

Medicine, healthcare, pharmacy and the law

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Educational aims

- To identify reasons for the regulation of medical, healthcare and pharmacy practice, as well as the limits of legislation
- To understand professional liability and required standard of care and diligence
- To understand principles established by Court judgments in Malta through case-law on negligence and malpractice

Key words

Liability, diligence, negligence, malpractice

“Laws may generally be regarded as requirements for human conduct, applying to all persons within their jurisdiction, commanding what is right, prohibiting what is wrong, and imposing penalties for violations”.¹ In the law’s efforts at safeguarding patient safety, it has also generated fear of legal reprisal. However a good understanding of the rules and regulation that govern day-to-day practice, and awareness of accountability and professional responsibility intrinsic to the healthcare professions is critical to maintaining the high standard and regard to which these professions are held.

Introduction

The working lives of health care professionals (HCP) are inextricably linked to the law. Health Law ranges from the qualifications and registration of health care professionals, to the prescription of medicines and the organisation of the national health system. Advances in medical science - extending life at one end and bringing new hope to the childless at the

other - have given rise to intricate problems of law. Law plays a role at every level of medical practice. European Union initiatives have led to legislation covering issues such as cross-border healthcare and medicines regulation. The changed legal landscape has also seen a rise in consumer awareness. People now seek to have a greater say in their own treatment. Patients are no longer prepared to be patient.² The objective of

this paper is to explore the law’s response to medical treatment that has gone wrong, the degree of responsibility that the law demands of healthcare professionals and the reasons for this.

Role and Limits of Law

Pharmacy laws stipulate the basic requirements of day-to-day practice of pharmacists. The law defines the relationship pharmacists have with patients/consumers. As healthcare professionals, pharmacists are highly regulated because the slightest error in medicines distribution or pharmaceutical care could cost a life. Pharmacists are subjected to broad regulation as the medicinal products in the pharmacist’s control and custody are held to the strictest and most rigorous standards of any consumer product. It is the law that establishes acceptable conduct for pharmacists and accountability in the event that this level of acceptability is not reached. In most ordinary pharmacy practice scenarios, the question of “What is legal” can be addressed by answering the question “What is best for the patient?” Pharmacists, even if not expertly-versed in the law, generally know what is best for the patient and in most cases this is sufficient. However things may get more complicated than this approach would suggest. Pharmacy legislation has been drafted to set-out rules and requirements to ensure patient safety. Although the law describes basic standards of practice, it cannot substitute sound professional judgment. Indeed, it is not within the law’s role or scope to dictate strategy and professional judgment.

The law attempts to be flexible while maintaining a sufficient degree of certainty. To achieve this level of certainty, the law necessitates the existence of decision-making bodies such as administrative agencies or court to resolve disagreements and interpret the law. Answers in law are rarely if ever black and white in nature and are dependent on the facts and circumstances of the case at hand. Recognition of the intrinsic flexibility of legislation is crucial to understanding why and how laws, regulations and court judgments are drawn up. Effective legal action is limited by constitutional parameters within which it must operate and also by human nature – the law’s attempt to achieve overly wide and ambitious objectives will bear no fruit if this conflict with popular custom and habit. Excessively harsh legal

Key points

- Medicinal products and medical procedures carry an inevitable degree of risk and potential for harm of the patient
- The law creates a framework of rules, requirements and codes of practice governing the safety of medicinal products and the conduct of the healthcare professions
- Actions under Criminal and Civil law establish professional liability. The standard of care and degree of responsibility expected has been examined and evaluated by the Maltese Courts
- Better HCP-HCP and HCP-patient communication, cross-disciplinary collaboration, continuous professional education, detailed record-keeping, and legal reform to reflect new realities are encouraged in order to minimise error and ensure better patient safety

enforcement and punishment is inevitably counterproductive. The role and impact of legislation in influencing human behavior through education and deterrence cannot however be underestimated.³

Standard of care

Pharmacy practice and pharmacy management in Malta is regulated by the Medicines Act⁴ and its subsidiary legislation. These provisions outline legal requirements and administrative penalties to be meted out in default. The Maltese Criminal Code⁵ punishes by fine and/or imprisonment, involuntary homicide or bodily harm caused through “imprudence, carelessness, unskilfulness in his art or profession or non-observance of regulations”. The patient/claimant may himself or herself institute legal action under tort (Civil law⁶) for damage caused through “fault and unskilfulness”.

In order to succeed in an action of negligence, the patient/claimant must prove and establish:

- a) owed duty of care by the defendant (professional having treated the patient/claimant)
- b) that the defendant breached that duty by failing to exercise reasonable care
- c) that the breach of duty caused the claimant’s injuries, and that those injuries are not too remote.

Not all mistakes and errors fall under medical malpractice/negligence. The law in fact does not require the very highest standard of care and competence. The duty owed to the patient is a fair and reasonable standard of care and competence of the healthcare professional. The standard of care expected of a healthcare professional is not that of the reasonable man or woman – it is the standard of the ‘reasonable healthcare professional’.⁷

Maltese Court judgments have held that the law subjects the healthcare professional to a degree of responsibility that is to be expected from one who has prepared himself and presents himself as competent and able to exercise that particular profession. The conferral of the warrant to practice does not constitute irrefutable proof of sufficient proficiency.⁸

The Court also ruled that unskilfulness arises when the professional fails to manifest the average degree of professional competence and ability required in exercising the specific skills of the profession (e.g. ensuring that the instruments are sterilised before the procedure, and carefully counted before and after the operation). Professional error is dependent on a number of factors, including level of expertise of healthcare professional, degree of scientific knowledge in the medical field etc. An examination of the particular circumstances in question is necessary, undergoing a subjective test. The element of risk involved must be taken into account.⁹

Interestingly, the First Hall Civil Court has held that architects, doctors and lawyers do not render work but provide a service. Therefore, it is not their duty to carry out all that is requested by their client, but to do all that is within their capacity to achieve the proper end result. This means that, for example, a doctor whose patient dies is not liable for damages as long as he has acted in accordance to the rules and principles which govern, and are established by, his profession.¹⁰

In claims for damages, Maltese law requires proof of actual, financial loss directly resulting from negligence. Compensation can therefore only be claimed by the claimant/patient for tangible losses – such as medical expenses, lost days of work, and permanent disability (physical and psychological, e.g. depression).¹¹

Conclusion: challenges and the way forward

The stark reality is that error is absolutely pervasive to healthcare practice. But there are ways of minimising it and decrease the likelihood of a healthcare professional facing proceedings before a Court of Law. Effective communication, both with patients and other healthcare professionals, is paramount. Creating the right environment for the sharing of past experiences and disclosure of errors go a long way in ensuring that mistakes are not repeated. It is often the abandoned patient that will seek legal recourse. Good record-keeping and the proper drawing-up and filing/preservation of detailed notes is also important, as is continuous professional education on updated legal requirements and codes of practice.¹²

It was perhaps physician Brian Goldman who said it best, opining “*In a hospital system, where medical knowledge is doubling every two or three years, we can’t keep up with it...sleep deprivation is absolutely pervasive, we can’t get rid of it...we have cognitive biases...I’m not a robot. I don’t do things the same way each time. And my patient’s aren’t cars. They don’t tell me their symptoms in the same way each time. Given all that, mistakes are inevitable. So if you take the system, as I was taught, and weed-out all the ‘error-prone health professionals’, well, there won’t be anybody left*”.¹³

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