEALTH) DATA - THE SPECIAL CASE OF REGISTERING PRESCRIPTIONS FOR PSYCHOTROPIC AND NARCOTIC SUBSTANCES

As mentioned below, there is a principle of prohibiting the handling of special categories of personal data, such as health data. This prohibition may be removed by the consent of the subject of this personal data or by legal authorisation. The General Data Protection Regulation itself provides for a number of legal authorisations for such processing. Such derogations to this prohibitory principle may be provided for sanitary reasons, including public health and health service management, in particular to ensure quality and efficiency in terms of the costs of the procedures used for settling claims for social benefits and services under the health insurance scheme, or for archiving in the public interest, for scientific research, historical or statistical purposes. As mentioned above, the special categories of personal data that deserve a higher protection should only be subject to processing for health-related purposes, when this is necessary to achieve the objectives in the interests of individuals and of society as a whole. This is especially the case in the management of health systems and services, including processing by the administration and the national central health authorities of these data for the purposes of quality control, management information and general supervision at national and local level of the health system or social project. This will ensure the continuity of the healthcare or social project and the provision of cross-border healthcare, or for security purposes, monitoring and alerts on health, or for purposes of archiving in the public interest, for scientific research or historical purposes or for statistical purposes based on Union or Member State law and which have to fulfil a goal, as well as studies conducted in the public interest in the field of public health. Therefore, this Regulation should lay down harmonised conditions for the processing of special categories of personal health data, taking into account specific needs, in particular where the processing...
of such data is made for certain purposes related to health for persons subject to a legal obligation of professional confidentiality. Union or Member State law shall provide specific and appropriate measures for the protection of individuals' fundamental rights and personal data. Member States should be allowed to maintain or introduce other conditions, including limitations, on the processing of genetic data, biometric data or health data. This should not, however, prevent the free flow of personal data within the Union, when these conditions apply to cross-border processing of such data (recital 53).

In Portugal, Decree-Law 15/93 of 22 January, subject to 25 amendments, refers to the drug law and is one of those legal authorisations for the processing of personal data. This is where we find the legal provisions that regulate the availability of certain prescription substances. Article 15 of the decree states that the substances and preparations included in Tables I and II (for example, cocaine, cannabis, morphine, etc.) are only provided to the public for treatment upon presentation of a special doctor's prescription with the details contained in the regulatory decree.

Pursuant to Article 16 of the same decree, only the pharmacist, or substitute if absent or indisposed, can supply prescriptions for substances or preparations included in Tables I and II, and must comply with the identification rules provided for in the decree. The pharmacist must refuse to supply prescriptions that do not comply with the conditions imposed in the previous article. Prescriptions may not be despatched if 10 days have elapsed from the date of issue, nor may substances or preparations based on the same prescription, as set out in the attached tables, be supplied more than once. Pharmacies are required to keep regular stocks of the substances or preparations referred to in paragraph 1 and to keep their prescriptions on file for a period not exceeding five years, in terms to be fixed by regulatory decree. Only in cases of urgent need may pharmacists, as part of their duties and for immediate use, supply substances and preparations in Tables I and II without prescription, provided that the total of the drug does not exceed the maximum dose when taken only once.

Pursuant to Article 18, the National Institute of Pharmacy and Medicine (INFARMED), in conjunction with the Directorate-General for Health, shall carry out checks on prescriptions by means of information technology. All those accessing this information shall be subject to professional secrecy. State or private health services send the National Institute of Pharmacy and Medicine a quarterly list of narcotic drugs used in medical treatment. Regulatory Decree No. 61/94 of 12 October (subject to various amendments) states that “pharmacies, state and private health services send the duplicate of each prescription for narcotic or psychotropic substances to INFARMED by the 8th of the month following the month to which it relates” (with details of the name of the user and their identification by ID or other document as long as it is identifiable) - Article 30(1). Article 34(2) and (3) states that “the supply of substances or preparations pursuant to Article 17 of Decree-Law 15/93 is subject to independent registration, with details of the identity of the patient, drug dose and delivery date”; “Pharmacists shall inform INFARMED within 10 days of cases
of supply in accordance with the previous paragraph, identifying themselves as well as the patient, and indicating the details contained in the prescription form referred to in Article 27.” (updated in accordance with Regulatory Decree No. 28/2009 of 12 October which became the third amendment to Regulatory Decree No. 61/94).

As managers of their own files, pharmacies may therefore process data on narcotic drugs and psychotropic substances by virtue of a legal provision that underlies the automated processing of such data and defines the type of data to be processed, its purposes and its shelf life. They must also communicate this data to INFARMED. This legal authorisation is in line with the possibility of derogation from the principle of prohibition on the processing of sensitive data. This is justified in defence of the public interest, in particular in national administrative authorities’ management of health data. Only in this way, through legal authorisation for the processing of these data and the obligation to submit them to INFARMED, is it possible to control the amount of psychotropic substances available through prescriptions and their intended recipients and to ensure a high level of quality and safety in healthcare and medicines.

4. CONCLUSION

In recent decades, with growing awareness of the issues surrounding data protection and privacy, there have been constant developments in guidelines and legislation. However, this is obviously a topical issue which is still far from fully resolved, if indeed it can ever be.

The issue of privacy and personal data protection is relevant to all of us. It is relevant to religion, to sexual orientation, to political convictions, to health and to many other aspects of each individual’s daily life.

In view of its importance, European and Portuguese legislation has defined very strict criteria for protecting privacy and informational self-determination. In terms of personal information, personal health data play a very important role as part of the last refuge in the intimate areas of a person’s private life. For this reason, the law imposes a prohibition on the processing of special personal data concerning certain categories such as health. This is not, however, an absolute principle. The prohibition on processing is removed whenever there is valid consent by the data subject or there is a legal authorisation for processing. In the prescription of psychotropic and narcotic substances, we are dealing with a legal authorisation for processing that is leveraged in the defence of the public interest of proper management and control by national regulatory authorities over the availability of certain substances.

REFERENCES


