

A European perspective on Medical Negligence Law

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European Union



- A union of 27 sovereign countries with a huge variety in cultural backgrounds
- European Union provides some central direction on harmonization of the law:
 - Regulations (binding legislation which must be applied across the EU)
 - Directives (setting out a goal that all countries should achieve, but they can decide how)

Consumer safety

- Products (directive 85/374/EEC):
 - No-fault liability on the part of the manufacturer for damages caused by a defect in his product
 - A product is defective when it does not provide the safety which a person is entitled to expect
 - Very limited grounds for defense
 - Member states had to comply in their national laws within three years

Patient safety

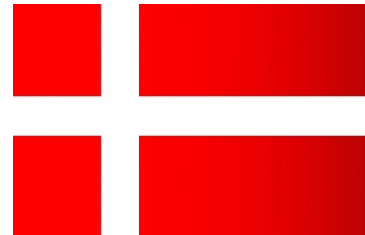
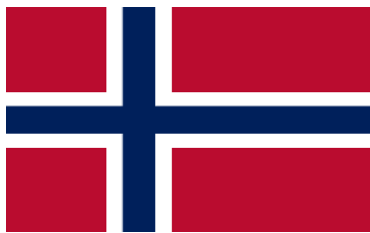
- In 1989/1990 the European Commission published a predraft of a directive regarding no-fault liability for damages caused by defective services.
- A service was proposed to be defective if it did not offer the safety one was entitled to expect.
- This directive was supposed to include medical care.
- After huge protests (also from the medical community) the proposal was withdrawn.

Medical negligence law

- Every country has its own liability law which also applies to medical negligence. The burden of proof is usually on the patient.
- High quality, independent and critical medical expertise is in general hard to find.
- Some countries have implemented a no-fault compensation scheme.

Alternative compensation schemes

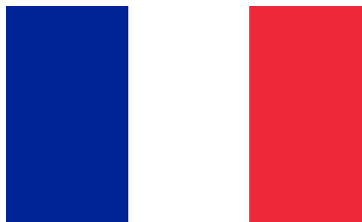
- Scandinavia



- Belgium



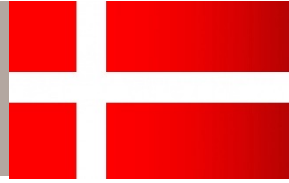
- France



Scandinavia

- Scandinavian countries have no-fault compensation schemes embedded in a large social benefits structure.

Denmark



Danish Act on the Right to Complain and Receive Compensation

Compensation (through a mandatory administrative procedure) is paid if the injury was most probably caused in one of the following situations:

- When it can be assumed that an experienced specialist would have acted differently, and the injury would have been avoided.
- When the injury was caused by a fault or failure of technical equipment.
- When the injury could have been avoided if a different available treatment technique or method had been used.
- **When a patient contracts an infection or other complications of a more complex nature than what a patient is generally expected to tolerate due to an examination, including diagnostic interventions or treatment.**
- *“... All authorized health personnel are responsible for informing the injured party if they become aware of injuries in their undertaking that will give entitlement to compensation ...”*
- 2022: 12.500 applications / €98M compensation

Thanks to Soeren Vagner Nielsen, Copenhagen

Belgium



A patient who suffers damages as a direct consequence of a medical treatment can apply for compensation if these damages are – all aspects taken into account - considered to be **an abnormal outcome of the treatment** and not primarily related to the condition of the patient him- or herself. The damages must also be **substantial**. The government Fund for Medical Accidents handles the applications for these ‘Medical Accidents without Liability’. If the fund finds that liability exists, it will reach out to the doctor and/or the hospital and their insurers. The procedure with the fund has no expense for the patient.

A patient holds the option to litigate in Court but not during the time the Fund is handling the application. Compensation cannot be received twice.

Thanks to Peter De Maeyer, Antwerpen

France



French Public Health Law provides that a patient needs to be compensated if he or she suffers from an “**abnormal and severe disadvantage**” as a result of medical treatment. France has schemes which provide no-fault compensation (barèmes) under such circumstances. CCI is the body which determines whether or not such a disadvantage exists. Payments are being done from a fund (ONIAM) which is publicly financed through a French social security organisation. The patient can sue ONIAM and/or the hospital in Court but cannot collect twice.

Thanks to Sebastian van Teslaar, Paris

The Netherlands



- The Dutch Bar Association has launched a strictly regulated experiment on contingency fee. It has created modest interest among plaintiff lawyers.
- Medical negligence is based on full fault liability.
- No-fault alternative is not available.
- Medical records play a crucial role:

Supreme Court (1987): “doctors and hospitals are under the obligation to provide sufficient information to the patient in order to enable him or her to proof the claim”. If this obligation is not met, it could lead to the shifting of the burden of proof.

- Distinction between medical advisors on both sides and medical experts who are mainly appointed by the Courts.

Access to Justice in European countries

- In most countries no contingency fees.
- In general no trials by jury, but by Courts with appointed judges.
- European damages generally lower than US without punitive damages.
- Suitable medical experts are hard to find.

Involvement of the criminal system

- In matters of severe negligence, it is possible to file a complaint under criminal law.
- It depends on National Law whether the criminal procedure can lead to compensation of damages.
- Common practice in some countries is to file a criminal complaint to have the Public Prosecutor determine whether there is negligence.

Criminal investigation of medical cases in Poland

- In 2016 prosecutor offices got the possibility to open medical malpractice departments.
- Thousands of medical cases investigated by criminal prosecutors each year (5739 in 2018 and 5206 in 2021), leading to 100-200 indictments
- No information about convictions
- At the same time in 2018 only 857 civil cases for compensation for damages caused by health institutions.
- The crimes taken into consideration are involuntary manslaughter and exposure to danger.
- Note: criminal cases concerning gynecologists and obstetricians pertaining to the very strict anti-abortion law in Poland are probably part of these numbers.
- The medical society is talking about “white witch hunting”.

Thanks to Sylwia Mysliwska, Kraków

European Court of Human Rights

- European Convention of Human Rights
 - Article 2 Right to life: Everyone's right to life shall be protected by law.
 - Article 6 Right to a fair trial
 - Article 8 Right to respect for private and family life
- European Court after exhaustion of national remedies
- In medical negligence cases the Court has handled complaints about the lack of an effective judicial system in case of the loss of life by medical negligence.

Case of Calvelli and Ciglio vs Italy

17 January 2002 (32967/96)

48. The Court reiterates that the first sentence of Article 2, which ranks as one of the most fundamental provisions in the Convention and also enshrines one of the basic values of the democratic societies making up the Council of Europe (see, among other authorities, *McCann and Others v. the United Kingdom*, judgment of 27 September 1995, Series A no. 324, pp. 45-46, § 147), enjoins the State not only to refrain from the “intentional” taking of life, but also to take appropriate steps to safeguard the lives of those within its jurisdiction ...

49. Those principles apply in the public-health sphere too. The aforementioned positive obligations therefore require States to make regulations compelling hospitals, whether public or private, to adopt appropriate measures for the protection of their patients' lives. They also require an effective independent judicial system to be set up so that the cause of death of patients in the care of the medical profession, whether in the public or the private sector, can be determined and those responsible made accountable.

Cross border cases I

- For example: a Spanish patient treated in The Netherlands
- What law applies to his or her negligence claim?
- Regulation Rome I (2008) on the law applicable to contractual obligations:
 1. Law of (expressly and clearly made) choice, or in absence thereof
 2. Law of the country where the service provider has his or her habitual residence

Cross border cases II

- Directive (2011) on the application of patient's rights in cross-border healthcare:
 - Rules for facilitating the access to safe and high-quality cross-border health care
 - Cross-border healthcare shall be provided in accordance with:
 - Legislation of member state of treatment
 - Standards and guidelines on quality and safety laid down by the member state of treatment
 - Union legislation on safety standards

Thank you for your attention!



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