Prescribing, dispensing and patient safety

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On the 1st December 2006 legal notice 292, Medicines Act (CAP 458) entitled Prescription and Dispensing Rules 2006, came into force. This legal notice seeks to lay down in a very clear manner the legal framework for prescribing and dispensing. It appears to have been welcome by pharmaceutical and medical professional associations as well as by the respective regulating bodies. However, the uptake by practioners appears to have been slow. It is indeed true that a change in practice tends to take time, yet in this case the stakes are high as the impact is on patient safety.

The collaboration of all stake holders is necessary for this framework to be effective. Apart from the obvious i.e. pharmacists, the legally recognised dispensers and medical doctors, dentists and veterinary surgeons, the legally recognised prescribers, patients also need to be involved in the process as ultimately they are the ones who experience the effects of the health care system or lack of it.

We also need to take a professional approach and do away with the blame culture. All too often one group of professionals is very ready to blame the other group or even worse, the blame is put on the patient. This is not about blaming either profession, individual professionals or patients but it is about adopting a professional practice that safeguards the health and safety of the patient. Most problems are caused by faulty systems, processes and conditions which lead practioners to make mistakes or fail to prevent them, subsequently resulting in patient morbidity and possibly mortality. Health care systems are at times criticised

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as being fragmented or even worse for being 'non-systems'. Globally, the current trend is to design healthcare systems to ensure patient safety.[1, 2]

The Legal Notice clearly describes the form and content of the prescription in line with the process of rational prescribing and rational treatment. Rational treatment is a multi-component logical process. First the patient's problem needs to be identified, therapeutic objectives specified, the most appropriate treatment of proven efficacy and safety chosen from a variety of alternatives. The start of treatment is heralded by writing a *clear, legible and accurate* prescription. This is followed by providing information and instructions to the patient in a manner which he/she can easily comprehend. The patient needs to be monitored to determine if the therapeutic objectives have been achieved. If successful, the treatment can be stopped, if not the above process needs to be repeated.[3] In the case of chronic diseases, patients need to be monitored on a regular basis to ensure that they are well controlled.

A prescription is hence an official form of communication between prescriber and pharmacist and should be thus respected. It indicates to the pharmacist that the prescriber has at least engaged in the first part of the above rational therapy process and is assuming responsibility for the therapy prescribed. In the absence of a prescription this cannot be determined.

It is the prescriber's legal obligation to write legibly. Failure to do so could lead to errors resulting in drug misadventure and have a negative impact on the patient. This has been emphasised by the UK Court of Appeal ruling in a case where a doctor wrote a prescription (in a manner which was insufficiently legible) for Amoxil® which the pharmacist misread and dispensed Daonil®. This resulted in the patient developing permanent brain damage as a result of taking the dispensed drug. The ruling by the UK Court of Appeal implied that doctors are under a legal duty to write clearly, that is with sufficient legibility not to allow for mistakes by others. When illegible, handwriting results in a breach of that duty, causing personal injury. When this is the case the courts will be prepared to punish the careless by awarding sufficient damages. Liability does not end when the prescription leaves the doctor's consulting room. Liability may also be a cause of the negligence of others.[4] It is also opportune to note that in the above case, the pharmacist could not have been exonerated had the evidence i.e. the prescription, not been produced. It was with this and similar scenarios in mind that the Malta College of Pharmacy Practice emphasised the need for the LN to state that the prescription should be retained by the pharmacist; a recommendation that unfortunately, was not taken up. However, the LN does not state who should retain the prescription and in so doing does not bar the pharmacist from keeping it.

Legibility is not only paramount when writing drug related information but is also essential when writing the prescriber's information relating to name, contact details and the relevant council's registration number. Very often the pharmacist is required to contact the prescriber to discuss therapeutic issues in the best interest of the patient, hence contact details are an absolute necessity. While it may be obvious that the prescriber's name and relevant council number is clearly written, this is very often not the case with the prescription including only an illegible signature. In practical terms this implies that the person responsible for issuing the prescription cannot be identified, unless the relevant council registration number is included (e.g. Medical Council Registration number xxxx). It cannot even be determined if the 'prescription' has originated from an authorised prescriber. This issue assumes even greater consequence when the drug is prescribed for an unlicensed indication, a practice which is on the increase. It is indeed the prescriber's prerogative to prescribe a licensed drug for an unlicensed indication i.e. in breach of the terms of its product licence. In this case there is no doubt that the prescriber (the person who signs the prescription) is assuming all the legal responsibility and placing his/her self in a position of increased vulnerability as he/she may be called upon to justify his/her actions in the event of an adverse event (the manufacturer is only likely to be found liable if harm results from a defect in the product). Pharmacists dispensing a prescription whose prescriber cannot be identified are exposing themselves unnecessarily. Prescribing a drug for an unlicensed indication also presents an additional problem for the pharmacist in terms of patient counselling. This situation necessitates optimal inter-professional communication between prescriber and pharmacist in the best interest of patient care.

The Legal Notice gives further details as to what should be included in a prescription such as patient name, which is essential when the pharmacist is presented with multiple prescriptions and age which is especially important in dosing for children. The duration of treatment is very often omitted. This is of particular importance in terms of expected treatment outcome. If the expected result is not achieved within the stipulated period, the therapy should be reviewed. This needs to be explained to the patient by the pharmacist as the situation may be one of failure to respond to prescribed therapy and the solution may not be to take more of the same as is usually the expectation of the patient. In the case where the prescriber considers that a repeat is required this is provided for in the LN.

The duration of validity of a prescription is specified to be 6 months unless it is a repeat. Repeats are usually issued for patients with chronic conditions such as hypertention and other cardiovascular disease, asthma, diabetes etc. In terms of therapeutic management, it is also essential that these prescriptions are not left 'open'. Patients with chronic disease need to be reviewed on a regular basis, to determine if

i) they are responding well to therapy,
ii) they are controlled,
iii) the prescribed therapy has led to undesirable and unacceptable effects,
iv) the original treatment prescribed is still optimal,
v) the prescribed treatment is still within currently recommended therapeutic approach and also
vi) the condition can be controlled by taking less medication.

In the light of the global public health concern regarding resistance to antibiotics, the validity for such a prescription is only 10 days from date of issue.

It is also important to highlight that verbal instructions over the phone are discouraged and only accepted in a case of emergency and the prescriber should provide the pharmacist with a prescription within 48 hours of the verbal instruction.

Section 4 (2) of the LN clearly states that *'It shall not be lawful for any pharmacist to dispense any product to which these regulations apply except on a prescription from persons duly authorised…'* Pharmacists argue that in the current situation this is not practical. This may very well be the case but, it must be emphasised that at times, due to practicality they may not be acting in the best interest of the patient as

i) they may be contributing to drug misadventure leading to drug related morbidity and possibly mortality
ii) they may be perpetuating or introducing errors
iii) they may simply be failing to intervene in order to prevent mistakes
iv) they are placing themselves in a position of increased vulnerability.

This cumbersome situation may be addressed in a number of ways. A first step could be reclassification of a number of prescription medicines to non-prescription. This is one of the main recommendations of the G10 Medicines Report which explains that within Europe there already exists a regulatory structure which sets out safety criteria for awarding non-prescription status to medicines. It recommends that *'For medicines whose indications are currently under prescription but which are regarded potentially suitable for self-medication, a regulatory switch mechanism should be in place encompassing appropriate safety measures.'* The possible advantages cited include a positive impact on public health costs and an ease on the burden of health care professionals.[5]

Pharmacists have a central role in contributing to and ensuring the rational use of medicines. Over the past 40 years there has been a shift from that of a dispenser to the current paradigm of drug therapy manager. Globally it is estimated that for those who receive medicines, more that half of all prescriptions are incorrect and more than half the people involved fail to take them correctly. [6] In addition there is the growing concern regarding the increase of antimicrobial resistance. Pharmacy practice is now patient-centred and includes the functions of counselling, providing drug information and monitoring drug therapy. Within the philosophy of pharmaceutical care pharmacists are involved in all stages of rational drug therapy and assume the responsibility, together with other health care professionals, for the outcomes of drug therapy. [7] The time is opportune to work towards an appropriate structure to be set up in order for pharmacists locally to be able to participate in the patients' drug management in collaboration with the prescriber and other health care professionals. Programmes exist which enable the pharmacist to detect and manage drug related problems, thereby increasing patient safety. [8] In this age of evidence-based practice, it is important to highlight that evidence exists which illustrates that pharmacists in Malta are competent to deliver Pharmaceutical Care and contribute the patients' positive health related outcomes.[9] The infrastructure should be set up in practice and should be protected by a legal framework.

As health care professionals we are committed to ensure the health and safety of our patients. During the last Malta Medical School Conference Professor Sir Liam Donaldson, Chair, World Alliance on Patient Safety, set us the challenge of making Malta the safest place in terms of patient safety. We can start by taking small steps and making the effort of respecting the legal framework which promotes rational therapy and patient safety. It is indeed true that we cannot possibly hope to eliminate all errors or drug-related problems but we can most definitely seek to actively practice in a manner which at least enables us to eliminate the avoidable ones. Let us make a concerted effort and work together to achieve this goal.

(A copy of LN292 of 2006 has been included at the back of this journal)

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