



Medico-legal Awareness and Structured Teaching as Proposed Requirements in Pharmacy Education

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Abstract

There is an undoubted shift in the very raison d'être of the profession of Pharmacy, now generally considered as a major health-care profession. This entails not only new duties, responsibilities, and the creation of sub-specialties and super sub-specialties, but also new rights and responsibilities. These are themselves guarded by evolving national and European legislation as well by local Pharmacy registering bodies empowered at law and responsible to the local constitutions. As in most other healthcare branches, awareness of medico-legal pitfalls leading to litigation and at times Court prosecution and liability still remains universally low.

This article argues for the need to increase and foster such awareness not only in daily clinical practice but on a higher level of organised, structured, academic embracement at both under and post-graduate levels. Furthermore, the authors hold that whether this advice is acted upon or not, time and circumstance will eventually force the issue in the future. Particularly emphasised and illustrated with examples is the fundamental point that academically embracing such medico-legal studies will in itself contribute in major ways to eventual Good Pharmacy Practice.

Keywords: Litigation; Pharmacy Practice; Education; Laws; Morality; Medico-legal Awareness; Jurisprudence; Mission Statement; Standard of Care; Laws; Regulations; Dispensing; Communication; Structured Teaching; Defensive Medicine; Confidence

Introduction

The practice of Pharmacy has numerous and extensive interactions with law at all levels of practice of the specialty. However, the academic teaching of pharmaco-legal studies remains an exception and not the rule in most European Universities. Yet, just as medico-legal studies are making inroads into a number of medical curri-

cula, the parallel situation in Pharmacy is likely, with time to follow suit. Related to but distinct in nature, is the morality and ethics of the profession, as the scientific basis of the subject moves into new directions with major ethical impact and queries.

The attitude that legal liability is the legal profession's province needs to change rapidly and drastically.

Most publications dealing with the subject are still most often written in general principles of the law. And yet one would expect that modern pharmacy would recognise and embrace the need of raising consciousness and awareness of litigation in a structured and positive way which can be exploited to raise the level of good pharmacy practice. This is even more crucial at a time when in most countries and states, the modern pharmacist's role has vastly evolved from the original dispensing chemist into a professional with multi-faceted autonomous duties and responsibilities regulated by specific laws, regulations and ethical considerations. Yet this new evolution still lacks behind in recognising, systemising and even exploiting its intrinsic and inescapable medico-legal scenario.

A shift in mentality

Pharmacy lawsuits have numerous facets and the defendant facing liability charges may range from whole drug firms and pharmaceutical companies to individual city and group practice down to the most junior of pharmaceutical technicians. However, let us look at the biggest ever pharmaceutical company lawsuits by settlement amount [1]:

- Amgen - \$762million
- Bayer and Johnson and Johnson - \$775million
- TAP Pharmaceutical - \$875million
- Merck - \$950million
- Eli Lilly and Company - \$1.4billionn
- Abbott Laboratories - \$1.5billionn
- Johnson and Johnson - \$2.2billionn
- Pfizer - \$2.3billionn
- Takeda Pharmaceutical - 2.4 billion
- GlaxoSmithKline - \$3billion

There is no doubt of the increase in court cases involving the drug industry particularly commencing at the turn of the present century [2]. Unfortunately, this has also been paralleled by a clear increase in appeals to the judiciary to hold individual pharmacists accountable at law on the basis that Pharmacists must protect customers from drug-related injuries [3].

There is no doubt that modern pharmacists rightly consider themselves far from being "tablet dispensers".

This fight is on-going and up to the late 1990's there were still USA States which did not even consider pharmacists as healthcare professionals! Great strides have been achieved and now Pharmacists actually advertise their potential while also inviting the public to take advantage of such expanded services [4]. A new patient-Pharmacist relationship has been born in our very lifetime and this implies a higher expectation of healthcare output, regulated by law and answerable at law. Indeed these expectations at law evolve as we write and it is the in the profession's interest to foster awareness and generate academic constructive input from Pharmacists from different specialties.

Pharmacy meets the law

Firstly, we stress that here we speak of civil liability and not criminal incursions, although life being what it is, the two elements may indeed coexist, albeit extremely rarely. Hence, we focus on situations where Pharmaco-malpractice exists as a result of practice falling below the expected standard with resultant harm or even death of the patient. Although laws and legal systems do vary from country to country or from State to State, the general principles of medico-legal medicine tend to hold universally. So do ethical principles. On such common and universal framework, one may then further build the details pertaining to specific laws/systems of the country or state in question.

As shown in figure 1, modern Pharmacy has many sub-specialties. An under-graduate curriculum which encompasses medico-legal studies obviously need not deal with all these aspects but generally aim at the Pharmacist in clinical practice. However, post-graduate curricula are a different story and must be adjusted according to the needs in question. Likewise, specialties such as pharmaceutical corporate legal principles must be taught and learnt as necessary. Once the system rolls, all facts fall into their ordained place. The subject is a living dynamic one and must evolve along contemporary needs, making the academia of the subject even more exhilarating.

The point is not to make lawyers out of Pharmacists but to enhance a working understanding which will enhance good Pharmacy practice. There will also be a minor group of Pharmacists who may decide to subspecialise in the subject, and these will prove to be an asset to their department or their particular industry.

The future will only bring increasing medico-legal challenges of various complexities which cannot even be currently conceived.

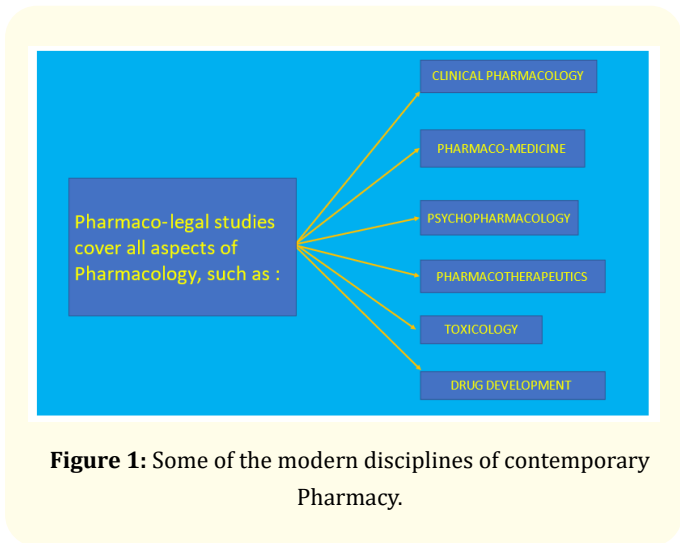


Figure 1: Some of the modern disciplines of contemporary Pharmacy.

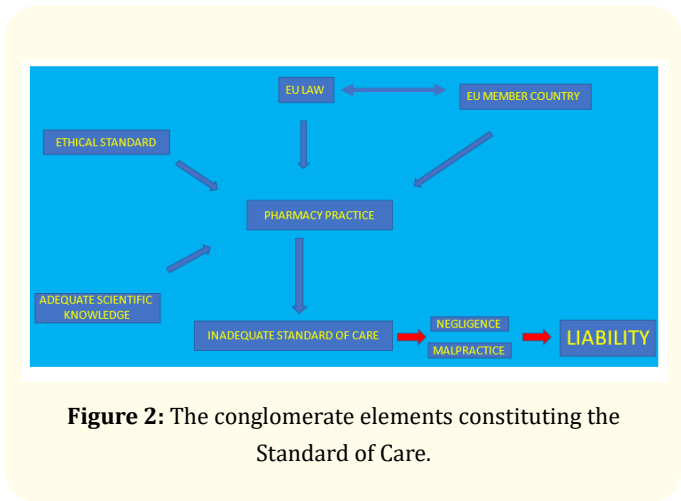


Figure 2: The conglomerate elements constituting the Standard of Care.

Once a departmental niche has been created in Pharmacy curriculum, its natural evolution will not only keep abreast but may even significantly contribute to future pharmaco-legislation.

Mission statement and the standard of care

The mission statement of the Pharmacist as a healthcare professional is the provision of focused pharmaceutical care as part of a concerted therapeutic approach to improve and optimally sustain health and life. This entails rights, responsibilities and duties in line with the scientific, moral and ethical aspects of Pharmacy and in conformity with the law of the country of practice and, where applicable, with EU law. This boils down to a requisite Standard of Care (SOC). As shown in figure 2, an individual’s practice below the SOC constitutes negligence or malpractice.

All actions, be they counselling, dispensing, drug therapy monitoring, etc. must fulfil the scientific, legal and ethical requirements of the SOC. The legal and ethical standards must also be commensurate with the laws of the country and where applicable, with EU requirements. Although the implications of liability can never be ignored, fulfilling the requirements of the SOC, automatically ensures Good Pharmacy Practice.

The SOC will vary from time to time and from circumstance to circumstance with different aspects of its contributing elements coming to the fore accordingly. Thus, the SOC associated with the

Pharmacist’s role of counselling regarding Covid-19 vaccinations requires heightened awareness of the element of disclosure either per se or as part of obtaining valid consent. Maintaining oneself updated of the relevant science is as much an obligation as the reportage of adverse effects. The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency has investigated the situation fully and has recommended both an update to the product information to reflect the current knowledge as well as stressed to physicians the need to continue reporting adverse reactions from the involved vaccine [5].

The SOC of any aspect of management in Pharmacy is in a state of continuing evolving flux and demands regular and departmental/unit reviews with individual updating.

Some aspects of medico-legal teaching in pharmacy

Looking through a small window of practice as an example in this discussion, the clinical pharmacist’s role say in dispensing of medicines, involves numerous steps with potential pitfalls for negligence as shown in figure 3. Here we have various aspects of practice which medico-legally may be sub-divided into communication, disclosure of relevant information, etc. each and every one of these steps has its own potential legal pitfalls with its own liability. Actual Court cases may be quoted to illustrate mistakes and the way they fell short of the specific SOC, with their resultant harm to the patient. This is far from instilling fear but the very opposite. It is about systematically showing the practical reality of knowing the SOC and why it is crucial to observe it.

- Knowing the medical and drug history of the patient .
- Reviewing a presenting prescription in the light of the patient's medical history.
- Warning about a drug's potential side effects.
- Ensuring multiple drugs CAN be taken together.
- Discussing and disclosing information to the patient about his medication.
- Contacting the prescribing doctor when worried about safety.

Figure 3: Potential steps for medico-legal pitfalls in dispensing.

Pharmaco-legal teaching offers new perspectives on daily practice. As an example, figure 4 is a schematic reflection of potential medico-legal problems based on absent or defective disclosure of information by Pharmacist to the patient. The nature of the actual information is immaterial to this example. Figure 4 refers to a case where the requisite SOC regarding disclosure of information is not reached with failure to achieve Good Pharmacy Practice. Here, we can pin-point the problem at Communication level - either at the afferent stage (e.g. patient's volunteered information ignored or patient not asked, etc.) or at the efferent stage (e.g. the patient cannot hear the Pharmacist's advice as deaf or has a language barrier, etc.). Each step leading to the eventual lowering of the SOC may be illustrated with actual Court cases.

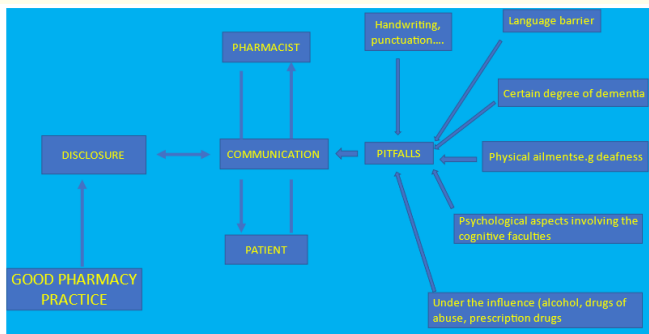


Figure 4: Communication as a central medico-legal pitfall.

And speaking about Communication and Disclosure raises the ethical and legal principle of the death of medical paternalism and 'Doctor knows best' which held reign from the 1950's well into the 1970's the final catalyst in this long evolutionary saga was the UK Supreme Court Ruling in *Montgomery v Lanarkshire Health Board* [6], where the patient's autonomy was unquestionably established. The patient has the right to know all and then effect his/her treatment or refuse it accordingly. Furthermore, further similar legal changes affecting not only communication and disclosure but also diagnosis and treatment are more than likely in the future [7].



Figure 5: Avoiding litigation through recognition of evolution of Communication and Disclosure.

Some benefits of introducing medico-legal studies in pharmacy curricula

Some of the main advantages are tabulated in figure 6. The final point is worth noting. The constant raising of the scientific and practical aspect of Pharmacy is a sine qua non demand of the need of the corresponding medico-legal demands and vulnerabilities. One may state, without equivocation that failing to study, analyse and recommend such conclusions is a disservice to Pharmacists be they pharmacy practitioners, industrial pharmacists or ones involved in any sub-specialty such as nephrology, transplant programmes or oncology, etc.

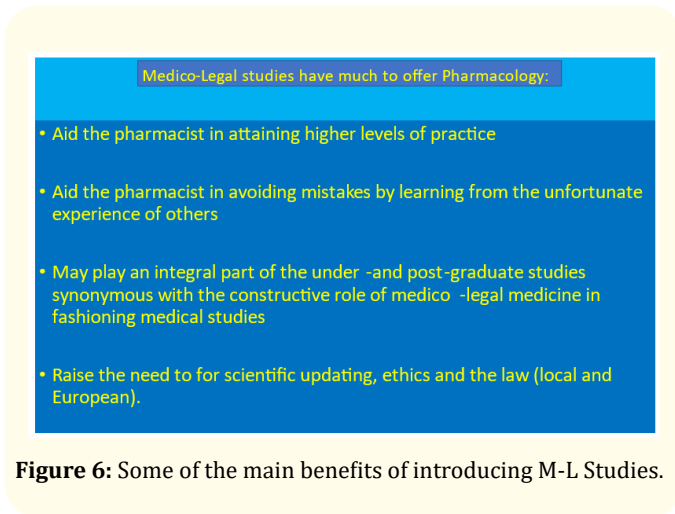


Figure 6: Some of the main benefits of introducing M-L Studies.

A final point regarding these advantages and illustrated in figure 7, refers to the simple but crucially important point that raising medico-legal consciousness may be the best antidote to the evils of defensive practice. This may be defined as Fear-Based Practice [8], in which the health professional manipulates his or her profession so as to seem to fulfil his or her duty but in reality, is seeking the least legally risky action to avoid future litigation. Potentially seriously harmful to the patient, it lowers the practitioner’s self-esteem and is extremely damaging to national budgets. Among the facets of prevention is the need for the health professional to fully understand his/her conduct obligations [9] and medico-leg: studies certainly fulfil both reason and motivation to fulfil thes obligations along the safety of the SOC.

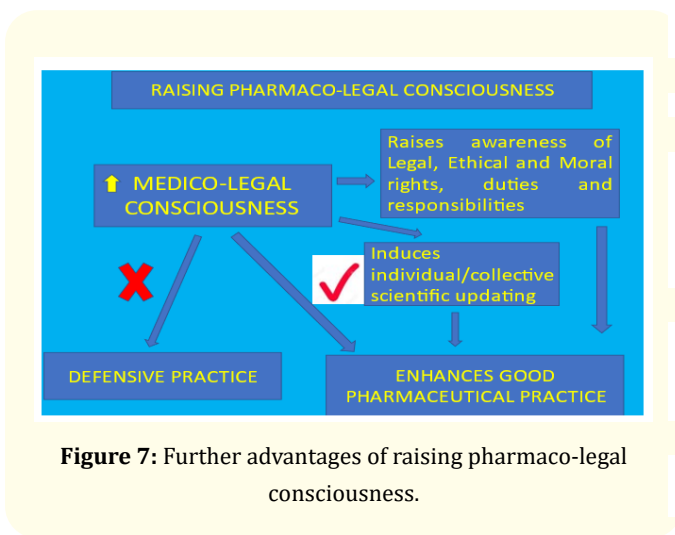


Figure 7: Further advantages of raising pharmacological consciousness.

Contrary to the paranoia which is rarely claimed by the uninformed in arguments against the institution of medico-legal studies, the subject tends to induce both self-confidence and serenity as is often the case when the fearful unknown is faced with the light of knowledge. Knowledge is power and by teaching what goes on in the foreboding halls of Court, a new self-empowerment is laid open for all who seek to practice correctly and provide vastly superior patient care [10].

Conclusion

Further loading of any healthcare specialty curriculum must be fully evaluated. Introducing structured teaching of medico-legal studies to Pharmacy education raises many understandable queries. However as briefly discussed here, not only is there a growing necessity to express more than nodding interest in an ever-increasing legally conscious society, but the subject provides a new medium of academic teaching. Such teaching for example may take the form of both case law discussions as well as evaluation of general principles and both have much to offer at academic and clinical level. As stated elsewhere, there is a unique role inherent in medico-legal studies as a major medium of healthcare studies [11]. Sooner or later, the hanging sword of Damocles must be faced. And the earlier the better.

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