

DRAFT Comments on the draft Pharmacy Profession Decree 2010

1.0 Introduction

The Council welcomes the drafting of this piece of legislation which is long overdue and has come at an appropriate time when consumers are facing problems in regards to the practice and business of pharmacies in the country. The Council, consumers and the general public have long yearned for an effective monitoring and redress system to govern professional oversight in the pharmaceutical industry. Pharmacists (and pharmacies) are looked upon by consumers with a high level of trust because they dispense medicines which can be a matter of life and death. An important development here is the separation of medicinal products and pharmacy profession which both had been part of the Pharmacy and Poisons Act (Cap 115). The assimilation of medicines, poisons and pharmacy under one piece of legislation has resulted in confusion, ambiguity and not to mention non-effectiveness. The 136-page Act has been cumbersome and ineffective, providing little protection to consumers and

2.0 PHARMACY PROFESSION DECREE 2010

The Council applauds the effort of the Government and the Ministry of Health in developing and drafting a stand-alone legislation to govern and administer the conduct and business of pharmacists. It is very appropriate that pharmacists are subject to a rigorous regulatory system in the same manner afforded to medical and dental practitioners. Pharmacists are a vital part of Fiji's health care system and their conduct and business practices cannot be divorced from that of medical and dental practitioners, who are now governed by newly introduced legislations and revamped regulatory controls. The Council notes that the Pharmacy Profession Decree 2010 has similar provisions to that of the Medical and Dental Practitioner Decree 2010. This is a very appropriate move and would provide a better harmonisation of the conduct and practice of professionals in the health sector. Also the draft Pharmacy Profession Decree 2010 looks leaner and less wordy than the Pharmacy and Poisons Act.

The Council agrees that such a reviewed and revamped legislation is necessary. Most of the provisions cater for the gaps in the existing law, in particular the new fines or penalties against pharmacists for misconduct, clarification on ownership

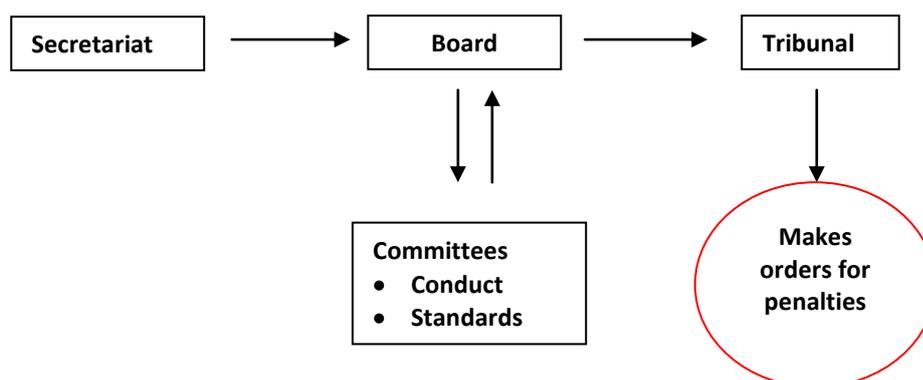
In the following sections, the Council puts forwards its comments and recommendations on the draft Pharmacy Profession Decree 2010 and sincerely hopes that our input will prove valuable in addressing any gaps in the draft.

2.1 Need for quick, effective and less costly redress

While the Council applauds the initiative to provide a redress system through the Pharmacy Profession Decree 2010, it feels consumer redress is not being adequately addressed. The Council has persistently sought for a proper redress system for consumers, which is visible, speedy, effective and less costly. In this draft legislation the term "consumer" is blaringly absent. Much more consideration should be given to the end-users of the pharmacy profession. Even in the draft, there appears to be more than one layer in the complaints process that may hinder consumers' need for effective, less costly and speedy redress. In the proposed system there are about four layers for redress such as the process a consumer has to go through to get his/her complaint address.

Complaints Handling

The diagram below shows what may actually happen in the redress mechanism. The Council assumes that the secretariat will be the principal entry point for lodgement of complaints. While the draft legislation allows for complaints to be lodged at the committee level by any aggrieved party (consumers etc), in practice it will be the Secretariat (and the Registrar) who will be the first point of contact. The complaint is then referred to the board who in most cases will likely refer it to the committee level. The committee then returns with its findings and recommendations to the Board who in turn refers it to the Tribunal for a decision. This process can be time consuming and expensive for consumers and also for the Board and all parties involved.



The Board and Registrar only impose fines in respect of administrative matters and pharmacy compliance with rules and regulations in the Decree. For example if a medically unfit pharmacist is fined \$10,000 (Section 9 *Registered person must report medical unfitness to Registrar*), there are no clearly defined compensation for a consumer who may have suffered (wrong medication, etc) from actions resulting out of a medically unfit pharmacist dispensing medication. The draft decree is not clear on the compensation aspect of consumer complaints. The Tribunal can impose fine to a maximum of \$75,000 or imprisonment (or both) on the offending pharmacists, but the consumer has no recourse for compensation or to recover costs.

2.2 Composition of the Fiji Pharmacy Profession Board

The Council objects to the number of persons on the proposed Pharmacy Profession Board. The Council feels that a 9-member board is too ambitious and experience has shown that large statutory boards are often cumbersome and the decision-making process is often delayed. In the Section 5 (3) of the draft, the Board meeting quorum is set as *...the Chairperson, or in his or her absence, the Deputy Chairperson, and four members present in person*. The quorum should be set realistically, i.e. a lesser number with chairperson or deputy, otherwise delays can become the norm rather than exception.

The Council proposes a 5-member board consisting of (1) Permanent Secretary for Health, (1) Pharmacist from the Government Department, (1) nominee of Fiji School of Medicine, (1) nominee of Fiji Pharmaceutical Society, and (1) consumer representative.

The Chief Pharmacist and her staff will be the Secretariat to the Board. Their key task is to investigate and make recommendation to the Board.

Members of the Board must declare their interest in any pharmaceutical business, either as a shareholder, director or in any way connected with a pharmacy business or a private medicinal practice.

2.2.1 Powers of the Board

Section 6 – Powers of the Board. The Council notes that amongst the range of powers (a-j) given to the board, there is power to **suspend** (Section 6, (2) (f)). However Part 8 – Practice of Pharmacy, Section 38 covers **suspension or revocation of license**. It would be appropriate that the term **revocation** be spelt out in Section 6 to clearly stipulated the power of the board.

2.3 Committees of the Board

The Council recommends that just as the Board membership number is revised downwards, so shall the number of members in the committees of the Board. The Council reiterates that past and current practices have shown that committees are ineffective and this contributes to delays in the decision-making process and other functions of Boards. The Secretariat with the Board Sub- committee can analyse cases or issues that is later presented to the full Board.

2.4 Ownership of Pharmacies

The Council commends the changes made to rules regarding pharmacy ownership. For instance Section 41(1) (i) makes it clear that directors of a company authorised to run a pharmacy business “...are all registered pharmacists...” Also Section 41 (c) includes “*a lawful partnership who partners are all registered pharmacists...*”

2.4.1 Requirement to provide information about pharmacy ownership

The Council commends the inclusion of this section (Section 42) which will bring a higher level of transparency than that offered in the existing legislation.

2.5 Complaints & Fiji Pharmacy Board Secretariat

The Council commends the inclusion of a secretariat to provide support to and take charge of operational aspects of the Board’s work. We note the functions of the board outlined in Section 11 (1) (a-k). Subsection (1,d) simply says “*to receive and process notifications about pharmacy practice matters from members of the public, registered persons and health service providers*” Consumers would be better served and protected if the term **complaints** (against pharmacists) is given prominence or clarity. By including the term **complaints** there would be reassurance that a complaints mechanism is in place for consumers (which is catered for through the Professional Standards Committee). The secretariat should be clearly identified as the point of contact for and recipient of consumer complaints.

The Council further recommends that the status of the Fiji Pharmacy Board Secretariat be that of an independent body.

2.5.1 Funding for the Secretariat

The draft provides funding for the Secretariat via fees for registration and other services provided by the board; and grants/loans from government. The Council feels that funding for the Secretariat can also be derived from the fines or penalties imposed on pharmacists or persons who have been found guilty and accordingly penalised under the decree. Many boards and tribunals in Fiji, although having powers to impose regulations, penalties etc. are mostly under-funded and this is one of the reasons why effective regulation has failed.

2.6 Code of Conduct and Business Practices of Pharmacists

The conduct and business practices of pharmacists are areas the Consumer Council has highlighted. The Pharmacy Professional Decree 2010 allows for *Codes of conduct and professional standards* to be established by the Board (Section 101). The Council recommends that in the event of the passing of this legislation, the Board to included the following as part of the practices to be required from pharmacists.

- Pharmacists or licensed persons dispensing medication to have a proper, standard and recognisable attire;
- Pharmacists of licensed persons display their name tags clearly while dispensing medicines or dealing with consumers;

2.7 Fiji Pharmaceutical Society

The Council notes that membership of the Fiji Pharmaceutical Society (FPS) is not mandatory for registered pharmacies. One of the reasons the Society has been virtually ineffective in terms of addressing professional conduct of pharmacists and consumer complaints is the fact that membership is not compulsory. The Council recommends that the FPS being the professional association of pharmacists be strengthened via mandatory membership of licensed pharmacists. The Council's research has found that there are unwritten rules of conduct that pharmacists subscribe to. However, such 'rules of thumb' are not properly codified and there are no regulatory requirements for pharmacies to follow such rules. The Council recommends that the Fiji Pharmaceutical Society, if strengthened through mandatory membership will be in a better position to impose such rules. The right and power to make such rules is already factored in Section 97 (Objects of the Society) and Section 98 (Rules of the Society) under the draft decree. The Society's functions should expand to also include self-monitoring; and consumer education and awareness.

2.8 Tribunal

The Council recommends that there should not be a separate tribunal for the pharmacy profession as outlined in the draft. Instead, we propose that the same Tribunal that deals with the Medical and Dental professions also deal with pharmacy matters. This would be appropriate considering that all three professions are related and consumers are mostly likely to deal with all three in the procuring of pharmaceutical products or services. Tribunals such as the one proposed under this draft decree can be costly and availability of judicial experts is never guaranteed. Thus, resolutions and imposition of orders can be hampered or delayed and consequently rendering the whole system ineffective. The Council notes that Section 69 (1) of the draft establishes a *Registrar of the Tribunal*. This seems to create more bureaucracy in a system where the aim is simplicity, timeliness and cost-effectiveness.

Conclusions

The Council is of the view that the drafting of this legislation is an important step towards reforming the pharmaceutical section. Despite some of the concerns raised above, the Council feels that some the progress towards change has been initiated, which is very important when dealing with a decadent legislation. The main area of concern of the Council is that a clear-cut redress system for consumers needs to be established and that the process of redress should be timely, less bureaucratic and cost effective. Secondly, the draft decree is not clear as to what

kind of compensation is there for consumers. While the conduct of pharmacists and necessary process for registration, practice, etc is covered with penalties and orders, there is no define compensation requirement for consumers in terms of recovering costs for injuries suffered and those incurred in raising the complaint. Thirdly, the draft decrees inadequately addresses the functions of the Fiji Pharmaceutical Society (FPS). The Council believes that the FPS can be in an influential position to address problems in this sector through mandatory membership. A strong FPS would be in a better position to hold pharmacists to account in terms of business practices and professional conduct. The Council hopes that these issues will be taken on board by the Ministry of Health.