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Negligenza medica e obblighi positivi in tema di diritto alla salute
(CEDU, sez. IV, sent. 8 febbraio 2022, ric. n. 5766/17)

Il caso XXX deciso dalla Corte EDU ha ad oggetto il ricorso presentato da una cittadina armena che, basandosi sull'articolo 8 della Convenzione, ha imputato l'origine della sua disabilità a cure mediche inadeguate ricevute presso un centro medico. E denunciava altresì le carenze del quadro normativo sanitario nazionale e di non essere stata informata sulla natura e sui rischi legati all'intervento. In fine, lamentava l'inesistenza di idonei strumenti procedurali volti a far valere la responsabilità per negligenza medica.

La Corte EDU, dopo aver ricordato che il diritto alla salute non è in quanto tale tra i diritti garantiti dalla Convenzione o dai suoi Protocolli, ha riaffermato che le Alte Parti contraenti hanno un obbligo positivo, ai sensi dell'art. 8, di disporre misure adeguate alla tutela della salute e di fornire in caso di negligenza medica l'accesso a procedimenti per il risarcimento del danno. In particolare, sul consenso informato la Corte ha poi sottolineato che gli Stati contraenti sono tenuti ad adottare le misure regolamentari necessarie per garantire la giusta informazione sulle possibili conseguenze post-operatorie.

Passando ai fatti della causa, la Corte ha osservato che essa non rientra nelle ipotesi eccezionali di casi che coinvolgono direttamente la responsabilità dello Stato per gli atti e le omissioni dei fornitori di assistenza sanitaria e che, pertanto, non vi è stata violazione della disposizione convenzionale. Non sussiste violazione dell'art. 8 CEDU neppure sotto il profilo del consenso informato, in quanto l'esistenza di una regolazione nazionale ha garantito alla ricorrente l'accesso a informazioni utili a valutare i rischi del suo intervento. In fine, sui rimedi processuali a disposizione della ricorrente per accertare i fatti e l'eventuale responsabilità medica, la Corte ha osservato che, pur avendo le autorità nazionali svolto un'indagine penale per l'accertamento del presunto nesso eziologico tra il danno alla salute della ricorrente e l'esercizio negligente dei doveri professionali degli operatori sanitari, in nessun momento del procedimento giudiziario sono state adeguatamente esaminate le doglianze della ricorrente e, pertanto, ha ritenuto le indagini non complete ed efficaci ai sensi dell'articolo 8 CEDU.

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EUROPEAN COURT OF HUMAN RIGHTS
COUR EUROPÉENNE DES DROITS DE L'HOMME

FOURTH SECTION

CASE OF XXX v. ARMENIA

(Application no. 5766/17)

JUDGMENT

STRASBOURG

8 February 2022

This judgment will become final in the circumstances set out in Article 44 § 2 of the Convention. It may be subject to editorial revision.

In the case of XXX v. Armenia,

The European Court of Human Rights (Fourth Section), sitting as a Chamber composed of:

Yonko Grozev, *President,*

Tim Eicke,

Iulia Antoanella Motoc,

Armen Harutyunyan,

Pere Pastor Vilanova,

Jolien Schukking,

Ana Maria Guerra Martins, *judges,*

and Ilse Freiwirth, *Deputy Section Registrar,*

Having regard to:

the application against the Republic of Armenia lodged with the Court under Article 34 of the Convention for the Protection of Human Rights and Fundamental Freedoms ("the Convention") by an Armenian national, Ms XXX ("the applicant"), on 29 December 2016;

the decision to give notice to the Armenian Government ("the Government") of the application;

the parties' observations;

Having deliberated in private on 11 March 2021 and 18 January 2022,

Delivers the following judgment, which was adopted on that last-mentioned date:

INTRODUCTION

1. The case concerns the applicant's complaints, under Article 8 of the Convention, that the State failed to comply with its regulatory duties, that failures in her treatment at a public hospital led to medical complications leaving her permanently disabled, and that she was not properly informed of the risks of the medical procedure she underwent. It also concerns her complaint that no effective mechanism was in place to enable her to obtain compensation for the damage suffered.

THE FACTS

2. The applicant was born in XXX and lives in XXX. She was represented by Ms A. Melkonyan and Ms H. Harutyunyan, lawyers practising in Yerevan, and Ms A. Aghagyulyan, a legal expert.

3. The Government were represented by their Agent, Mr G. Kostanyan, and subsequently by Mr Y. Kirakosyan, Representative of the Republic of Armenia to the European Court of Human Rights.

4. The facts of the case may be summarised as follows.

I. THE APPLICANT'S SURGERY AND ITS COMPLICATIONS

5. On 6 February 2008 the applicant fell on the stairs and broke her left leg.

6. On the same date she was taken by ambulance to Artik Medical Centre, a public hospital under the control of the Shirak regional authority.

7. According to the applicant's medical file, she was admitted to Artik Medical Centre at 10.30 p.m. on 6 February 2008. The file further stated that the applicant had been admitted for inpatient treatment in the surgical department and was diagnosed with a closed comminuted fracture of the left distal tibia (lower leg bone) with significant displacement.

8. On 7 February 2008 Dr A.A., a general surgeon at Artik Medical Centre, operated on the applicant. The surgery included the insertion of metal implants into her leg to stabilise the bone fracture.

9. The applicant's medical file also stated the type of medical intervention, its date and time and the type of anaesthetic administered. According to the medical file, the applicant had been informed that she had received treatment under the public healthcare system. This was confirmed by her signature in the relevant part of the file.

10. According to the Government, prior to the surgery the applicant was informed orally of the consequences, in particular, that she would be able to walk but not in the same way as before. The Government averred that the applicant had also been informed that the surgery would be performed free of charge under the public healthcare system. The applicant partially contested this argument, claiming that she had only been informed of the financial aspects of the surgery but not as to the possible risks of the medical intervention. Nor had she been informed of the origin of the metal implants used – she had not been asked to pay for them and they had not been obtained under the public healthcare system.

11. On 13 March 2008 the applicant was discharged. She was not provided with any medical documents attesting to her state of health.

12. Following her discharge from hospital, the applicant remained under Dr A.A.'s supervision: he visited her several times at home, enquired about her condition and personally treated her wound.

13. In the meantime, the applicant's wound became infected, she suffered from fevers regularly and her leg started to hurt.

14. On 26 May 2008 the applicant was operated on by Dr K.K., a traumatologist at G. Gyulbenkyan Surgical Hospital in Gyumri. During the operation the metal implants were removed from her leg. She remained under medical supervision for a month following discharge.

II. THE APPLICANT'S COMPLAINTS TO THE AUTHORITIES

15. Thereafter the applicant sent complaint letters to various State officials and bodies, including the Ministry of Health, alleging that Dr A.A. was liable for the damage caused to her health.

16. On 12 October 2009 the Department of Health and Social Security of the Shirak regional authority ("the Department of Health") held a consultation with the participation of the head and a divisional head of the Department of Health, the chief orthopaedic surgeon and the chief surgeon of the Shirak region, Dr A.A. and the head of Artik Medical Centre. The minutes of that

consultation contained the names and signatures of the participants, reference to a complaint sent by the applicant to the National Assembly and a brief description of her medical history.
The relevant parts of the minutes read as follows:
"... On 07.02.2008 osteosynthesis with an orthopaedic plate and screw was performed. The surgery was performed correctly; fixation of the bone fracture was done with the use of State standard metal implantable devices ... At present the patient has post-traumatic deformative osteoarthritis of the ankle joint ... Deformative osteoarthritis is a common complication for this type of inner joint fracture ... and has no connection to the surgery ..."
17. On 10 January 2010 the applicant qualified for permanent disability benefit, having been diagnosed with severe contracture of the left ankle after a lower leg bone fracture, with limited mobility of the lower limbs.
18. On 4 October 2010 the Department of Health held another consultation with the same participants (see paragraph 16 above), referring to a complaint sent by the applicant to the President of Armenia. The minutes of that consultation were similar in content to the minutes of the consultation held on 12 October 2009.
III. THE APPLICANT'S CRIMINAL COMPLAINT
19. On 17 December 2013 the applicant lodged a criminal complaint against Dr A.A. for medical malpractice resulting in serious damage to her health.
20. On 26 December 2013 the police instituted criminal proceedings under Article 130 § 1 of the Criminal Code (medical negligence – see paragraph 47 below).
21. On the same date the investigator ordered a forensic medical examination of the applicant.
22. In the course of the investigation Dr A.A. was questioned as a witness. He stated, in particular, that he had worked as a general surgeon at Artik Medical Centre since 1998. He had qualified as a general surgeon and in 2001 had been authorised by the Ministry of Health to practise general surgery. On 7 February 2008 he had operated on the applicant: bone fractures had been stabilised with metal orthopaedic plates and State standard screws. During surgical dressing, a collection of pus had been discovered, but this had cleared up and the applicant had been discharged in a good state of health. He had regularly visited her after her discharge from hospital and offered to surgically remove the metal implants, but she had refused, stating that she wished to have the operation performed in another hospital.
23. Dr K.K. was also questioned as a witness and stated, *inter alia*, that a collection of pus was a possible, undesirable and rare complication. Such a complication could appear in circumstances outside the practitioner's control but it was necessary to inform the patient of the possible complications prior to surgery and ensure that the latter still consented to the intervention, a protocol which was mandatory abroad and had started to apply in Armenia a couple of years previously.
24. On 21 February 2014 a panel of forensic medical experts issued a report. The relevant parts read as follows:
"... [the applicant's] medical examinations, diagnoses and treatments were carried out correctly and in a timely manner.

... According to the medical records submitted, the first operation (osteosynthesis) was performed correctly but later a complication developed in the form of an infection which had brought about osteomyelitis, the reason for which is impossible to determine precisely at the present time ..."

25. In the course of the investigation G.H., a member of the expert panel, was questioned and stated, *inter alia*, that a number of factors could have contributed to the appearance of the osteomyelitis; it had therefore not been possible to identify its specific cause. According to medical data, metal implants could also be a cause of subsequent infection bringing about osteomyelitis since in any case they were a foreign body.

26. On 7 June 2014 the investigator decided to terminate the proceedings for lack of *corpus delicti* in Dr A.A.'s actions. The decision referred, *inter alia*, to the forensic medical report of 21 February 2014 (see paragraph 24 above), the records of the consultations of 12 October 2009 and 4 October 2010 held by the Department of Health (see paragraphs 16 and 18 above) and the statements of the applicant, Dr A.A., Dr K.K. and other doctors, including forensic expert G.H. (see paragraphs 22, 23 and 25 above).

IV. THE APPLICANT'S APPEALS

27. On 20 June 2014 the applicant appealed against the investigator's decision to the prosecutor on the grounds that, *inter alia*, in the course of the investigation several issues had not been clarified, notably whether Dr A.A. had had the authority to perform the surgery, how long the metal implants should have stayed in the applicant's body, her reasons for not wanting Dr A.A. to surgically remove the implants, and the type of post-operative care she should have been provided with and by whom. In addition, she had not been informed of the possible complications that could arise from the surgery.

28. By a decision of 30 June 2014, the prosecutor dismissed the applicant's appeal, finding, in particular, that it had been established that A.A., as a qualified doctor, had had the authority to perform the surgery in question and had done so correctly.

29. On 25 August 2014, the applicant lodged an application for a judicial review of the investigator's and prosecutor's decisions of 7 and 30 June 2014 respectively (see paragraphs 26 and 28 above).

30. On 28 November 2014 the Shirak Regional Court ("the Regional Court") fully upheld the investigating authorities' decision not to prosecute Dr A.A.

31. The applicant lodged an appeal. She reiterated her previous arguments, including her complaints that she was not informed about the risks of the medical procedure she underwent at Artik Medical Centre and that Dr A.A. was not qualified to perform the surgery in question.

32. On 18 February 2015 the Criminal Court of Appeal allowed the applicant's appeal, quashed the Regional Court's decision of 28 November 2014 (see paragraph 30 above) and returned the case file to the prosecution. The relevant parts of its decision read as follows:

"... according to the material in the criminal case file, Dr [A.A.] is a qualified 'general surgeon' but not a specialist in 'traumatology and orthopaedics'. That is to say [Dr A.A.] did not have the authority to perform surgery on a person diagnosed with a 'closed comminuted fracture of the left distal tibia (lower leg bone) with significant displacement'.

... the [forensic medical] experts had not been informed that, following her discharge, [the applicant] had been treated by [Dr A.A.], who had visited the patient regularly; documents

attesting [to Dr A.A.'s] specialisation had not been submitted, therefore the experts did not have all the necessary information concerning the case at their disposal and their report cannot be considered to be full and accurate. Hence it is necessary to further question the experts to clarify the above-mentioned issues and, if necessary, to order an additional forensic medical examination by a medical panel.

The forensic [medical] examination should also clarify whether ... the complications and the disability resulted from the doctor's [surgery and post-operative care]."

V. RESUMPTION OF THE INVESTIGATION

33. On 5 March 2015 the criminal proceedings were resumed.

34. An additional forensic medical examination was ordered on 30 March 2015.

35. The investigator questioned Dr A.A. again as a witness. He submitted, in particular, that the metal implants used in the applicant's surgery had been State standard and had not been acquired by Artik Medical Centre. At some point in 2007 a patient with a fracture had left him the metal implantable devices during a consultation and stated that they could be used for surgery on other patients. The metal implants in question, which had been new and disposable, had been used in the applicant's surgery after disinfection.

36. On 15 July 2015 the panel of forensic medical experts delivered its report, the relevant parts of which read as follows:

"... According to the medical records submitted and X-ray images ... [the applicant's] examinations at Artik Medical Centre were carried out in a timely manner and the resulting ... diagnosis was correct. The surgical treatment offered to [the applicant], that is to say osteosynthesis with metal plates and screws, was indicated and, according to the X-ray images, generally performed correctly ... As regards the complications which arose at the post-operative stage ... not ruling out the probability of their development even in the event of quality specialist medical assistance ... it is not possible to state with certainty that there is a direct causal link between the actions of Artik Medical Centre personnel and the complications in question.

... taking into account [A.A.'s] narrow specialisation and in the absence of an orthopaedic trauma specialist, given the nature of [the applicant's] trauma, her transfer to a medical facility with an orthopaedic trauma unit was required so that specialist medical care could be provided. However, taking into account the nature of the trauma received, it is not possible to make definitive predictions as to whether or not in such a case it might have been possible to avoid the development of such complications at the post-operative stage.

... based on the medical records submitted and the material in the criminal case file, it is not possible to conclude definitively that [the applicant's] post-operative complications ... resulted from failures, omissions or errors on the part of the medical personnel of Artik Medical Centre.

... in view of [Dr A.A.'s] specialisation ... and the nature of [the applicant's] trauma, [Dr A.A.'s] duty was to ensure emergency first-aid medical assistance (immobilisation of the fracture, administration of analgesics ...). As regards [the applicant's] specialist treatment ... it was not within the scope of [Dr A.A.'s] specialist qualification but could be more suitably provided by an orthopaedic traumatologist. The provision at Artik Medical Centre of this type of medical assistance by a surgeon who was not a qualified orthopaedic traumatologist is an organisational

failure which, however, as noted above, in this case is not directly linked to the development of the complications ..."

37. In response to an earlier enquiry by the investigator, by a letter of 14 August 2015 the Ministry of Health submitted, in particular, as follows:

"... there are currently no unified legal acts setting out treatment guidelines and the rights and obligations of medical personnel of healthcare facilities, particularly those of a surgeon and traumatologist. A draft order of the Minister of Health on establishing the organisation of general surgical services is being prepared."

VI. TERMINATION OF THE INVESTIGATION AND THE APPLICANT'S APPEALS

38. On 18 September 2015 the investigator decided to terminate the criminal proceedings referring to, *inter alia*, the results of the additional forensic medical examination and Dr A.A's additional statement (see paragraphs 35 and 36 above). The investigator's decision stated, among other things, that in the course of the investigation the Ministry of Health had submitted that there were no legal acts regulating the activity of medical staff, particularly that of surgeons and traumatologists (see paragraph 37 above). Furthermore, according to information provided by the Shirak regional authority, the metal implants used during the applicant's surgery had not been acquired by Artik Medical Centre. In 2008 there had been no legal provisions specifying whether the sourcing of metal implants was the responsibility of the patient or the medical facility. It could not therefore be concluded that Dr A.A. was liable for any unlawful action.

39. The applicant appealed against the investigator's decision to the prosecutor, arguing, in particular, that it had not been clarified whether Dr A.A. had had the right to use the metal implants returned to him by another patient about a year before the applicant's surgery, whether those metal implants had been of a State-approved standard and good for use and whether there was a link between Dr A.A.'s actions and the complications that she had experienced. The appeal was dismissed by a decision of 15 October 2015 which stated, in particular, that it had been established during the investigation that A.A., as a doctor by profession, had had the right to perform the surgery, that the applicant's diagnosis had been correct and that the recommended surgery had corresponded to her diagnosis.

40. The applicant lodged a court complaint against the investigator's decision of 18 September 2015, which was upheld by the prosecutor on 15 October 2015.

41. On 24 December 2015 the Regional Court upheld the investigating authority's decision to terminate the criminal proceedings on the grounds that it had not been established during the investigation that there was a direct causal link between Dr A.A.'s actions and the damage to the applicant's health. In doing so, the Regional Court referred to the medical report of 15 July 2015 (see paragraph 36 above).

42. The applicant lodged an appeal. She raised similar arguments as before.

43. On 16 February 2016 the Criminal Court of Appeal dismissed the applicant's appeal, finding, in particular, that no link could be established between the applicant's post-surgical complications and the fact that she had been operated on by a surgeon who was not a qualified orthopaedic traumatologist which, as had been established, was an organisational failure on the part of the hospital. As regards the use of metal implants not obtained either by the hospital or the applicant, the Court of Appeal referred to the statement of Artik Medical Centre, according to which there

had been no legal provisions in place at the relevant time specifying whether the sourcing of metal implants was the responsibility of the patient or the medical facility.

44. The applicant lodged an appeal on points of law. She reiterated her previous arguments with regard to negligence on the part of Dr A.A., the latter's lack of relevant qualifications and his failure to provide her with information about the surgery and its possible complications. The applicant asked the Court of Cassation to determine, *inter alia*, whether the absence of relevant State regulations at the material time could be interpreted as being favourable for a medical practitioner who had acted outside the scope of his qualifications.

45. The applicant's appeal on points of law was declared inadmissible for lack of merit by a decision of the Court of Cassation of 4 May 2016. The applicant's representative in the domestic proceedings received that decision on 14 July 2016.

RELEVANT LEGAL FRAMEWORK AND PRACTICE

I. RELEVANT DOMESTIC LAW AND PRACTICE

A. Liability for medical negligence and the right to compensation

46. Armenian law does not provide a specific set of rules and principles concerning civil or disciplinary liability for medical negligence. The law does not define the concept of "medical error" or "medical malpractice". There are no professional disciplinary bodies competent to examine cases of medical negligence. Provisions relating to liability for medical negligence and the right to compensation are found in the Criminal Code, the Medical Care and Services of the Population Act and the Civil Code.

1. Criminal Code

47. Medical negligence is a criminal offence under Article 130 § 1 of the Criminal Code, which provides that failure to perform or improper performance of professional duties by medical and support personnel as a result of negligence or bad faith, which has negligently caused serious or moderately serious damage to the patient undergoing treatment, is punishable by a fine of one hundred to two hundred times the minimum salary or a maximum of three months' detention.

2. Medical Care and Services of the Population Act

48. The relevant provisions of the Medical Care and Services of the Population Act adopted on 4 March 1996 (hereinafter "the Medical Care Act") provide as follows:

Section 1: Basic concepts

"...

2. Providers of medical care and services: private entrepreneurs or legal entities providing a certain type or types of medical care and services, licensed in accordance with the legislation of the Republic of Armenia, irrespective of their legal and organisational structure, legal status and type of ownership, or public or community establishments which are not State or local governance bodies."

Section 6: Right to receive compensation for damage sustained during the provision of medical care and services

"Everyone shall have the right to receive compensation for damage caused to his or her health during the organisation and performance of medical care and services in accordance with the legislation of the Republic of Armenia."

Section 18: Medical care and service providers and their rights

"Providers of medical care and services in the Republic of Armenia shall have the right to provide appropriate medical care and services of selected types if they have obtained a licence to do so.
Individuals who have received the relevant education and specialisation in the Republic of Armenia and who hold a licence to practise certain types of medical activity in accordance with the procedure established by the legislation of the Republic of Armenia shall have the right to perform medical activity.
Individuals who have received medical education in other countries shall be allowed to carry out medical activity in the Republic of Armenia in accordance with the procedure established by the Government of the Republic of Armenia in compliance with the relevant international treaties ratified by the Republic of Armenia.
Providers of medical care and services ... shall have the right to ... insure their professional activity."
Section 19: Obligations and responsibility of medical care and service providers
"Providers of medical care and services must ... ensure compliance of medical care and services being provided with the established quantitative and qualitative standards ...
Providers of medical care and services, as well as individuals engaged in unlawful medical activity, shall be liable in accordance with the legislation of the Republic of Armenia for damage caused to a person's health through their own fault ..."

3. Civil Code

49. The relevant provisions of the Civil Code, as in force at the time material time, provide as follows.

50. Under Article 17 § 1, a person whose rights have been violated may claim full compensation for the damage suffered, unless the law or contract provides for a lower amount of compensation.
Damage is the expenses borne or to be borne by the person whose rights have been violated, in connection with restoring the violated rights, loss of property or damage to it (material damage), including loss of income, as well as non-pecuniary damage (Article 17 § 2).
Under Article 17 § 4, non-pecuniary damage may only be compensated in the cases provided for by the Civil Code (see paragraphs 52 and 57 below).

51. Article 129 § 1 provides that State bodies can appear in court on behalf of the State within the scope of their powers.

52. Article 162.1 § 2 provides that a person has the right to claim compensation for non-pecuniary damage if it has been established by the prosecuting authority or a court that, as a result of a decision, action or omission of a State or local governance body or one of its officials, a person's right to, *inter alia*, respect for his private life has been violated.

53. Article 332 provides for a general statutory limitation period of three years.

54. Article 344 sets out a list of types of civil claim to which the statutory limitation period does not apply. That list includes claims concerning compensation for damage caused to an individual's life and limb. However, where such claims are lodged more than three years after the right to claim compensation has arisen, they can be allowed only in respect of the three-year period preceding the lodging of the claim.

55. Article 1058 § 1 provides that damage caused to a person or his or her property, as well as damage caused to the property of a legal entity, is to be compensated in full by the person who has

caused such damage. A person not responsible for causing the damage may also be liable for compensation where stated by law. A person who has caused damage is exempted from paying compensation if it is established that the damage was caused through no fault of his or her own (Article 1058 § 2).

56. Article 1062 § 1 states that a legal person must compensate damage caused by its employees during the performance of work (service, official) duties.

57. Article 1087.2 §§ 3 and 4 provide that non-pecuniary damage suffered as a result of a violation of fundamental rights is to be compensated, irrespective of whether there is any fault on the part of a State official. Non-pecuniary damage is compensated from the State budget. If the fundamental right included in Article 162.1 (see paragraph 52 above) has been violated by a local governance body or one of its officials, non-pecuniary damage is compensated from the relevant local budget.

The amount of compensation for non-pecuniary damage suffered as a result of a violation of a person's right to respect for his or her private life shall not exceed two thousand times the minimum salary (Article 1087.2 § 7 (2)). The amount of compensation for non-pecuniary damage may, in exceptional cases, exceed the limit set out in paragraph 7 if the damage has had serious consequences (Article 1087.2 § 8).

A claim for compensation for non-pecuniary damage may be submitted to a court together with a claim seeking to establish a breach of the rights set out in Article 162.1 (see paragraph 52 above), within one year of the time the person became aware of the breach, as well as within six months of the date on which the judicial decision establishing the breach of the right in question came into force. If the breach has been established by a law-enforcement body, the claim for compensation for non-pecuniary damage may be submitted no earlier than two months but no later than one year after the date on which the person concerned became aware of the matter (Article 1087.2 § 9).

58. Since 1 November 2014 Article 17 § 2 (see paragraph 50 above) has included non-pecuniary damage in the list of types of civil damage for which compensation can be claimed in civil proceedings.

As a result, the Civil Code was supplemented by new Articles 162.1 and 1087.2 (see paragraphs 52 and 57 above), which regulate the procedure for claiming compensation for non-pecuniary damage from the State for a violation of certain rights guaranteed by the Armenian Constitution and the Convention.

Until the introduction of further amendments on 30 December 2015 (in force from 1 January 2016), compensation in respect of non-pecuniary damage could be claimed from the State where it had been established by a judicial ruling that a person's rights guaranteed by Articles 2, 3 and 5 of the Convention had been violated, as well as in cases of wrongful conviction. As a result of the amendments that entered into force on 1 January 2016, compensation for non-pecuniary damage could be claimed from the State for the finding of breach of a number of other rights, including those guaranteed under Article 8 of the Convention.

B. Informed consent

59. The relevant provisions of the Medical Care Act, as in force at the material time, read as follows:

Section 5: Rights of a person when receiving medical care and services

"When requesting and receiving medical care and services, everyone shall have the right to:

(a) choose a medical care and service provider;
...
(d) be informed about his or her disease and give consent to medical intervention;
(e) refuse medical intervention, except in the cases stipulated by this Law ..."
Section 7: An individual's right to information concerning his or her state of health
"Everyone shall have the right to easy access to information as to the state of his or her health, the results of examinations, the methods of diagnosis and treatment of the disease and related risks, the possible options for medical intervention, the consequences and results of treatment ..."
Section 8: Consent to medical procedures
"A person's consent is a necessary precondition for a medical procedure, except in the cases stipulated by this Law.
At the request of the practitioner or the patient, consent may be in writing."
Section 16: Medical care and services without a person's consent
"It shall be permitted to provide medical care and services without the consent of the patient or his or her legally authorised representatives in cases of life-threatening disease and in cases of disease posing a danger to the health of others in accordance with the legislation of the Republic of Armenia."
C. Administrative procedure
60. Under Article 3 § 1 of the then Code of Administrative Procedure, a person had the right to apply to the administrative court if he or she considered that his or her rights guaranteed by the Constitution, international treaties, laws and other legal acts had been or could have been violated as a result of administrative decisions, action or omissions of State or local governance bodies or their officials.
61. The relevant provisions of the Fundamentals of Administration and Administrative Procedure Act state as follows:
Section 3: Basic concepts
"The basic concepts used in this Act are defined as follows:
(1) administrative bodies: central and territorial governance bodies of the Republic of Armenia, as well as local governance bodies:
(a) central governance bodies of the Republic of Armenia: ministries... and other State bodies exercising administrative power [administration] in the territory of [Armenia];
(b) territorial governance bodies: governors (*մարզպետներ*);
(c) local governance bodies: community council and head of community ...
If there are State bodies other than those listed exercising administrative power [administration], they shall be considered administrative bodies for the purposes of this Act;
(2) administration: action of administrative bodies having external effect resulting in the adoption of administrative or normative decisions, as well as action or inaction which have actual consequences for individuals."
Section 53: Definition and types of administrative decision (*վարչական ակտ*)
"1. An administrative decision is a decision, instruction, order or other individual legal action having external effect adopted by an administrative body for the purposes of regulating a specific

case in the field of public law, and is directed to the prescription, amendment, elimination or recognition of rights and obligations for individuals.

...

2. For the purposes of this Act:

(a) a favourable administrative decision is a decision by which administrative bodies confer rights on individuals or create any other condition that improves the legal or factual situation of those individuals,

(b) an unfavourable administrative decision is an administrative decision by which administrative bodies refuse, interfere, restrict the enjoyment of the rights of individuals, impose any obligation on them or in any other way worsen their legal or factual situation,

(c) a combined administrative decision is an administrative decision which combines both the favourable and unfavourable provisions contained in administrative decisions."

Section 54: Forms of administrative decision

"1. As a rule, an administrative decision is adopted in writing as a decision, order, instruction or other form as provided for by the law.

Only a written administrative decision may be adopted as a result of administrative proceedings instituted on the basis of a complaint.

..."

Section 55: Requirements in respect of a written administrative decision

"...

4. A written administrative decision should contain the following:

...

(h) the period for contesting the administrative decision and the body, including the court, to which the administrative decision may be appealed;

...

(j) the official stamp of the administrative body which has adopted the administrative decision."

D. Relevant domestic case-law

62. The Government provided two examples of domestic court practice in which the issue of civil liability for medical malpractice was examined. They included, in particular, the following judgments:

1. Kentron and Nork-Marash District Court of Yerevan, case no. ԵԿԴ/2601/02/11, judgment of 2 November 2012; and

2. Avan and Nor-Nork District Court of Yerevan, case no. ԵԱՆԴ/0510/02/13, judgment of 16 September 2014.

The first case concerned the plaintiff's claim against a private clinic and two private hospitals as co-defendants seeking compensation for damage and costs and expenses sustained as a result of a medical error during surgery performed at the defendant private clinic and the subsequent treatment she had to undergo in the co-defendant hospitals. The plaintiff also complained that the doctor at the defendant clinic had not provided her with full and accurate information about the nature of the surgery and its possible risks, and had performed more extensive surgery without her consent. The civil claim was lodged shortly after criminal proceedings relating to the same allegations had been suspended for an indefinite period on the grounds that it had been

impossible to identify the person to be charged. Referring to the material in the criminal case file, including the relevant expert reports, the civil courts dismissed the claims, finding that no causal link could be established between the relevant medical professionals' guilt and the damage sustained by the plaintiff. The courts also found that the plaintiff had been properly informed of the nature and possible complications of the surgery prior to signing the general consent form and that the decision to perform more extensive surgery had been based on medical necessity which had arisen during the surgery.

The second case concerned a claim by a plaintiff who sought to recover the amount of her payment made to a private entity practising non-traditional treatment methods, on the grounds that her daughter's hearing function had not improved after the relevant treatment, contrary to what had been promised initially. The examination of the case was suspended by the civil court for several months until the criminal proceedings relating to the same facts were terminated. The plaintiff's claims were dismissed on the grounds that, *inter alia*, it had not been established that any damage had been caused to her daughter's health, and that she had paid the amount in question voluntarily.

63. The Government also provided several examples of recent domestic practice concerning compensation in respect of non-pecuniary damage for violations of Convention rights. Those examples concerned, in particular, cases of established violations of the rights guaranteed under Articles 5 and 6 of the Convention. In all cases, the domestic courts' awards in respect of non-pecuniary damage were based either on another judicial decision establishing a violation of the person's right guaranteed by the Convention or a decision of the investigating authority terminating the proceedings against the person on exonerating grounds. Furthermore, in one of the cases relied on by the Government (Ajapnyak and Davtashen District Court of Yerevan, case no. ԵԱԴԴ/3611/02/14, judgment of 10 February 2016) the domestic court dismissed the claim in respect of non-pecuniary damage on the grounds that, *inter alia*, the claimant had failed to submit a decision of the court or investigating authority establishing that there had been a violation of a Convention right as a result of a decision, action or omission on the part of a State or local governance body or one of its officials.

II. RELEVANT INTERNATIONAL LAW

64. Article 5 of the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine) reads as follows:

"An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time."

65. Paragraph 35 of the Explanatory Report to the Convention on Human Rights and Biomedicine states as follows:

"The patient's consent is considered to be free and informed if it is given on the basis of objective information from the responsible health care professional as to the nature and the potential consequences of the planned intervention or of its alternatives, in the absence of any pressure from

anyone. Article 5, paragraph 2, mentions the most important aspects of the information which should precede the intervention but it is not an exhaustive list: informed consent may imply, according to the circumstances, additional elements. In order for their consent to be valid the persons in question must have been informed about the relevant facts regarding the intervention being contemplated. This information must include the purpose, nature and consequences of the intervention and the risks involved. Information on the risks involved in the intervention or in alternative courses of action must cover not only the risks inherent in the type of intervention contemplated, but also any risks related to the individual characteristics of each patient, such as age or the existence of other pathologies. Requests for additional information made by patients must be adequately answered."

THE LAW

I. ALLEGED VIOLATION OF ARTICLE 8 OF THE CONVENTION

66. Relying on Article 8 of the Convention, the applicant complained that her disability had resulted from inadequate medical care received at Artik Medical Centre. She also complained that there had been no specific regulations relating to orthopaedic surgery in force at the relevant time and that she had not been informed of the nature and risks of the procedure before her operation. She lastly complained of the lack of an effective mechanism enabling her to hold accountable those at fault and obtain adequate redress. Article 8 of the Convention reads as follows:

"1. Everyone has the right to respect for his private and family life, his home and his correspondence.

2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."

A. Admissibility

1. The parties' submissions

67. The Government raised two objections in connection with the applicant's complaints.

68. Firstly, they submitted that the complaint concerning failure by the State to establish relevant regulations compelling hospitals to adopt appropriate measures for the protection of patients' physical integrity had been lodged outside the six-month time-limit. They contended that the applicant should have become aware of the level of the State's compliance with its positive obligation to have in place relevant regulations following the consultations held at the Department of Health, that is to say by 4 October 2010, the date of the second consultation (see paragraph 18 above). The applicant had failed to challenge the results of those consultations. Had she considered that taking any further action to challenge the results of the consultations in question would be ineffective, she should have lodged her complaint within six months from the date of the second consultation at the latest.

69. The applicant did not make any submissions in this connection.

70. Secondly, the Government raised an objection concerning exhaustion of domestic remedies in various aspects.

Firstly, they submitted that the applicant had failed to challenge the results of the consultations held by the Department of Health (see paragraphs 16 and 18 above). They argued that she could have appealed against the findings of those consultations as an administrative decision before the administrative court.

Secondly, the Government stated that the applicant had failed to lodge a civil claim for damages against Artik Medical Centre, it being a publicly funded healthcare facility, or the State.

The Government submitted that the applicant's complaints raised at domestic level had pursued the mere purpose of having Dr A.A. punished, rather than raising the issue of the liability of the State or the State-run Artik Medical Centre.

71. The applicant maintained that she had made use of the only effective remedy that had been available to her, that is, the criminal remedy.

2. The Court's assessment

72. The general principles on the rule of exhaustion of domestic remedies have been summarised in *Vučković and Others v. Serbia* ((preliminary objection) [GC], nos. 17153/11 and 29 others, §§ 69-77, 25 March 2014). That rule obliges those seeking to bring a case against the State before an international judicial body to use first the remedies provided by the national legal system, thus dispensing States from answering before an international body for their acts before they have had an opportunity to put matters right through their own legal systems. In order to comply with the rule, normal recourse should be had by an applicant to remedies which are available and sufficient to afford redress in respect of the breaches alleged (ibid., §§ 70 and 71, with further references).

73. The only remedies to be exhausted are those which are effective. It is incumbent on the Government claiming non-exhaustion to satisfy the Court that the remedy was an effective one, available in theory and in practice at the relevant time, that is to say, that it was accessible, was one which was capable of providing redress in respect of the applicant's complaints and offered reasonable prospects of success. Once this burden of proof has been satisfied, it falls to the applicant to establish that the remedy advanced by the Government was in fact exhausted, or was for some reason inadequate and ineffective in the particular circumstances of the case, or that special circumstances existed which absolved him or her from this requirement (ibid., § 77; see also *Kalashnikov v. Russia* (dec.), no. 47095/99, ECHR 2001-XI (extracts), with further references).

74. As a rule, the six-month period runs from the date of the final decision in the process of exhaustion of domestic remedies. Where it is clear from the outset, however, that no effective remedy is available to the applicant, the period runs from the date of the acts or measures complained of, or from the date of knowledge of that act or its effect on or prejudice to the applicant, and, where the situation is a continuing one, once that situation ends (see, among other authorities, *Mocanu and Others v. Romania* [GC], nos. 10865/09 and 2 others, § 259, ECHR 2014 (extracts)).

75. In this sense, the requirements contained in Article 35 § 1 concerning the exhaustion of domestic remedies and the six-month period are closely interrelated, since not only are they combined in the same Article, but they are also expressed in a single sentence whose grammatical

construction implies such a correlation (see *Berdzenishvili v. Russia* (dec.), no. 31697/03, ECHR 2004-II (extracts)).

(a) Six-month rule

76. The Government argued that the applicant's complaint with regard to the absence at the relevant time of regulations compelling hospitals to adopt appropriate measures for the protection of patients' physical integrity had been lodged outside the six-month time-limit. In particular, they contended that the six-month time-limit in respect of this complaint should be calculated at the latest from 4 October 2010, the date of the second consultation held by the Department of Health (see paragraphs 18 and 68 above).

77. The Court observes, however, that there is nothing to suggest that the questions relating to Dr A.A.'s medical specialisation or the origin of the metal implants used during the applicant's surgery were discussed by the Department of Health during the consultations referred to by the Government. In any event, the Government failed to indicate the competence of the Department of Health, if any, to examine issues with regard to the State's compliance with its regulatory duties and the possible redress it could afford to the applicant. In those circumstances, the Court finds that the minutes of the consultation held by the Department of Health cannot be considered a "final decision" within the meaning of Article 35 § 1 of the Convention. It cannot therefore be said that the applicant failed to comply with the six-month rule by not bringing her complaint concerning the lack of a relevant regulatory framework to the Court within six months of the consultation on 4 October 2010. The Court observes in this regard that issues relating to the lack of a regulatory framework were addressed in the criminal proceedings brought by the applicant against Dr A.A. (see, in particular, paragraph 38 above). The final decision in those proceedings was served on the applicant's representative on 14 July 2016 (paragraph 45 above), and the application was lodged within six months, on 29 December 2016. The Government's objection as to the failure to respect the six-month rule should therefore be dismissed.

(b) Non-exhaustion of domestic remedies

78. The Government argued that the applicant had failed to seek compensation from Artik Medical Centre or the State for the damage caused to her health. They also argued that she should have challenged the results of the consultations held by the Department of Health (see paragraphs 70 above and 87-89 below).

79. The Court notes that the Government's objection concerning the applicant's failure to exhaust the available domestic remedies is closely linked to the substance of her complaint concerning the State's failure to comply with its obligation under Article 8 of the Convention to set up an effective independent judicial system (see paragraphs 84-85 below). In particular, it concerns the options open to the applicant in terms of domestic avenues capable of clarifying the circumstances of the case, holding those responsible accountable and covering the damage she had suffered (see, *mutatis mutandis* and within the ambit of Article 2 of the Convention, *Scripnic v. the Republic of Moldova*, no. 63789/13, § 24, 13 April 2021).

80. Consequently, the Court decides to join the Government's objection of non-exhaustion of domestic remedies to the merits of the applicant's complaint under Article 8 of the Convention.

(c) Other grounds for inadmissibility

81. The Court notes that the application is neither manifestly ill-founded nor inadmissible on any other grounds listed in Article 35 of the Convention. It must therefore be declared admissible.

B. Merits

1. The parties' submissions

(a) The applicant

82. The applicant submitted that her disability had been caused by medical malpractice during her surgery at Artik Medical Centre, a public healthcare facility. Dr A.A. had lacked the necessary qualifications to perform the surgery since, as a general surgeon, he had not possessed the necessary specialisation in orthopaedic traumatology to allow him to perform the type of surgery that he had performed on her. At the same time, the respondent State had failed to establish relevant regulations. In particular, at the material time there had been no legal acts in place regulating surgical and traumatological services, nor any treatment guidelines in that area. Furthermore, the procedure for the procurement and use of orthopaedic appliances, including splints and screws, had not been regulated at the material time either.

83. In addition, prior to the surgery the applicant had not been informed of the possible complications, including the risk of osteomyelitis, a rare but possible side effect and foreseeable risk for that type of medical intervention, or of the origin of the metal implants placed in her leg. As had later become apparent, the metal implants had not been acquired by the hospital but had been left with Dr A.A. by another patient about a year before the surgery.

84. The applicant argued that the only effective mechanism for establishing the liability of a medical practitioner for medical negligence under domestic law was the criminal remedy provided for under Article 130 of the Criminal Code (see paragraph 47 above). However, in her case the investigating authorities had failed to conduct an effective and comprehensive investigation. The possibility of obtaining civil redress where the liability of the practitioner had not been established in criminal proceedings existed only in theory. The Government had not provided any evidence of existing judicial practice on compensation for damage, including non-pecuniary, caused to a person's health independently of criminal proceedings. On the contrary, both domestic cases relied on by the Government (see paragraph 62 above) demonstrated that the civil courts required a victim of medical negligence to prove the illegality of the doctor's actions and the causal link between those actions and the damage to the victim's health. The medical practitioner in question would be exempted from liability in the absence of guilt. The mechanism for establishing medical malpractice provided for by the general law of tort was therefore deficient. As regards, in particular, the possibility of claiming compensation for non-pecuniary damage from the State for a violation of a Convention right, this depended on whether or not the fact that there had been such a violation had been established by the investigating authority or a court.

85. Lastly, the applicant argued that no proper disciplinary remedy to establish the liability of medical practitioners was available in the domestic legal system.

(b) The Government

86. The Government maintained that the relevant provisions of the Medical Care Act (see paragraph 59 above) required medical practitioners to inform patients in advance of the type and methods of treatment, while consent of the patient to a medical intervention was a necessary precondition for treatment. Referring to the applicant's medical file at Artik Medical Centre, the

Government claimed that she had given informed consent to the surgery. The post-surgical complications experienced by the applicant were, as attested by medical experts, rarely encountered, while it had not been established that they had any connection to the surgery or post-operative treatment provided to her by Dr A.A.

87. The Government further maintained that domestic law had provided the applicant with an effective mechanism for establishing the possible liability of the medical practitioner and that of the State for the damage caused to her health and obtaining compensation. In particular, the applicant had had three types of remedies at her disposal: disciplinary, civil and criminal. However, she had only pursued the criminal remedy, which was an effective one, permitting liability of the practitioner to be established for alleged medical malpractice.

88. They argued that the civil courts had full jurisdiction to examine claims concerning medical malpractice in accordance with Articles 1058 and 1062 of the Civil Code (liability to compensate damage caused to another person and liability of an employer for damage caused by an employee – see paragraphs 55 and 56 above) independently from the outcome of the criminal proceedings. The civil courts were entitled to examine such claims in an independent manner, including ordering separate expert examinations and were not bound by the findings of the investigating authorities. Given that Artik Medical Centre had been a public hospital, the applicant could have claimed compensation from the State for damage caused to her health, including non-pecuniary, on the basis of the new Article 162.1 of the Civil Code (see paragraphs 52 and 58 above). In support of their arguments, the Government submitted two examples of medical negligence claims examined by the civil courts, and several recent examples of case-law in which awards of compensation for non-pecuniary damage were made against the State for violations of Convention rights (see paragraphs 62 and 63 above).

89. The Government finally submitted that domestic law provided for the possibility of appealing against administrative decisions. However, the applicant had failed to challenge the results of the consultations held by the Department of Health (see paragraphs 16 and 18 above) before the administrative court.

2. The Court's assessment

(a) General principles

90. It is now well established that although the right to health is not as such among the rights guaranteed under the Convention or its Protocols (see *Fiorenza v. Italy* (dec.), no. 44393/98, 28 November 2000; *Pastorino and Others v. Italy* (dec.), no. 17640/02, 11 July 2006; and *Dossi and Others v. Italy* (dec.), no. 26053/07, 12 October 2010), the High Contracting Parties have, parallel to their positive obligations under Article 2 of the Convention, a positive obligation under Article 8, firstly, to have in place regulations compelling both public and private hospitals to adopt appropriate measures for the protection of their patients' physical integrity and, secondly, to provide victims of medical negligence with access to proceedings in which they can, where appropriate, obtain compensation for damage (see *Trocellier v. France* (dec.), no. 75725/01, ECHR 2006-XIV; *Codarcea v. Romania*, no. 31675/04, §§ 102 and 103, 2 June 2009; *Spyra and Kranczkowski v. Poland*, no. 19764/07, §§ 82 and 86-87, 25 September 2012; *Csoma v. Romania*, no. 8759/05, §§ 41 and 43, 15 January 2013; and *S.B. v. Romania*, no. 24453/04, §§ 65-66, 23 September 2014).

91. The Court reiterates that the principles which emerge from its case-law under Article 2 of the Convention in the field of medical negligence also apply under Article 8 when it comes to breaches of physical integrity that do not involve the right to life (see *Aksoy and Others v. Turkey* (dec.), no. 12370/10, § 48, 23 January 2018 and, for these principles, *Lopes de Sousa Fernandes v. Portugal* [GC], no. 56080/13, §§ 185-96, and §§ 214-21, 19 December 2017, with further references).

92. In the context of alleged medical negligence, the States' substantive positive obligations relating to medical treatment are limited to a duty to have in place an effective regulatory framework compelling hospitals, whether private or public, to adopt appropriate measures for the protection of patients' health (see, *mutatis mutandis*, *Lopes de Sousa Fernandes*, cited above, § 186).

93. As regards, in particular, the issue of informed consent, the Court has stressed the importance for individuals facing risks to their health to have access to information enabling them to assess those risks. It has considered it reasonable to infer from this that the Contracting States are bound, by virtue of this obligation, to adopt the necessary regulatory measures to ensure that doctors consider the foreseeable consequences of a planned medical procedure on their patients' physical integrity and to inform patients of these consequences beforehand, in such a way that the latter are able to give informed consent (see *Trocellier*, cited above, and *Codarcea*, cited above, § 105).

94. In determining whether the State has fulfilled its positive procedural obligation to set up an effective independent judicial system, the Court will examine whether the available legal remedies, taken together, as provided for in law and applied in practice, secured the effective legal means capable of establishing the relevant facts, holding accountable those at fault and providing appropriate redress to the victim (see *Sarishvili-Bolkvadze v. Georgia*, no. 58240/08, § 79, 19 July 2018).

95. At the same time, the choice of means for ensuring that the positive obligations under the Convention are fulfilled is in principle a matter that falls within the Contracting State's margin of appreciation. There are different avenues for ensuring that Convention rights are respected, and even if the State has failed to apply one particular measure provided by domestic law, it may still fulfil its positive duty by other means. However, for this obligation to be satisfied, such proceedings must not only exist in theory but also operate effectively in practice (see *Lopes de Sousa Fernandes*, cited above, § 216, with further references).

(b) Application of those principles to the present case

96. Turning to the facts of the present case, the Court notes that following the surgery performed by Dr A.A. in a public hospital, the applicant experienced post-surgical complications in the form of osteomyelitis. She was then obliged to undergo further medical procedures but was eventually left permanently disabled (see paragraphs 7-14 and 17 above).

97. The Court notes that there is nothing to indicate, and it has not been suggested by the applicant, that the damage to her health was caused intentionally. Furthermore, no issue of knowingly endangering an individual's physical integrity by denial of access to relevant treatment was raised either at domestic level or before the Court. Nor was there any question of a systemic or structural dysfunction in hospital services. Therefore, the present case does not fall within the two exceptional categories of cases directly engaging State responsibility for the acts and omissions of healthcare providers (see, in particular, *Lopes de Sousa Fernandes*, cited above, §§ 191-92). Under

these circumstances, the Court is unable to find a Convention breach on the sole basis of the doctor's alleged negligence in performing the medical procedure on the applicant.

98. The applicant's complaints, however, mainly refer to the absence at the material time of a relevant regulatory framework, the failure to provide her with information about the procedure and the associated risks and an inadequate response from the authorities (see paragraphs 66 and 82-85 above). The Court will examine these allegations in turn.

(i) Existence of a relevant regulatory framework

99. The Court reiterates at this juncture that it has interpreted the positive obligations in the context of healthcare as requiring States to put in place an effective regulatory framework (see *Lopes de Sousa Fernandes*, cited above, §§ 185-96, and paragraph 92 above). Accordingly, the applicant's complaints must be addressed from the angle of the State's compliance with its regulatory duties.

100. Having regard to the material before it, the Court takes note of the fact that at the material time there was a requirement that medical practitioners hold a licence corresponding to their specialisation to practise certain types of medical activity (see section 18 of the Medical Care Act cited in paragraph 48 above). At the same time, there were no legal regulations regarding the surgical specialisms of general surgery and traumatology and orthopaedics or regarding the procurement of orthopaedic appliances (see paragraphs 37 and 38 above).

101. The Court takes further note of the fact that it was established in the course of the criminal proceedings relating to the applicant's complaints of medical malpractice that her surgery had been performed by a medical practitioner who did not have the relevant specialisation (see paragraph 36 above). It was also established that during the surgery in question, metal implants not officially obtained by Artik Medical Centre had been placed in the applicant's leg (see paragraph 38 above). These facts are not in dispute between the parties.

102. That said, the Court observes that although it was indicated in the additional forensic report that the nature of the applicant's trauma had required specialist treatment which was not within the scope of Dr A.A.'s qualifications, the experts nevertheless concluded that her surgery had generally been performed correctly and that the complications which had arisen at the post-operative stage were not directly linked to the fact that she had not been operated on by a relevant specialist. In addition, even though they did not specifically address the question of the possible link between the post-operative complications experienced by the applicant and the metal implants used during her surgery, the forensic experts found no established link between those complications and any failures, omissions or errors on the part of the personnel of the Artik Medical Centre (see paragraph 36 above).

103. The Court notes in this connection that, as stated in the case of *Lopes de Sousa Fernandes* (cited above, § 188, with further references), the mere fact that the regulatory framework may be deficient in some respect is not sufficient in itself to raise an issue under Convention. It must be shown to have operated to the patient's detriment. In the Court's opinion, in the present case there is insufficient evidence to demonstrate that the regulatory deficiencies mentioned in paragraph 100 above operated to the applicant's detriment (compare and contrast *Sarishvili-Bolkvadze*, cited above, §§ 74-77). That is, in the material before the Court (see paragraphs 36 and 102 above) there is insufficient evidence to indicate that the deficiencies at issue led or contributed to the damage

caused to the applicant's health (see *Lopes de Sousa Fernandes*, cited above, § 188, and the case-law cited therein).

104. As regards the specific matter of informed consent, the Court notes that there was a relevant legal framework allowing individuals facing risks to their health to have access to information enabling them to assess those risks (see paragraph 93 above). In particular, under sections 5 and 7 of the Medical Care Act at the material time, a patient had the right to be informed of, *inter alia*, the methods of diagnosis and treatment of the disease and the related risks, as well as the consequences and results of treatment. Furthermore, under section 8, a patient's consent to a medical procedure, which could be given in writing at the request of the patient or the relevant medical practitioner, was a necessary precondition for receiving the proposed treatment (see paragraph 59 above). Thus, the Court does not consider that the regulatory framework for obtaining a patient's informed consent was defective.

105. In view of the above, the Court concludes that there has been no violation of Article 8 of the Convention in respect of the alleged absence of a relevant regulatory framework.

(ii) Access to a procedure capable of establishing the relevant facts, holding accountable those at fault and providing the applicant with appropriate redress

106. It remains for the Court to ascertain whether the applicant had access to a procedure capable of establishing the relevant facts, holding accountable those at fault and providing her with appropriate redress.

107. The Court observes that the applicant initially complained about her treatment by Dr A.A. to various State agencies and then sought to establish the latter's liability in criminal proceedings. In those proceedings she alleged, in particular, that she had been the victim of medical malpractice, which had resulted in serious damage to her health (see paragraph 19 above), and that she had not been informed about the risks of the medical intervention she had undergone (see paragraphs 27, 31, 42 and 44 above). She did not bring a civil claim for damages, arguing that it would have been ineffective (see paragraph 84 above).

108. In this connection, the Court reiterates that in view of the broad margin of appreciation enjoyed by the High Contracting Parties in laying down their healthcare policy, and in choosing how to comply with their positive obligations and organise their judicial systems, there is no basis on which to hold that the Convention requires a special mechanism which facilitates the bringing of medical malpractice claims at domestic level. It should further be borne in mind that in discharging their positive obligations towards the alleged victims of medical malpractice, the authorities must also have regard to counter-considerations, such as the risk of unjustifiably exposing medical practitioners to liability, which can compromise their professional morale and induce them to practise, often to the detriment of their patients, what has come to be known as "defensive medicine" (see *Vasileva v. Bulgaria*, no. 23796/10, § 70, 17 March 2016, and *Jurica v. Croatia*, no. 30376/13, § 89, 2 May 2017).

109. Furthermore, in medical negligence cases, where the infringement of the right to physical integrity is not caused intentionally, the positive procedural obligation, which concerns the requirement to set up an effective judicial system, will be satisfied if the legal system affords victims a remedy in the civil courts, either alone or in conjunction with a remedy in the criminal courts, enabling any liability of the doctors concerned to be established and any appropriate civil

redress to be obtained. Disciplinary measures may also be envisaged (see *Calvelli and Ciglio v. Italy* [GC], no. 32967/96, § 51, ECHR 2002-I, and *Vo v. France* [GC], no. 53924/00, § 90, ECHR 2004-VIII). In such cases, therefore, the Court, having regard to the particular features of a respondent State's legal system, has required applicants to make use of the legal avenues whereby they could have their complaints of medical negligence duly considered. This is because of the rebuttable presumption that any of those procedures, notably civil redress, are in principle apt to satisfy the State's obligation to provide an effective judicial system (see *Lopes de Sousa Fernandes*, cited above, § 137). Therefore, the positive procedural obligation under Article 8 to set up an effective judicial system did not necessarily call for a criminal-law remedy on the facts of the instant case. However, if deemed effective, such proceedings would by themselves be capable of satisfying the procedural obligation of Article 8 (see *Mehmet Ulusoy and Others v. Turkey*, no. 54969/09, § 92, 25 June 2019, with further references, and, *mutatis mutandis*, and albeit in the context of defamation proceedings examined under Article 6 § 1 of the Convention, *Petrella v. Italy*, no. 24340/07, § 53, 18 March 2021).

110. In this connection, the Court observes that the criminal-law remedy was made available to the applicant and that she pursued it. In view of the facts of the present case and the state of the domestic criminal law (see paragraph 47 above), her recourse to the criminal-law remedy does not appear unreasonable. This is also evident from the fact that the domestic authorities instituted criminal proceedings and carried out a criminal investigation into the possibility that the damage to the applicant's health had been caused by the negligent performance of Dr A.A.'s professional duties (see paragraph 20 above).

111. As noted in paragraph 102 above, the investigation into the applicant's allegations of malpractice, with reference to the findings of experts, the objectivity of which was at no point questioned by her, did not reveal a direct causal link between the damage to her health and the medical treatment provided to her by Dr A.A. Although it was established that Dr A.A. had operated on the applicant without having the relevant qualifications for the surgery in question and had implanted metal devices of unknown origin into her leg, the investigative bodies and, subsequently, the courts found that he was not subject to criminal liability (see paragraphs 38 and 43 above). The Court notes here that, except in cases of manifest arbitrariness or error, it is not its function to call into question findings of fact made by the domestic authorities, particularly when it comes to scientific expert assessments, which by definition call for specific and detailed knowledge of the subject (see *Počkajevs v. Latvia* (dec.), no. 76774/01, 21 October 2004).

112. That said, the Court observes that at no point during the investigation or court proceedings were the applicant's complaints with regard to the absence of her informed consent to the surgery and its possible risks examined (see paragraphs 19, 27, 31, 42 and 44 above). Notably, the courts carrying out a judicial review of the decisions of the investigative authorities did not decline jurisdiction to examine the applicant's complaints in that regard.

113. The Court further observes that, after it was established that the metal implants used during the applicant's surgery had not been officially sourced by the hospital but had been left with Dr A.A. by another patient more than a year before the surgery (see paragraphs 35 and 38 above), the applicant specifically complained about the fact that the investigation had failed to clarify whether those metal implants had been good for use and whether there was a link between Dr A.A.'s

actions and the complications she had experienced (see paragraph 39 above). However, her complaints in this regard were also either left unexamined (see paragraphs 40 and 41 above) or rejected with reference to the absence at the relevant time of regulations concerning the sourcing of metal implants, without addressing the substance of the applicant's complaint in that regard (see paragraph 43 above).

114. In the Court's view, the matters raised by the applicant concerned important factual issues pertaining to the medical care provided to her and the possible liability of the health professionals involved, which called for a proper examination (see, *mutatis mutandis*, *Csoma*, § 52, and *Lopes de Sousa Fernandes*, § 172, both cited above). However, as noted above, those matters were not addressed in the course of the criminal proceedings, which leads the Court to conclude that they did not meet the requirement of thoroughness (see *Lopes de Sousa Fernandes*, cited above, § 226).

115. In view of the above shortcomings, the Court considers that the criminal proceedings in the present case were not effective for the purposes of Article 8. It is further necessary to examine whether the applicant had a civil-law remedy available to her.

116. In particular, considering that the applicant only pursued the criminal-law remedy, the Court has to determine whether it was incumbent on her to pursue the civil-law remedy in order to dispose of the obligation to exhaust domestic remedies. This requires establishing, firstly, whether the civil-law remedy was effective in theory and in practice at the relevant time; that is to say that the remedy was accessible, capable of providing redress in respect of the applicant's complaints and offered reasonable prospects of success and, secondly, whether it would pursue essentially the same objective as the criminal-law remedy, that is to say, whether the civil-law remedy would add any essential elements that were unavailable through the use of the criminal-law remedy (see *Dumpe v. Latvia* (dec.), no. 71506/13, § 61, 16 October 2018).

117. The Government argued that the applicant could have brought a civil action against Artik Medical Centre on the basis of Articles 1058 and 1062 of the Civil Code. They relied on two examples of domestic case-law where the civil courts had examined medical negligence claims (see paragraphs 55, 56, 62, 87 and 88 above).

118. It appears that in Armenia compensation for damage to health can in principle be claimed under tort law or contract law (see paragraphs 49-57 above). Indeed, the domestic case-law relied on by the Government shows that medical negligence claims have been the subject of adjudication before the civil courts (see paragraph 62 above).

119. That said, the Court notes, however, that compensation for non-pecuniary damage is not included in the general right to compensation under domestic law. In particular, although since the legislative amendments, which entered into force on 1 November 2014, Article 17 of the Civil Code has included the possibility of claiming compensation for non-pecuniary damage (see paragraph 58 above), it is clear from Articles 17 § 4, 162.1 and 1087.2 of the same Code that such a possibility is strictly limited to claiming compensation for non-pecuniary damage from the State for an established violation by State or local governance bodies or their officials of the fundamental rights guaranteed under the Convention (see paragraphs 50, 52 and 57 above).

120. In so far as the Government argued that, Artik Medical Centre being a public hospital, the applicant could have claimed compensation for non-pecuniary damage from the State directly under Article 162.1 of the Civil Code, as amended since 1 January 2016 to provide for the

possibility of claiming compensation for non-pecuniary damage for a violation of the rights protected by the Armenian Constitution and the Convention (see paragraphs 52 and 58 above, as well as the Government's argument summarised in paragraph 88 above), the Court observes the following.

121. It is true that while those provisions entered into force long after the applicant's operation which gave rise to her complaints, it appears that in principle her claim would not be statute-barred (see paragraphs 53 and 54 above). That said, the Court notes that the newly introduced Article 162.1 of the Civil Code states that a person may claim compensation for non-pecuniary damage from the State if a violation has been established by a judicial ruling (see paragraph 52 above). At the same time, the newly introduced Article 1087.2 of the same Code, which sets out the relevant procedure, provides that a claim against the State for compensation for non-pecuniary damage may be submitted to a court together with a claim seeking to establish a breach of the rights guaranteed by the Convention (see paragraph 57 above). The Court observes, however, that in accordance with the current practice, the domestic courts require that a claim for compensation for non-pecuniary damage for a violation of a Convention right be based on a decision of the prosecuting authority or a court ruling obtained in another set of judicial proceedings (see, in particular, the examples of domestic practice summarised in paragraph 63 above).

122. Furthermore, there is nothing to suggest that under domestic law a public hospital can be subject to litigation as a State or administrative body in the civil or administrative courts (see paragraphs 51 and 60 above). The Court observes, in this connection, that section 1 of the Medical Care Act expressly states that public hospitals are not State bodies (see paragraph 48 above), while it does not follow from section 3 of the Fundamentals of Administration and Administrative Procedure Act that a public hospital could be considered an administrative body within the meaning of that provision (see paragraph 61 above).

123. Therefore, having regard to the above-mentioned provisions of domestic law and in the absence of any domestic case-law provided by the Government, the Court finds that there is nothing to support their argument that compensation in respect of non-pecuniary damage could be claimed from the State directly in relation to the activity of a public hospital (see the Government's arguments in this respect, summarised in paragraph 88 above).

124. Besides, as noted in paragraph 97 above, the present case does not fall within the two exceptional categories of cases directly engaging State responsibility for the acts and omissions of healthcare providers. In those circumstances, it is very doubtful what prospects of success, if any, a claim seeking to establish a breach of Article 8 of the Convention by the State on account of the alleged medical malpractice by Dr A.A. could have had so that, as argued by the Government (see paragraph 88 above), it could have resulted in compensation for non-pecuniary damage based on Article 162.1 of the Civil Code (see paragraph 52 above).

125. In these circumstances, the Court finds that it has not been established that there was an effective civil-law remedy capable of providing redress in respect of the applicant's complaints and offering reasonable prospects of success. In view of this finding, the Court considers that it is not necessary to further determine whether the civil-law remedy would have pursued essentially the same objective as the criminal-law remedy (see paragraph 116 above).

126. The Government also claimed that the applicant had had disciplinary remedies available to her (see paragraph 87 above). They further argued that an administrative action against the results of the consultations held following the applicant's complaints to various State agencies (see paragraph 89 above) had constituted an effective remedy for her complaints.

127. The Court observes that in Armenia there are no professional disciplinary bodies with the authority to examine cases of medical malpractice (see paragraph 46 above). It is true that disciplinary measures may be applied by the relevant authorities, including the Ministry of Health. However, those measures are connected to employment regulations rather than the establishment of medical malpractice as such (see *Movsesyan v. Armenia*, no. 27524/09, § 71, 16 November 2017).

128. As to the argument that the applicant could have contested the results of the consultations held by the Department of Health (see paragraph 89 above), the Court notes that the Government did not to provide any examples of domestic administrative case-law where a "minutes of a consultation", that is, the transcript of a meeting, had been considered an administrative decision subject to administrative judicial review.

129. The Court observes, in this connection, that under domestic administrative law a person can seek a judicial review of an "administrative decision" which has been defined in the law as "a decision, instruction, order or other individual legal action" which has been adopted by an administrative body and which creates rights and obligations for the person concerned (see paragraphs 60 and 61 above). At the same time, section 3 of the Fundamentals of Administration and Administrative Procedure Act, which sets out the types of administrative bodies with the authority to adopt administrative decisions, defines territorial governance bodies as governors. Furthermore, section 55 of the same act states that a written administrative decision must indicate the body, including the court, to which an appeal can be made and contain the official stamp of the administrative body which has adopted it (see paragraph 61 above). The Court observes that none of those requirements were met in the minutes of the consultations concerned (see paragraphs 16 and 18 above).

130. The effectiveness of this remedy therefore appears highly questionable, all the more so since it is not clear what type of redress the applicant could have been provided with had she pursued such a complaint.

131. In view of the foregoing, the Court considers that it cannot be said that the State provided the applicant with an effective procedure enabling her to bring her medical malpractice claim and obtain compensation for the medical malpractice to which she alleged to have fallen victim.

132. For these reasons, the Court dismisses the Government's objection of non-exhaustion of domestic remedies and concludes that there has been a violation of Article 8 of the Convention.

II. APPLICATION OF ARTICLE 41 OF THE CONVENTION

133. Article 41 of the Convention provides:

"If the Court finds that there has been a violation of the Convention or the Protocols thereto, and if the internal law of the High Contracting Party concerned allows only partial reparation to be made, the Court shall, if necessary, afford just satisfaction to the injured party."

A. Damage

134. The applicant claimed 6,000 euros (EUR) in respect of non-pecuniary damage.

135. The Government submitted that the amount claimed in respect of non-pecuniary damage was excessive and unreasonable.
136. Making its assessment on an equitable basis, the Court awards the applicant EUR 4,500 in respect of non-pecuniary damage.
B. Costs and expenses
137. The applicant also claimed EUR 2,900 for the costs and expenses incurred before the Court.
138. The Government submitted that the applicant's claim for costs had not been duly substantiated.
139. According to the Court's case-law, an applicant is entitled to the reimbursement of costs and expenses only in so far as it has been shown that these have been actually and necessarily incurred and are reasonable as to quantum. In the present case, the applicant has failed to submit any legal documents, such as a contract signed with her representatives or invoices issued by them, in support of her claim. In such circumstances, the Court rejects the applicant's claim under this head.
C. Default interest
140. The Court considers it appropriate that the default interest rate should be based on the marginal lending rate of the European Central Bank, to which should be added three percentage points.

FOR THESE REASONS, THE COURT, UNANIMOUSLY,

1. *Joins* to the merits the Government's objection of non-exhaustion of domestic remedies and *dismisses* it;
2. *Declares* the application admissible;
3. *Holds* that there has been no violation of Article 8 of the Convention with respect to the obligation to provide a relevant regulatory framework;
4. *Holds* that there has been a violation of Article 8 of the Convention with respect to the lack of access to a procedure capable of establishing the relevant facts, holding accountable those at fault and providing the applicant with appropriate redress;
5. *Holds*
(a) that the respondent State is to pay the applicant, within three months from the date on which the judgment becomes final in accordance with Article 44 § 2 of the Convention, EUR 4,500 (four thousand five hundred euros), to be converted into the currency of the respondent State at the rate applicable at the date of settlement, plus any tax that may be chargeable, in respect of non-pecuniary damage;
(b) that from the expiry of the above-mentioned three months until settlement simple interest shall be payable on the above amount at a rate equal to the marginal lending rate of the European Central Bank during the default period plus three percentage points;
6. *Dismisses* the remainder of the applicant's claim for just satisfaction.
Done in English, and notified in writing on 8 February 2022, pursuant to Rule 77 §§ 2 and 3 of the Rules of Court.

Ilse Freiwirth Deputy Registrar
Yonko Grozev President