Norton White
Lawyers & Consultants

Level 14
150 Lonsdale Street
Melbourne Vic 3000
Tel: (03) 9667 2480
Fax: (03) 9667 2490
Email:
info@nwmelb.com.au

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Ms Di Ford
Executive Director
GMiA
PO Box 12
Balmain 2041 NSW

By facsimile: (02) 9818 8565

Dear Ms Ford

National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007

As requested, we have reviewed the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007 ('Bill') as it was introduced to the Australian Parliament on 24 May, including against the stated aims of the Bill as articulated in the Second Reading Speech and the Explanatory Memorandum.

We have taken as our riding instructions that you do not intend at this stage to take issue with the public policy behind the Bill. Our review is directed primarily at the implementation of the policy as it is reflected in the Bill.

Summary

In summary, we consider that, under the Bill, the Pharmaceutical Benefits Scheme ('PBS), the commercial environment for suppliers of generics (and others) will be very much dependent on determinations made by the Minister of the day. Many such determinations will be substantially unreviewable by the courts and tribunals. The relevant sanctions and pressures will largely be political. A Minister who was determined to slash the costs of the PBS could make life very difficult for suppliers of generics (and others).

In addition, there are some dangers of unintended consequences in the Bill, which we seek to highlight below.

Determinations

To a quite remarkable extent, the Bill gives to the Minister the power to make determinations on matters of major significance to the operation of the PBS from the perspective of members of the Generic Medicines Industry Association ('GMiA'). Many of the major parameters of the PBS will be set by Ministerial determination. Amongst these are as to:

- many aspects of *pricing* including:
  - the *appropriate maximum price* to approved pharmacists and the *circumstances* in which the Commonwealth is to pay the *special patient contribution*
  - *price reductions* based on information provided under the *price disclosure requirements*
  - to which items *administrative price reductions* will apply
  - the *weighted average disclosed price* of a brand of item
  - the *claimed price;* and
  - the *determined price*
- which *items* are *exempt*
- which *brands* are *listed*
- which *forms of drugs* are *affected* by various determinations
- which *brands* are *affected* by various determinations
- how *therapeutic groups* are constituted
- which drugs are *pharmaceutical items*
- which drugs are respectively *F1 and F2*
- which drugs are respectively *F2A and F2T*
- which *brands* are *co-marketed; and*
- making brands subject to *guarantees of supply* ('guaranteed brands').

Notably, the Bill seems to envisage that the Minister may – again by determination - remove brands from the PBS for alleged shortcomings in price disclosure or supply[1].

Most of these determinations are said by the Bill to be legislative instruments.

But at least one category of determinations is <u>not</u> to be legislative instruments: a determination to relieve a person of a 'voluntary' obligation to provide price disclosure information in the event that the related mandatory brand is delisted[2].

The implications of being a legislative instrument include that the decisions contained in the legislative instrument will be subject to the provisions of the *Legislative Instruments Act 2003* (Cth) but will be out of the realm of the Administrative Appeals Tribunal ('AAT') and the *Administrative Decisions (Judicial Review) Act* ('ADJR Act').

The Legislative Instruments Act provides inter alia for Parliamentary scrutiny of legislative instruments, including for their disallowance by votes of the respective Houses. Other implications of being a legislative instrument are suggested by the Objects of the Legislative Instruments Act:

> "(1) The object of this Act is to provide a comprehensive regime for the management of Commonwealth legislative instruments by:
>
> (a) establishing the Federal Register of Legislative Instruments as a repository of Commonwealth legislative instruments, explanatory statements and compilations; and

[1] Proposed clause 99ADG(2) and clause 99AEH(2) in Item 81
[2] Proposed clause 99AEL(4) in Item 81

(b) encouraging rule-makers to undertake appropriate consultation before making legislative instruments; and

(c) encouraging high standards in the drafting of legislative instruments to promote their legal effectiveness, their clarity and their intelligibility to anticipated users; and

(d) improving public access to legislative instruments; and

(e) establishing improved mechanisms for Parliamentary scrutiny of legislative instruments; and

(f) establishing mechanisms to ensure that legislative instruments are periodically reviewed and, if they no longer have a continuing purpose, repealed."[3]

The AAT and ADJR Act are available for administrative decisions. Determinations which are legislative instruments are likely to be much more in the political arena than the judicial. Sanctions against "bad" decisions are likely to depend in most cases on disallowing determinations in the Parliament – where those determinations are disallowable – and other political sanctions. The courts are unlikely to intervene in most cases, even if – if they were administrative decisions rather than legislative instruments – there would be grounds to do so.

One clear example of the difference relates to the power of the Minister to determine to relieve a person of a 'voluntary' obligation to provide price disclosure information in the event that the related mandatory brand is delisted[4]. (As noted above, that particular class of determination is declared by the Bill not to be a legislative instrument, so its proper classification is questionable). If the decision of the Minister whether to take that course were an administrative decision, the *failure* by the Minister to make a decision could be challenged under the ADJR Act. However, if making such a determination were classified as a legislative or quasi legislative matter, it would be difficult to force the Minister's hand except politically.

A similar example arises if a "guaranteed brand" is delisted, as to whether or not the Minister redresses any price reduction for competitors – either promptly or at all[5].

Another potential advantage lost to the disgruntled generic supplier if the decision is legislative rather than administrative, is that s13 of the ADJR Act will not be in play. When it applies, s13 enables one to get an extensive statement of reasons for the decision. Without such a statement it is often difficult to know – and to prove – that the decision was made on a faulty basis. If one cannot show that the decision was made on a faulty basis, one cannot challenge it in the courts effectively.

In respect of various categories of determinations, the Bill lays down criteria[6] for the making of those determinations. Will determinations made in apparent disregard of such criteria be liable to challenge as ultra vires? This country is little explored. While we consider that they would be challengeable, desirably the bill should make clear that it is the Parliament's intention that determinations made in disregard of such criteria are liable to challenge as ultra vires.

[3] s3
[4] Proposed clause 99AEL(4) in Item 81
[5] See proposed clause 99AEI in Item 81
[6] e.g., proposed clause 84AE(3) in Item 34

In respect of numerous other categories of determinations[7], the Bill lays down no criteria for the making of those determinations. Those determinations are not likely to be reviewable in most cases.

It appears likely that many of the determinations which the Bill envisages will be about very specific issues (e.g., one particular drug). Such decisions are normally considered to be administrative in character rather than properly the subjects of legislation. Accordingly, many of the envisaged determinations are likely to be unusual hybrids which the courts might be tempted to treat as administrative although they are stated by the legislation to be legislative.

Notices and Regulations

As well as *determinations*, the Bill gives the Minister power to issue *notices* imposing price reductions based on information provided under the price disclosure requirements[8]. Such notices are stated not to be legislative instruments[9]. Such reductions will override price agreements[10] - for which agreements the Bill provides. Another example is notices adjusting prices based on information provided under the price disclosure requirements[11]

As well as *determinations*, the Bill gives further power to make *regulations*. An important example is as to the types of information to be provided under the price disclosure requirements[12]. In that particular example, the regulation making power is very broad. Without knowing what regulations will be proposed, the provision is something of a blank cheque.

Biosimilar

Three words of the Bill could have a major effect in relation to the grouping of goods for pricing – and price reduction – purpose: "*bioequivalent* includes biosimilar[13]. The intended effect appears to be that, as well as bioequivalent goods being grouped, biosimilar ones may be[14]. That may assist suppliers of generics, at least in some circumstances, but it also has the potential to rebound against suppliers of all types in price terms.

Confidentiality

Another possible concern about the proposed requirements for price disclosure – whether 'mandatory' or 'voluntary' is confidentiality. The information that the regulations will require to be provided may be very sensitive commercially. It is not apparent to us that its confidentiality is adequately protected by law.

Guarantees to supply

The guarantee to supply does not appear to be excused even if the price for the affected goods is radically slashed. The Bill envisages that the guarantee will be in place for up to two years. There is thus nothing to prevent the Minister reducing prices even early in the two-year period.

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[7] e.g., proposed clause 84AG in Item 34
[8] Proposed clause 99ADH in Item 81
[9] Proposed clause 99ADH(6) in Item 81
[10] Proposed clause 99ADH(1)(b) in Item 81
[11] Proposed clause 99ADH(6) in Item 81
[12] Proposed clause 99ADC in Item 81
[13] Proposed insertion in s84(1), in Item 4.
[14] See proposed clause 84AE, clause 84AH(b), clause 85AB(4) and (5) all in Item 34, proposed s88(8) in Item 7, proposed clause 99ACB(1)(c)(ii), clause 99ACC(1)(e)(i), clause 99ACD(1)(c)(ii), clause 99ADD(1)(d)(i), clause 99AEC(2)(c)(ii), clause 99AEC(3)(b)(ii), clause 99AED(3)(b)(ii), clause 99AED(3)(c)(ii),clause 99AEJ(c), clause 99AEK(c), all in Item 81

One concern about the guarantee to supply provisions is that the regulations can prescribe[15] a period within which the goods must be supplied in response to a request. If such a period is prescribed, the initial requirement of supply within a reasonable period is overridden. A quite unreasonable period could be prescribed. In particular, there is the danger that a period might be prescribed which is reasonable in some circumstances but quite unreasonable in others.

The Bill does not recognise any excuses for failure or inability to supply – we have in mind force majeure type events. While failure or inability to supply is not itself an offence, it creates exposure to delisting.

The Bill provides that, where a "guaranteed supply" brand is delisted, the Minister may make determinations[16] redressing price reductions that resulted from the delisted brand[17]. However there would probably not be any way to force the Minister to do that, or to do it expeditiously. Nor, to take a step back, does there appear to be any way to force the Minister to delist a brand that has ceased to be available, or to do it expeditiously.

Overview

As noted above, to a quite remarkable extent, the Bill gives to the Minister the power to make determinations on matters of major significance to members of GMIA. To put the matter starkly, the Minister would determine:

- whether the products of those members are covered by the PBS
- whether the products of those members are removed from the PBS
- whether requirements for price disclosure are imposed on those members
- how listed products are treated for pricing purpose, including price reductions. There are a number of separate determination mechanisms that can affect pricing, including a number of separate determination mechanisms that specifically can effect price reductions
- issues as to co-branding and grouping, which will affect pricing; and
- who is subjected to guarantees to supply (and the disadvantages attaching thereto).

The exercise of these powers will be difficult to control through the courts and problematic if one were seeking parliamentary action to overturn them.

Constitutional Issues

The National Health Act, as it would be amended by the Bill, is unprecedented to our knowledge in the extent to which it would empower the Minister to make decisions having enormous commercial impacts, including to override commercial agreements (including in particular price agreements) essentially by fiat. That leads us to wonder at the constitutional soundness of the legislation.

Two possible bases of attack are under placitums (xxxi) and (xxiiiA) of s51 of the Constitution.

Section 51(xxxi) of the Constitution is interpreted as preventing the Commonwealth making laws which take away rights of property (broadly interpreted) other than on just terms. The legislation could certainly result in significant loss of earnings and diminution in the value of intellectual property rights. The Bill should include a provision for a court to have jurisdiction to award just compensation in relevant cases. That is commonly done in Commonwealth

[15] Proposed clause 99AEE(1)(b)(ii) in Item 81
[16] There are various mechanisms to do so
[17] Purposed clause 99AEI in Item 81

legislation to prevent preaching s51(xxxi) and rendering the provision unconstitutional. Indeed two examples appear in the National Health Act[18]; but not in the context of the PBS.

Section 51(xxiiiA) is the head of power under which the PBS is established. It provides:

> "The Parliament shall, subject to this Constitution, have power to make laws for the peace, order, and good government of the Commonwealth with respect to … the provision of maternity allowances, widows' pensions, child endowment, unemployment, pharmaceutical, sickness and hospital benefits, medical and dental services (but not so as to authorize any form of civil conscription), benefits to students and family allowances"[19].

We query whether, as amended, the legislation goes so far as to no longer to be justified as a law with respect to the provision of pharmaceutical benefits. There is also a substantial prospect that a law requiring a person to continue to supply goods despite the price being unilaterally reduced by Ministerial determination offends the civil conscription prohibition in 51(xxiiiA) of the Constitution.

Yours sincerely

Ian Cunliffe
Norton White

[18] Sections 11(4)(b) and 90(3AA)
[19] Emphasis added