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## WEAKNESSES IN THE PROTECTION OF VULNERABLE PERSONS UNDERGOING CLINICAL TRIALS

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### Abstract

*The article seeks to highlight certain shortcomings at the legislative level in a certain area of health – clinical trials, referring to the protection of vulnerable patients and their rights. Conducting clinical trials on patients with mental illness raises several questions, in terms of obtaining Informed Consent. Thus, chronic patients with mental illness, that are hospitalized in medical units can be subjected to clinical tests for drugs for human use only in exceptional conditions, they are integrated into the category of vulnerable patients, which requires special care in terms of meeting the legal conditions for their participation in clinical trials performed. Are their protection mechanisms sufficient so that chronic patients understand the risks and consequences of participating in such tests?*

**Keywords:** vulnerable patients, chronic mental disorders, clinical trial, informed consent, discernment.

### Introduction

Article 211 of Law no. 71/2011 defines the expressions mental insanity or mental weakness: “For the purposes of the Civil Code, as well as of the civil legislation in force, the expressions mental insanity or mental weakness mean a mental illness or a mental disability that determines the person's mental incompetence to act critical and predictive on the social-legal consequences that may arise from the exercise of civil rights and obligations”. Also, according to article 164 of the Civil Code<sup>1</sup>, the person who does not have the necessary discernment to take care of his interests, due to alienation or mental weakness, will be placed under judicial interdiction.

Therefore, the law overturns the burden of proof regarding people suffering from these mental illnesses, being presumed to have no discernment. Also, in the absence of discernment, as an intrinsic *de facto* element of the capacity to exercise, the latter, as a matter of law, is also absent, an aspect achieved by the procedure of judicial interdiction. These are the only mental disorders expressly provided by the Civil Code with such consequences, so that, in the case of other mental disorders, the rule of relative presumption of the existence of discernment and the capacity to exercise works.

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<sup>1</sup> *Romanian Civil Code*, republished pursuant to art. 218 of Law no. 71/2011 for the implementation of Law no. 287/2009 on the Civil Code, published in the Official Gazette of Romania, Part I, no. 409 of 10 June 2011.

Only on the basis of medical documents attesting to the lack of discernment, the court will be able to order the placing under judicial interdiction, at the initiative of one of the persons or authorities provided by law.

In reality, a discrepancy is created between the state of fact and the state of law, when we talk about chronic patients with mental illness, hospitalized in medical units specially authorized for their hospitalization. Often, the fact is that discernment is lacking, but the person is not placed under judicial interdiction, is presumed to have the capacity to exercise, does not have a legal representative and, therefore, can express informed consent to participate to a clinical study for drugs for human use. This aspect is a relative one, the existence of discernment being necessary for the expression of the agreement, since at that moment the contractual legal relationship is born.

### **Legal Framework**

According to article 43 of Law no. 487/2002 on mental health and protection of persons with mental disorders<sup>2</sup>: “Clinical trials and experimental treatments, psychosurgery or other treatments likely to cause harm to the integrity of the patient, with irreversible consequences, *do not apply to a person with mental disorders than with her informed consent* (my italics), and subject to the approval of the ethics committee of the psychiatric unit, who must declare that the patient has actually given his or her informed consent , and that it responds to the patient's interest”.

According to article 46 of the same normative act, “The conditions of assistance and mental health care of persons who serve prison sentences or who are detained or arrested on remand and who have been established to have a mental disorder, as well as persons hospitalized of psychiatry as a result of the application of medical safety measures provided by the Criminal Code may not be discriminatory in relation to other mentally ill persons”.

The provisions of article 701<sup>1</sup> paragraph (1) of Law no. 95/2006 on health care reform<sup>3</sup>, republished, with subsequent amendments and completions regulates the fact that “The National Agency for Medicines and Medical Devices (NAMMD) authorizes and controls clinical trials in the field of medicines for human use by verifying the conformity with the good practices in the clinical study with or without therapeutic benefit, as well as their place of development”. Also, according to paragraph (2) of the same article, “clinical trials are conducted in compliance with the Principles and detailed guidelines on good practice in the clinical trial for medicinal products for human use for clinical investigation approved by order of the Minister of Health and the Norms on authorization of the place of development, as well as those related to the implementation of the rules of good practice in conducting clinical trials performed with drugs for human use, approved by order of the Minister of Health, at the proposal of NAMMD”.

According to article 4 point 4 of the Regulation on the organization and functioning of the National Agency for Medicines and Medical Devices, approved by Order of the Minister of Health no. 938/2016<sup>4</sup>: “authorizes and controls the clinical trials that are

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<sup>2</sup> Republished in the Official Gazette of Romania, Part I, no. 652 of 12 September 2012.

<sup>3</sup> Republished, in the Official Gazette of Romania, Part I, no. 652 of 21 August 2015.

<sup>4</sup> Published in the Official Gazette of Romania, Part I, no. 820 of 18 January 2016.

performed for medicinal products for human use, in accordance with the guideline on good practice in clinical trials and with the legal provisions in force in the field”.

Also applicable: The norm of application of the Law on mental health and protection of persons with mental disorders no. 487/2002, approved by the Order of the Minister of Health no. 488/2016<sup>5</sup>; Chapter VII entitled "Clinical trials performed on adults with disabilities who are unable to express their informed legal consent" of the Rules on the implementation of rules of good practice in the conduct of clinical trials conducted with medicinal products for human use, approved by Order of the Minister of Health no. 904/2006.

At European level we have the Regulation (EU) no. 536/2014 of the European Parliament and of the Council of 16 April 2014 on interventional clinical trials with medicinal products for human use and repealing Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of laws and the administrative acts of the Member States concerning the application of good clinical practice in the case of clinical trials for the evaluation of medicinal products for human use<sup>6</sup>. However, the regulation has not yet entered into force, only subsequently will it be applied directly within the EU Member States, and national legislation will be amended accordingly.

Currently, the norms regarding the implementation of the rules of good practice in conducting clinical trials performed with drugs for human use, approved by the Order of the Minister of Health no. 904/2006<sup>7</sup> transpose the provisions of Directive 2001/20/EC.

According to the Order of the Minister of Health no. 904/2006, which transposes Directive 2001/20/EC on the harmonization of the laws, regulations and administrative measures of the Member States, concerning the implementation of rules of good practice in conducting clinical trials on medicinal products for human use<sup>8</sup>, especially for vulnerable persons, such as adults with disabilities, who are unable to express their informed legal consent, obtaining informed consent being the task of the principal investigator.

According to the Helsinki Declaration<sup>9</sup>, chronic patients are vulnerable patients. Moreover, most patients are real social cases, being abandoned by their families and remaining hospitalized here for a long time, even until the end of their lives.

Therefore, in the case of clinical trials, the patient's consent is required to participate in the study. Also, very clear criteria for admission / selection of patients are regulated, rigorous procedures, no clinical study in Romania can be performed without the prior approval of the European Medicines Agency (EMA) or the American Food Drug Administration (FDA). Subsequently, the clinical study, in order to begin, goes through

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<sup>5</sup> Published in the Official Gazette, Part I, no. 340 of 4 May 2016.

<sup>6</sup> Published in the Official Journal of the European Union L 158/1 from 27 May 2014.

<sup>7</sup> *Order of the Minister of Health no. 904 of 25 July 2006*, for the approval of the Norms regarding the implementation of the rules of good practice in conducting clinical trials performed with drugs for human use, published in the Official Journal of Romania, Part I, no. 671 of 4 August 2006.

<sup>8</sup> Declaration of Helsinki – *Ethical Principles for Medical research Involving Human Subjects*, adopted by the 18th World Medical Association General Assembly, Helsinki, Finland, June 1964 and amended several times.

<sup>9</sup> Published in the Official Journal of the European Union L 121 from 1st of May 2001.

several stages, including the analysis of the National Ethics Council, the Hospital Ethics Commission and the decision of the approval manager, depending on the assessment of the benefits of the study, being issued the authorization to conduct studies clinics in the field of medicines establishes the points of work / section / location. Each study has an information and consent document for the researched subject. It is mentioned that the subject can withdraw from the study at any time, without sanctions. The form is drawn up in two copies: one for the investigator, one for the patient and is dated including the time of signing. In the observation sheet, it should be mentioned that the patient was offered the opportunity to participate in the clinical study, that he was informed about the study medication, risks, etc. This procedure is mandatory, according to EMA's Good Clinical Practice (GCP).

One thing to note is that the sponsor pays the investigator money based on the number of visits, so he may be tempted, despite the fact that the subject is not feeling well, to continue the visits and add medication, thus obtaining more money.

Regarding the legal framework applicable to clinical trials, we find that patients with hospitalized mental illness are part of the category of vulnerable patients. The World Health Organization's Guide to the Practice of Clinical Trials (GCP)<sup>10</sup> and the Helsinki Declaration stipulate that vulnerable and mentally incapacitated persons may undergo a clinical trial with the consent of their legal representative, which requires special attention to be paid to this categories of people, also taking into account the fact that the patient's discernment can be affected by certain mental illnesses.

On the other hand, according to Law no. 134/2019 on the reorganization of the National Agency for Medicines and Medical Devices<sup>11</sup>, this public institution has responsibilities for collaboration with other institutions in the health field (in this case, the Bioethics Commission) and control, through *ante-* and *post-*authorization inspections of clinical trials, their locations, but also relevant documents.

A person's rights are practically inapplicable if there is no special legal mechanism to provide special protection to the person in case of violation of his or her rights. In the sense of the above, vulnerable persons, as consumers of health services subject to clinical trials, also enjoy the special protection of the law, through the guarantees established for this purpose, represented in particular by NAMMD. These guarantees are regulated by various normative acts, previously specified, which regulate the field of legal relations of medical law between the patient subject of the clinical test and the medical staff that monitors the study.

In practice, however, some people with mental illness hospitalized in the departments of chronic patients have impaired discernment, either permanently or at certain times, specific to the disease.

**Conclusions:** From the point of view of civil law, the person who is not placed under judicial interdiction is presumed to have discernment – an aspect that benefits from performing a clinical test. In reality, however, very few patients in such a situation go through the aforementioned judicial procedure, and the legal representatives or

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<sup>10</sup> World Health Organization, *Handbook for good clinical research practice (GCP): guidance for implementation*, 2005: <https://apps.who.int/iris/handle/10665/43392>, accessed on 13 June 2020.

<sup>11</sup> Published in the Official Gazette, Part I, no. 587 of 17 July 2019.

guardians are not nominated in this way. Relatives are the ones who generally represent their interests and they are also the ones who decide to hospitalize the mentally ill person, although the latter is given consent when hospitalized in a specialized medical centre. This contradiction between the state of affairs and the rule of law can lead to abuses of this category of people who do not understand what a clinical trial involves and what consequences it can produce.

Moreover, there is the possibility that the doctor who conducts the clinical test and monitors its results on the patient is at the same time his doctor, a situation that leads to a report of mental subordination of the patient (accepts the clinical test so as not to upset his doctor).

We specify that, according to civil law, the legal capacity of any subject, including a subject of medical law, means both the capacity to use, i.e. its general ability to have rights and obligations, and the capacity to exercise their rights and assume their obligations<sup>12</sup>. In this sense, the legal capacity of the patient, as a consumer of health services depends on several criteria, the most important being the volitional criterion, which we suspect is often met only formally.

As we have seen, the chronic patient with mental illness may invoke the provisions of Article 13, Thesis I of Law no. 46/2003 according to which medical intervention assuming, in writing, the responsibility for his decision<sup>13</sup>.

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<sup>12</sup> Diana-Geanina Ionaș, *Legatul – principala dispoziție cuprinsă în testament*, Universul Juridic Publishing House, Bucharest, 2020, p. 15-18.

<sup>13</sup> For another situation in which the subject may invoke this regulations, see Silviu-Dorin Șchiopu, *Despre lipsa obligării la internare sau tratament a persoanelor infectate cu SARS-CoV-2*, in “Revista Universul Juridic” nr. 5/2020: <http://revista.universuljuridic.ro/despre-lipsa-obligarii-la-internare-sau-tratament-persoanelor-infectate-cu-sars-cov-2/>; Șchiopu Silviu-Dorin, *Despre (im)posibilitatea reținerii infracțiunii de zădărnire a combaterii bolilor în cazul persoanelor infectate cu SARS-CoV-2 care au refuzat internarea în perioada stării de urgență*, under review to be published in “Revista Dreptul”, 2020: <https://www.juridice.ro/684729>, accessed on 13 June 2020.

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*Declaration of Helsinki – Ethical Principles for Medical research Involving Human Subjects*, adopted by the 18th World Medical Association General Assembly, Helsinki, Finland, June 1964 and amended several times.

## Deficiențe ale protecției persoanelor vulnerabile asupra cărora se efectuează teste clinice

### **Rezumat**

*Prezentul articol dorește să reliefeze anumite deficiențe la nivel legislativ, în diverse ramuri ale domeniului sănătății, identificate pe mai multe paliere. Efectuarea studiilor clinice pe pacienții cu afecțiuni psihice ridică mai multe semne de întrebare, sub aspectul obținerii Consimțământului Informat. Astfel, pacienții cronici cu afecțiuni psihice internați în unități medicale pot fi supuși unor teste clinice pentru medicamente de uz uman doar în condiții excepționale, aceștia fiind integrați categoriei de pacienți vulnerabili, ceea ce implică o atenție deosebită sub aspectul îndeplinirii condițiilor legale pentru participarea acestora la studiile clinice efectuate. Sunt suficiente mecanismele legale în așa fel încât acestea să garanteze faptul că pacienții cronici cu afecțiuni psihice au reprezentarea reală a riscurilor și consecințelor studiilor clinice la care participă?*