

SUMMARY OF THE LEGAL ASPECTS AFFECTING THE PROCESS OF APPROVING PHARMACISTS' APPLICATION TO SUPPLY PHARMACEUTICAL BENEFITS IN THE PERIOD FROM AUGUST 1990 TO JANUARY 1991

1. **The 'Old' Law**

1. When the Minister for Aged, Family and Health Services, the Hon Peter Staples, issued his media release 'Pharmacy Restructuring – Restrictions on Approvals' on 8 August 1990, the main existing provisions for dealing with applications by pharmacists for approval were ss.90 and 105AB(7) of the *National Health Act 1953* and the non-legislative procedures, Approval to Supply Pharmaceutical Benefits, which became effective on 1 July 1981 and were apparently unchanged.
2. Section 90 gave the Secretary a very wide discretion (delegated to the Health Insurance Commission in 1989) to grant or reject a pharmacist's application. Section 105AB(7) imposed limitations on the exercise of that discretion by providing for review by the AAT of a decision under s.90 if an application was rejected. The AAT could ensure that the discretion was exercised consistently and fairly. The Committee was given the procedures, which, apart from restrictions on friendly societies and medical practitioners, dealt mainly with matters such as premises, approval by State authorities, changes of partnerships and similar matters. From these provisions, it appears that, until restructuring commenced, if State and local laws were complied with and a person was professionally qualified, the law of supply and demand virtually took over.
2. **Possible Changed Guidelines under the 'Old' Law**
3. The old form of s.90 gave a wide discretion and it was possible to change the way it was exercised, provided that natural justice and fairness, as interpreted by the Courts and the AAT, were complied with.
4. Was a document called *Guidelines Relating to the Granting of an Approval Pursuant to Section 90 of the Act*, which I am told was to be applied from 3 December 1990, such a change? There is nothing on the document that I have to indicate under what authority these *Guidelines* were formulated or issued. They appear to be almost identical to clauses in the second Agreements of 23 November 1990 and 6 December 1990 referred to below. In one clause the *Guidelines* refer to the disallowance of guidelines under the Act and to the Authority. Neither of these yet existed, so it is unclear how the *Guidelines* were to operate. Their status and operation needs to be clarified.

3. Development of the 'New' Law

(a) The Minister's Media Release of 8 August 1990

5. The Minister's media release of 8 August 1990 spelled out some details of the restructuring process. Of course, the media release was not legally binding on anyone. Indeed, the release is careful to use such phrases as 'in accordance with criteria presently being established' and 'will be developed over the next few weeks'.

(b) Agreements of 23 November 1990

6. The next development was the signing of two inter-related Agreements of 23 November 1990 between the *Commonwealth* and the Pharmacy Guild. These Agreements were not ones to which s.98BAA of the *National Health Act 1953* applied. Such an Agreement had to be made 'between the *Minister* and the Pharmacy Guild of Australia or another pharmacy organisation representing a majority of approved pharmacists'.

(c) Agreements of 6 December 1990

7. Two Agreements that are almost identical with those of 23 November 1990 were entered into between the Minister and the Pharmacy Guild of Australia on 6 December 1990.
8. The first Agreement is a s.98BAA Agreement dealing with pricing and was later given effect to by the Pharmaceutical Benefits Remuneration Tribunal on 20 December 1990 as required by s.98BAA. It has little relevance to our issues, but the second Agreement of 6 December deals with approvals in some detail in paragraphs that were also in the Agreement of 23 November 1990 and in the 3 December 1990 *Guidelines*. It specifically states that it is not a s.98BAA Agreement, so it does not directly impact on individual approved pharmacists through the Tribunal's Determinations. Indeed, unless there are special rules, the Agreement could not bind individual pharmacists as they are not parties to it. It provided that it did not come into effect until the Remuneration Tribunal made its Determination under the first Agreement and that occurred on 20 December 1990. In addition, the paragraph containing the new rules for approvals provided that that part was not to be effective until there was an Authority and the guidelines had not been disallowed by Parliament. This takes us well into 1991.

(d) Changes to the National Health Act 1953

9. A new regime was set in place as from 18 December 1990 by the *Community Services and Health Legislation Amendment Act 1990*. Henceforth, a s.90 approval required both a recommendation from the Authority and approval by the Secretary. However, s.99K(2) provides that, in recommending under s.99K(1), the Authority 'must comply with the relevant guidelines determined

by the Minister under section 99L'. Section. 99L(1) states that the 'Minister must determine in writing the guidelines subject to which the Authority is to make recommendations under subsection 99K(1)'.

10. Until the Minister had determined guidelines, the new machinery could not operate. The guidelines became effective on 23 January 1991.

(e) **The New Guidelines**

11. The s.99L Ministerial guidelines in *Determination No. PB 1 of 1991* came into operation on 23 January 1991 and were amended by correcting two statutory references and adding paragraph 3(h), by *Determination No. PB 4 of 1991*, on 29 May 1991. They bear very little relation to the statements in the Minister's media release of 8 August 1990, but are similar to, but not identical with, those in paragraph 8 of the second Agreement of 6 December 1990 between the Minister and the Pharmacy Guild.

12. I quote clause 3, Applications for Approval to Supply Pharmaceutical Benefits, of *Determination No. PB 4 of 1991*:

'For the purposes of paragraph 99K(1)(b) of the Act, the following are guidelines with which the Authority must comply in making a recommendation on an application by a pharmacist under section 90 of the Act:

- (a) approval of a pharmacist shall not be recommended in respect of premises located within 5 kilometres by normal access routes from other premises in respect of which a pharmacist is already approved;
- (b) approval of a pharmacist in respect of particular premises shall not be recommended unless the pharmacist demonstrates to the Authority that there is a definite unmet public need for that approval;
- (c) approval of a pharmacist in respect of particular premises shall not be recommended (except in the circumstances provided for in subparagraph (d) if those premises are situated within 5 kilometres by normal access routes of other premises in respect of which there has been granted financial assistance under section 99ZC or 99ZD of the Act;
- (d) approval of a pharmacist in respect of particular premises shall be recommended where those premises are located not more than 500 metres from other premises in respect of which that pharmacist is already approved under section 90 of the Act and from which the pharmacist proposes to cease supplying pharmaceutical benefits;

- (e) approval of a pharmacist in respect of particular premises shall be recommended where those premises are located more than 500 metres but not more than 5 kilometres by normal access routes from other premises in respect of which that pharmacist is already approved under section 90 of the Act and from which the pharmacist proposes to cease supplying pharmaceutical benefits, provided that –
 - (i) there has been no grant of financial assistance made under section 99ZC or 99ZD of the Act in respect of any other premises situated within 5 kilometres by normal access routes from the first-named premises; and
 - (ii) the pharmacist demonstrates to the Authority that there was a definite unmet public need for that approval;
- (f) approval of a pharmacist in respect of particular premises shall be recommended where a pharmacist is approved under section 90 of the Act in respect of those premises and where that approval is to be cancelled immediately prior to the granting of the first-named approval, as a consequence of a change of ownership arrangements of the premises;
- (g) notwithstanding anything contained in subparagraphs (a) to (f), approval of a pharmacist in respect of particular premises shall be recommended where the pharmacist entered into a financial commitment prior to 9 August 1990 (being the date on which the granting by the Secretary of approvals to pharmacists under section 90 of the Act was restricted pending passage of legislation for pharmacy restructuring) in the expectation that an approval would be granted in respect of those premises, provided that the Authority is satisfied that there was such a prior commitment and the pharmacist produces to the Authority either –
 - (i) a bank statement, supported if necessary by an affidavit by the pharmacist's solicitor or accountant; or
 - (ii) details of any contractual arrangements together with an affidavit by the pharmacist's solicitor or accountant attesting to the correctness of the date that commitment was entered into.
- (h) notwithstanding anything contained in subparagraphs (a) to (g), approval of a pharmacist in respect of particular premises shall be recommended where the application for approval of the pharmacist in respect of those premises was made prior to 9 August 1990 (being the date on which the granting by the Secretary of approvals to pharmacists under section 90 of the Act was restricted pending the passage of legislation for pharmacy restructuring).'

13. The gazettal of *Determination No. PB 1 of 1991* on 23 January 1991 put in place the last piece of the legal jigsaw of the new approval process. Thus, in my opinion, the changes effecting pharmacy restructuring and the restrictions on approvals to dispense PBS prescriptions took effect in law on 23 January 1991 and were slightly amended as from 29 May 1991 by *Determination No. PB 4 of 1991*.

4. **Retrospective Effect of Guidelines in PB 1 and PB 4 on Intervening Period Applications**

14. From the gazettal of *Determination No. PB 1 of 1991* on 23 January 1991, there were certainly legally binding guidelines. However, an amendment to s.48 of the *Acts Interpretation Act 1901*, which became law on 21 December 1990, clarified the law and outlawed retrospectivity in specified kinds of delegated legislation that prejudices anyone other than the Commonwealth or an authority of the Commonwealth.

15. This provision applies to *Determinations Nos. PB 1 and PB 4 of 1991*. Those making recommendations or decisions on applications relating to periods before 23 January 1991 would need to bear this mind and compare the 'old' law and the 'new' law to make sure that there is no retrospective prejudice to an applicant. Of course any retrospective aspects beneficial to an applicant would be valid.

5. **Review by the AAT**

16. The point about beneficial retrospectivity is also relevant under my final point. We recall that once the 1990-1991 provisions became effective, there is a two stage process: first, there is recommendation by the Pharmacy Restructuring Authority and then decision by the Secretary. In *Re Shortis and Secretary of Department of Community Services and Health* (Judgment 21 June 1991) the President of the AAT, Justice Deirdre O'Connor, held that she could not review the decision of the Authority under the existing review provision, s.105AB(7), but review only the decision of the Secretary. This gap is being filled by clause 46 of the Health and Community Services Legislation Amendment Bill 1991, which inserts s.105AD to permit the AAT to review decisions of the Authority. The provision is made retrospective to the day these provisions of the *Community Services and Health Legislation Amendment Act 1990* commenced, namely 18 December 1990. So the amendment would allow an applicant who is, or has been, rejected by the Authority to seek review by the AAT.