“Gelli” Law – The introduction of a two paths for medical liability

The so-called “Gelli” Law (Law no. 24 of 8 March 2017), named after its main drafter, finally came into force on 1 April 2017. The new law sets the framework for medical malpractice.

According to the Italian Parliament, the objective of this new regulation is to harmonize the relationship between doctors and patients, in particular: monitoring the medical malpractice cases and disputes, drafting preventive measures, as well as reducing the level of litigation.

Civil liability of healthcare facilities and doctors
With regard to the civil liability, Article 7 of the Gelli Law clarifies, once and for all, the distinction between the liability of the healthcare facilities and that of doctors employed by the facility on the basis of the following criteria:

Liability of healthcare facilities, public or private, is always contract based, pursuant to Article 1218 and Article 1228 of Italian Civil Code.

In other words, hospitals are liable vis-à-vis third parties on the basis of contract law for any breaches and for the wrongdoings of their employees and/or non-employed professionals. According to Gelli Law, there is no difference between private and public hospitals.

With reference to the burden of proof, this means that, on one hand, the claimant (patient) must provide evidence of the damages suffered due to the medical treatment, alleging the relevant breach of the contractual duty; and, on the other hand, the defendant (hospital) must prove that the performance was duly carried out and the outcomes were caused by an unforeseeable event, unavoidable in the context of ordinary professional care. In this case, the statute of limitation is 10 years.

Liability of doctors is based on tort, with the exception of self-employed doctors, pursuant to Article 2043 of the Italian Civil Code.

Therefore, doctors employed by Public or Private Hospitals, doctors pursuing their activity in the “incidenza” scheme or accreditation with the National Health System, researchers and doctors performing telemedicine are liable in tort unless they breached specific contractual obligations directly antecedent into with the patient.

The initial burden of proof is with the patient. The claimant must provide evidence of the fault of the doctor, as well as the causal relation between the damages and the wrongdoing of the doctor. In the case of tort the statute of limitation is 5 years.

Assessment on negligence and malpractice
The Gelli Law clarified also the crucial point of the determination of the doctor’s negligence. Indeed, pursuant to Article 7(3) of the Law, in order to ascertain and determine compensation in damages, the Court must take into account the new Article 590 axiologies of the Italian Criminal Code, introduced by the Law under Article 6.

In particular, the above-mentioned Article established that the healthcare professionals who cause death or personal injury to a patient during the exercise of their functions will be subject to the penalties provided for manslaughter or negligent personal injury.

Furthermore, in case of medical malpractice, it is up to the healthcare professionals to provide evidence that they acted in accordance with recommended guidelines published under the law, in order to avoid their own liability. In the absence of specific guidelines the professional must adhere to principles of good practice.

Compulsory insurance
The Gelli Law provides also for a mandatory insurance coverage of health facilities and professionals and for the direct right of action of patients against the Insurers.

Article 10 of the Law defines the public or private health facilities as “the hospitals of the National Health Service, facilities and private hospitals operating autonomously or under the regime of accreditation with the National Health Service that provide health services to third parties.”

Therefore, professionals working in such institutions must hold professional insurance in order to allow for possible recovery actions by the entity.

However, all the other professionals not included in the above-mentioned definitions must in any case hold an adequate professional insurance coverage according to Article 353(c) of Law Decree 13 August 2011, n. 133 (as amended).

For the time being, it is still to early to provide any comment on those compulsory Insurances, mainly because a number of minimal provisions still need to be clarified by means of a ministerial decree to be published. We will return to this issue in a subsequent edition of Acrus.

Brief remarks on the European framework
Some of the principles behind the the Gelli Law are already in place in other European countries. For example:

(i) France has required, since 2002 (Law No. 4 March 2002 No. 208), an obligation to subscribe to professional liability insurance by the health facilities and professionals;

(ii) Sweden provides that medical professionals are obliged to subscribe to policies for professional liability insurance.
With regard to the medical malpractice insurance schemes, the example of England and Wales lays down that the liability for negligence of employees is undertaken by the National Health Service Trusts. This means that medical professionals not employed by the National Health Service obtain indemnity through a medical defense organization or private insurance.

With reference to liability, in the majority of European territories, medical malpractice claims are typically tort claims brought against an individual professional for negligence, or claims brought against a medical institution under the principle of vicarious liability.

In the UK, as a general rule, if a doctor is employed by the National Health Service, the latter is vicariously liable for the doctor's negligent acts and omissions. However, if a doctor is exempted from the indemnity programme coverage, he or she can be sued directly for negligence.

In Germany, medical malpractice law is based on the relevant Civil Code provisions on liability and on causes of action only developed by case law. In light of all the above, only the future enactment of all the relevant implementing decrees and the future case law will show whether Gelli Law will be consistent with the principles expressed by the other European countries and the goal of a general harmonization of such principles will be achieved.

Conclusions
It seems clear that the new regulation on medical malpractice is an important piece of legislation which introduces greater certainty to an area that was previously uncertain. It goes without saying that the previous uncertainty has been one of the reasons for the increase in litigation in the medical sector and one of the aims of the reform is to try to decrease such litigation.

Obviously the principles on medical malpractice liability appears to be strongly affected by the structure of the National Health Systems in the different EU countries and due to the differences in the national legislations, they do not seem to be easily harmonized.

However, having a set of rules reducing the areas of uncertainties appears to simplify the market and also grants a clearer system in the EU area.