



Therapeutic Products and Medicines Bill

103—1

Report of the Government Administration Committee

Recommendation

The Government Administration Committee has examined the Therapeutic Products and Medicines Bill. We have been unable to reach agreement and therefore cannot recommend that the bill be passed.

Introduction

The Therapeutic Products and Medicines Bill is an omnibus bill. Parts 1 to 5 seek to establish a new scheme for the joint trans-Tasman regulation of therapeutic products, covering the manufacture, supply, importing, exporting, and promotion of therapeutic products; the setting of quality, safety, and performance standards for therapeutic products; post-market monitoring; and the enforcement of the scheme's requirements.

Parts 1 to 5 of this bill seek to implement the legislation required by the Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products signed in December 2003. The Agreement defines the role and governance arrangements of a new body, the Australia New Zealand Therapeutic Products Authority, which will take responsibility for regulating various aspects of therapeutic products. The Authority would be given its body corporate status by the Australian implementing legislation. The Agreement is appended as Schedule 1 of this bill.

Parts 6 and 7 seek to repeal the Medicines Act 1981 (and various regulations made under that Act) and would be split off to become a new Medicines Act. The new Act would include updated controls on medicines at the consumer end of the supply and distribution chain, such as controls on the retail and wholesale of medicines in New Zealand, dispensing and compounding scheduled medicines, the licensing of pharmacies, and prescribing rights.

While the bill provides the essential statutory basis for the proposed joint scheme, the scheme's operational detail would be contained in the Rules and Orders. We understand that consultation with industry and other stakeholders on the more significant Rules began in 2006 and is continuing.

Submissions received

We received and considered 895 written submissions to this bill. Over three quarters of these submissions were from individuals and the remainder from various organisations and groups. Most individual submitters were consumers of dietary supplements and natural health products and generally opposed the joint regulation of therapeutic products. Recurring concerns were that the costs and other consequences of complying with the new regulations could reduce choice for the consumer, that the products remaining on the market might become more expensive, the new Authority might undermine New Zealand's sovereignty, and that small and innovative New Zealand-based businesses might be adversely affected. A number of submitters questioned the need for regulation of complementary medicines, given the apparently low risk they pose to public health.

Submissions from groups or organisations represented various interests including

- manufacturers and distributors of pharmaceutical medicines, complementary medicines, medical devices, and cosmetics
- therapeutic products industry associations (covering the medical device, prescription medicine, over-the-counter medicine, natural products, and cosmetic industries, as well as direct marketers)
- health professional associations and practitioner groups
- advertising industry associations
- employer and employee associations
- specialists in law and regulatory matters
- consumer groups.

Many submissions from these groups supported the overall intent of the bill, while seeking changes to specific provisions. Among the reasons given for supporting the bill were arguments that it would benefit the New Zealand economy and facilitate the growth of the New Zealand therapeutic products industry and workforce. A number of supporters also argued that the bill would be beneficial to public health by making medicines available sooner, by facilitating access to medicines used to treat rare diseases, and by bringing New Zealand's regulation of therapeutic products into line with international best practice by establishing a joint Authority.

We received substantial advice on the potential health risk posed by complementary medicines and the lack of information available to consumers about safety and efficacy.

A key industry body for the natural products industry supported the bill's intent. However, the majority of submissions from dietary supplement and natural healthcare consumers, practitioners, producers, or distributors opposed the bill either in its entirety or in its specific application to complementary medicines. The proposed regulation of complementary medicines is discussed below.

Complementary medicines

Much of the opposition to the regulation of complementary healthcare products through the joint scheme centred on their comparative safety, the perceived high cost of the proposed regime, and the argument that it is thus inappropriate to impose a pharmaceutical model of regulation and licensing upon them.

To an extent, the nature of the current regulation of complementary medicines makes it difficult to get absolute data about their risks and benefits. Much of the discussion about complementary medicines was, therefore, anecdotal.

Structure of report

As the committee was unable to reach agreement that the bill be passed, the remainder of this report outlines the views of the Labour members in support of the bill, followed by the views of the National members and of the non-voting Green Party member.

View of Labour members

While we agree that complementary medicines generally pose minor risks compared with pharmaceuticals, we do not believe that they are entirely risk-free.

Treatment of complementary medicines under the joint scheme

In view of the need for better regulation of complementary medicines and also the widespread recognition of their relative safety, we were reassured that the joint scheme proposes a risk-based approach, meaning that the degree of regulation will be commensurate with the risk associated with a particular therapeutic product.

The differences in the treatment of prescription pharmaceutical and complementary medicines would be most evident in the requirements to gain a product licence, which authorises the import, export, supply, and promotion of a therapeutic product. A licence would be issued for a prescription medicine after the Authority evaluated data relating to the manufacture of the active ingredient, toxicology studies in animals, clinical trials, manufacture of dose form, stability, and prescribing information. Evaluation would take approximately 15 months. In contrast, a product licence for a complementary medicine would be issued after the sponsor entered a description of the product and the manufacturer's name and address into a web-based database and declared that they held the evidence to support any claims made for the product, providing that the ingredients in the product were on the permitted list. We were advised that the data entry requirements would take about 20 minutes and a product licence would be issued straight away.

In addition, we were told that under the Authority's draft Rules, certain complementary medicines were likely to be exempt from the requirement to acquire a product licence. An unconditional exemption was proposed for a medicine (other than a medicine used for gene therapy, xenotransplantation, or somatic cell therapy) that is extemporaneously compounded by a medical practitioner, pharmacist, or complementary healthcare practitioner for one particular person for therapeutic application to that person. A medicine manufactured by a complementary healthcare practitioner might also be exempted if it were manufactured on premises occupied by the manufacturer which could be closed to the public, and the practitioner supplied the product to a person after

consultation with that person, and used his or her own judgment as to the treatment required. If a traditional medicine were commercialised in any way, it would be subject to the regulatory scheme.

We believe these exemptions would address some of the concerns expressed by practitioners of traditional medicines and their clients. The application of traditional medicines often relies on the collection and supply of plant materials, and the compounding of a treatment from a range of substances, which in combination address the particular circumstances of the individual patient.

Opposition to joint regulation of complementary medicines

Many submitters presented evidence on the safety of complementary medicines compared with pharmaceutical medicines.

We also heard from numerous small-to-medium-sized enterprises who feared that higher compliance costs resulting from trans-Tasman regulation would either force them to move aspects of their operation, such as the manufacture of products, off-shore or threaten the viability of their business entirely. A particular concern was that the proposed scheme included a “white list” of permitted ingredients for use in therapeutic products. According to some submitters, up to 700 ingredients present in New Zealand products were currently not on the Australian permitted ingredients list.

Many consumers of natural health products feared the loss of products they had been using to maintain their health. They also expressed concern that increased compliance costs incurred by manufacturers would be passed on to them. While some people use complementary products as proactive and preventative health measures, others have found that such therapeutic products helped deal with existing conditions where mainstream pharmaceutical medicines have failed.

Scope for exemption of complementary medicines

We fully recognise the strength of feeling expressed by members and supporters of the complementary health industry who are opposed to this bill. However, we must stress that our remit extends only to the implementing bill before us, and not the Agreement to be signed by the New Zealand and Australian Governments. The intention of the parties at the time of signing the Agreement was that the joint scheme would cover all therapeutic products—that is, all products that make any sort of therapeutic claim, which complementary medicines do. Were a decision made to exempt complementary medicines from the proposed scheme, it could not be implemented merely by amending this bill. Exemption would require a renegotiation of the bilateral Agreement.

Rongoā Māori

An important element of the debate about complementary medicines from a New Zealand perspective concerned the treatment of rongoā Māori (traditional Māori medicine).

At present the preparation of products in the traditional practice of rongoā Maori is exempt from the requirements of the Medicines Act. The policy of the joint scheme was to continue the exemption of products produced in the practice of rongoā Māori, provided they were not commercialised

Most rongoā Māori would be covered by the exemptions in the Rules concerning complementary healthcare practitioners and extemporaneous compounding, as discussed above. We would have recommended inserting a new clause requiring that the Minister of Health must first consult the Minister of Māori Affairs before agreeing to make Rules that affect, or might affect, rongoā Māori. This is consistent with a similar provision in clause 12 about consulting the Minister of Finance about Rules relating to the governance and accountability of the Authority.

Rules and Orders

Central to the joint regulatory scheme is the use of a single joint set of Rules and Orders rather than domestic regulations. Regulatory requirements (relating, for example, to medicines, medical devices, administration matters, and advertising) would be set down in the Rules, which were to be made by the Ministerial Council, which would oversee the workings of the Authority. The Authority's Managing Director would be responsible for making the Orders, which contain more technical details such as labelling requirements and standards.

Provisions relating to the Rules and Orders are detailed in Part 1 of the bill. Clause 8 bound the Crown to the Rules and Orders, even though they would be finally determined only once implementing legislation is passed in both New Zealand and Australia. While we share the concerns of some submitters that the Rules and Orders should receive thorough and appropriate scrutiny before they are promulgated, we acknowledge that the Crown would have to be bound to Rules and Orders made for the purposes of the joint scheme, in view of the fact that the proposed legislation created the framework for their implementation.

We would have recommended the insertion of a new clause explaining the difference between Rules and Orders, as we believe that it would facilitate understanding of the operation of the joint scheme.

Parliamentary scrutiny of Rules and Orders

As Rules and Orders are not regulations for the purposes of the Regulations (Disallowance) Act 1989, they do not come within the jurisdiction of Parliament's Regulations Review Committee unless amendments are made to Standing Orders. We believe that this should be done and that in its scrutiny the Regulations Review Committee should be empowered to consider matters raised by the public and industry relating to Rules and Orders. To ensure consistency with the scrutiny of all other delegated legislation, we would have recommended that the powers of the Regulations Review Committee include a complaint jurisdiction over Rules and Orders. Given that complaints generally relate to the operation of regulations, and time and experience of how they operate in practice would be needed before circumstances leading to a complaint would usually arise, we would have recommended that there be no time limit on the complaint jurisdiction, rather than the three-month limitation period available for review and disallowance of Rules and Orders.

The Agreement, in articles 9 and 10, specifies the regulatory requirements that might be addressed by a Rule and those that may be addressed by an Order. It establishes that there is a hierarchy of matters relating to therapeutic products and that the Rules deal with those

that are high-level, and the Orders with more technical issues. This was also reflected in the bill's offence provisions; some more significant offences relate only to matters that are provided for in Rules. Examples of what may be included in the Rules are the products subject to the regime, and the circumstances in which a therapeutic product could not be manufactured, supplied, imported, exported, or promoted. We note that the scope of the Rules was left deliberately broad to ensure that the regulatory scheme was established jointly by the Ministerial Council and not by one or the other sovereign power. As a result, many significant policy decisions resided with the Council. It is unusual for delegated legislation to deal with matters of policy, and we therefore believed it was extremely important that the proposed accountability framework accommodated further parliamentary scrutiny of the Rules on policy grounds.

We believe the most suitable vehicle for achieving such scrutiny would be the referral of Rules and Orders to a subject select committee for consideration once they have been tabled. A precedent can be found in Standing Order 385, which provides for civil defence emergency management national strategies and proposed plans to be referred to the Government Administration Committee. We believe the Health Committee is most appropriately placed to undertake the examination of policy in Rules and Orders.

Accordingly, we would have recommended that:

- the House make sessional orders to provide for scrutiny by the Regulations Review Committee of Rules and Orders made under the joint scheme, including, without time limitation, the complaint jurisdiction of the Regulations Review Committee
- the House make sessional orders, to take effect as soon as the bill came into force, providing for the referral to the Health Committee of all Rules and Orders made pursuant to the joint scheme
- all sessional orders recommended above be incorporated into Standing Orders at the earliest opportunity, where necessary.

Disallowance of Rules and Orders

Clauses 21 to 27 establish a discrete disallowance scheme for Rules and Orders by Parliament. This follows the approach outlined in the Regulations (Disallowance) Act as closely as possible, except where adjustment was necessary to align with Australian processes.

Clause 22 provided that Rules and Orders can be disallowed in whole only, rather than in part. We were concerned that such a provision would mean that if there were concern about a single aspect of a Rule, the only way to prevent its implementation would be to disallow the entire Rule, which might represent a substantial number of regulations.

However, we were advised that the Agreement required disallowance in whole, in order to preserve the workability and integrity of the joint scheme. If Rules could be disallowed in part, there was a risk that piecemeal regulation would result and inconsistencies between the scheme as it applies in New Zealand and Australia would create ambiguity and, also, enforcement difficulties. It was hoped that the significant consequences of disallowance of

a Rule or Order would put the onus on the Authority to draft Rules and Orders well and ensure that robust consultative processes were followed in their formulation.

In addition, we believe the parliamentary scrutiny procedures recommended above would allow recommendations to be made on Rules and appropriate revisions made before the disallowance scheme was invoked.

Publication of Rules and Orders

We would have recommended the insertion of a new clause and amendments to clause 17 to increase public access to Rules and Orders. Both amendments would have had the effect of ensuring that hard copies of all Rules and Orders were available for inspection without charge, and could be purchased at reasonable cost.

Presenting explanatory statements

We would have recommended the insertion of a new clause specifying the information an explanatory statement to a Rule or Order must contain. The statement would explain the purpose and operation of the Rule or Order and the consultation undertaken in its formulation. If there was no consultation, the explanatory statement should account for this also. We believe that this recommended amendment would make the process for developing Rules and Orders more transparent.

Enforcement of regulatory scheme

The efficacy of the joint regulatory scheme would rely on the enforcement regimes in the two countries being as similar as possible. Consistent with the harmonisation principles behind the bill, clause 29 provides that for jurisdictional purposes, a person may be convicted of an offence under New Zealand law for conduct occurring in Australia.

We would have recommended the insertion of a new clause to allow evidence obtained in Australia under the equivalent Act to this bill to be treated as if it had been obtained under the power exercised by this bill.

Advertising

We would have recommended a number of changes to the provisions for the enforcement of the Advertising Code for therapeutic products (established under the Rules) and any Rules and Orders related to advertising. These provisions are detailed in clauses 61 to 67. They sought to encourage businesses to be socially responsible and ensure that advertisements for therapeutic products were balanced, truthful, and substantiated.

Publishing or broadcasting proscribed advertisements

The definition of a proscribed advertisement in the bill as introduced includes one that makes a false or misleading claim or representation about a therapeutic product. We would have recommended that clause 62(1), which lists proscribed advertisements, be amended to refer also to advertisements that do not make specific claims, but that in their entirety constitute a claim that is false and misleading.

We would have recommended the amendment to clause 62(1)(d) because, as some submitters pointed out, the practical effect of this clause as introduced was to prohibit all

therapeutic product advertisements to consumers, even advertisements making truthful claims.

We acknowledge that there are instances where a broadcaster or publisher runs an advertisement in breach of the advertising regulations, but does not know, or could not reasonably know, of the breach. Clause 63(3) exempted such broadcasters and publishers from liability, but clauses 62 and 64 as introduced contained no such equivalent. We would have recommended the insertion of the same exemption for clauses 62 and 64 to ensure consistency.

We would have recommended an amendment to clause 62(1)(c)(i) to ensure that it was the therapeutic product licence holder, rather than the supplier of the product, that is responsible for substantiating any claim about a product. This amendment would ensure consistency with the relevant Advertising Code principle.

Guidelines for setting penalty levels relating to advertising offences and civil penalties

Clause 67 applies to any court that imposes a civil penalty or sentences a person in relation to the advertising provisions in clauses 62 to 66. The bill as introduced required the court to evaluate the claims an advertisement makes for a therapeutic product against available “scientific evidence”.

However, the Authority would accept various kinds of evidence when making decisions about licensing complementary medicines, including traditional evidence or anecdotal evidence. We therefore would have recommended an amendment to clause 67(2)(a) to reflect this, by requiring the courts to take account of “scientific or other evidence.”

False or misleading information in applications and declarations

A person or body corporate would be liable to prosecution if they made a false or misleading statement on an application for a manufacturing licence, a product licence, or a conformity assessment certificate, other applications regarding these items, or in declarations related to conformity assessment procedures.

To avoid doubt and jurisdictional arguments, we would have recommended amendments to clauses 74 and 75 to provide that statements made in applications or declarations must be treated as if they were made in Australia or New Zealand, irrespective of where they were actually made.

Treatment of documents

We would have recommended a new clause providing a civil penalty and offence relating to damaging, destroying, altering, concealing, or falsifying documents relating to the scheme. This should be a serious offence because the scheme would rely on accurate documentation and a strong deterrent to damaging, destroying, altering, concealing, or falsifying documents would be needed.

Non-compliance notices

The bill authorises the Authority to issue a non-compliance notice to a person whose conduct may render them liable to a civil penalty or may constitute a strict liability offence.

We would have recommended some amendments to clause 95 which specifies the form a non-compliance notice should take. We would have recommended that the notice clarify that if the recipient paid the stated penalty, this person could not be pursued in civil or criminal proceedings in respect of the same conduct. We also would have recommended that the notice be required to include the date of its issue and how payment was to be made, and cite the relevant offence or civil penalty provision.

We believe these recommended amendments would make the non-compliance notice clearer to the recipient.

Search and seizure

The bill provides authorised officers with powers to enter a place (other than a marae or dwelling house) without a search warrant to monitor compliance with Rules and Orders or where there are grounds for serious concern regarding public health.

We would have recommended that the definition in clause 98 of “evidential material”, which is material that may be seized, be expanded to ensure that all appropriate material was covered. We would have recommended that the definition be extended to include evidence of conspiring to commit an offence.

We would have recommended that clause 101(3) be amended to clarify that material could be seized only on the basis of actual offending (that is, an offence has been or is being committed, or a civil penalty provision has been or is being breached), rather than on the basis of possible future offending or breaches.

In the bill as introduced, a person is considered to have committed an offence in relation to search and seizure if he or she “actively or passively obstructs an authorised officer” or other person exercising their power under this part of the bill. We would have recommended replacing the phrase “actively or passively obstructs” with “obstructs, hinders, resists, or deceives” in clause 121(1)(a). We believe that “passive obstruction” is a contradictory concept and could lead to misinterpretation.

Some submitters expressed concern about the amount of power afforded to officers by the search and seizure provisions in the bill. We were advised that these powers were not unprecedented, and are consistent with existing provisions in New Zealand legislation, such as the Health and Safety Disability Service (Safety) Act 2001, the Agricultural Compounds and Veterinary Medicines Act 1997, and the Customs and Excise Act 1996. We note that a similar approach is taken in Parts 6 and 7 of the bill, which would form the new Medicines Act.

We note too that though the powers of search and seizure in this bill are similar to officers’ powers in section 63 of the current Medicine Act, they were designed to take into consideration the principles of the New Zealand Bill of Rights Act 1990 and to allow the powers to be exercised in a practical way in today’s environment. Therefore, authorised officers could seize things only where there are reasonable grounds for believing that an offence has been, or is being, committed; things seized without a warrant would have to be returned as soon as practicable if the grounds for believing an offence has been committed no longer existed; and the Authority would have to apply to a District Court Judge, Community Magistrate, Justice of the Peace, or Registrar of a District Court (not being a

member of the Police) to retain things seized without a warrant if they were to be retained for more than 90 days.

Reviewable decisions

Part 3 of the bill covers various administrative law matters in respect of the Authority, establishes a system for reviewing decisions made by the Authority, and addresses the way judicial review applies to the Authority.

We believe the definition of “reviewable decision” in the bill as introduced is overly broad and could result in people attempting to take non-substantive issues to review. We would have recommended amending the definition in clause 128 so that a reviewable decision was a final decision by the Authority to grant or decline an application for an approval, to amend, revoke, or suspend an approval, or to decline to amend an approval. The Rules could also specify other matters that were open to merits review.

Information management

We understand that the Official Information Act 1982 applies for the most part to the Authority. Exceptions are certain Australian Government information and information held by the current Australian regulator, the Therapeutic Goods Administration, at the time of its disestablishment. To avoid doubt, we would have recommended the insertion of a new clause to make it clear that information held by the Minister as a member of the Ministerial Council is official information and subject to the requirements of the Official Information Act.

Clauses 172 to 177 authorise the release of specific types of information to specific people or organisations in specific circumstances. Clause 172, for example, authorises the release of therapeutic product information to the World Health Organisation. We would have recommended that this clause be amended to allow manufacturing information and information about counterfeit therapeutic products to be released to the World Health Organisation.

In some circumstances information would have to be released to other New Zealand or Australian bodies with therapeutic functions. This is provided for in clause 173. However, we would have also recommended that clause 173 be amended to allow information to be released to any New Zealand and Australian authority where it required this information to carry out its functions.

Duties of Authority employees

Under clauses 241 to 247 of the bill as introduced a senior officer of the Authority (senior manager or member of the Board) is obliged to act in an appropriate manner, to comply with Acts and Rules, and not to misuse information. Failure to comply with these duties would have both civil and criminal consequences.

The obligation not to disclose information or misuse one’s position is extended to all Authority employees through clauses 201 and 202 in the bill as introduced. Conviction under either of these offences would also carry a term of imprisonment, a fine, or both.

While the Tax Administration Act 1994 and the Statistics Act 1975 both contain provision for penalising employees for breach of duties, we note that it is not the norm in New Zealand for employees to be subject to provisions such as clauses 201 and 202. Misbehaviour would normally be covered by an organisation's code of conduct, breaches of which would lead to dismissal (and possibly criminal charges for a serious offence).

The provisions regarding the duties of employees in this bill reflect the Australian provisions. We were advised that the potential for business loss and gain is greater in Australia, and might provide stronger motivation for misconduct by employees. Experience of such situations may also have given rise to these penalty provisions. We were advised that for the joint scheme to operate successfully, legislative provisions in Australia and New Zealand must be aligned as closely as possible.

However, we believe that some amendments should have been made to the clauses relating to the duties of all employees to ensure clarity around the extent and meaning of duties, and establish more appropriate severity of applicable offences and civil penalties.

We would have recommended omitting clauses 201 and 202. We would have liked these matters to be addressed in new clauses establishing the offence of intentionally disclosing information or producing a document. They would apply to every current or former employee of the Authority, including the Managing Director, and also contractors and members of expert advisory committees. A new clause could detail the liabilities for breach of this provision and differentiate between different types of employee. A senior, or former senior officer would be liable on conviction to a term of imprisonment of up to two years, a fine of 300 penalty units, or both. All other employees might be imprisoned for up to one year, fined 150 penalty units, or both.

We would have recommended minor amendments to clauses 241 to 243, and the replacement of clauses 245 and 246 with three new clauses, each dealing with a single duty.

We also would have recommended the replacement of clause 247 to more clearly identify the offences that related to the revised duties set out in clauses 245 and 246. Under the bill as introduced, conviction for a breach of senior officer duties carried a term of imprisonment of not more than five years, a fine of not more than 300 penalty units, or both. We would have recommended that the level of fine be increased to not more than 600 penalty units, in order to reflect the potential gravity of an offence under this clause.

Immunity for Authority and Authority's employees

The bill as introduced provides immunity from civil or criminal proceedings, unless they have acted in bad faith, for senior and former senior officers, members and former members of Authority Board committees, members and former members of expert advisory committees, and employees and former employees of the Authority. While we endorse the civil immunity, we would have recommended that immunity from criminal prosecution be deleted from clause 205, as this is not generally granted in New Zealand.

We would have recommended an amendment to clause 205(2)(a) to ensure that employees, members of Board committees, and members of expert advisory committees could still have action taken against them by the Authority in the event that they breached their obligations to the Authority.

We would have recommended a further amendment to the immunity provisions to the effect that the immunity applies only to New Zealand citizens and permanent residents, wherever they reside.

Clause 208 of the bill as introduced provides a similar immunity from civil and criminal proceedings for the Authority itself. We would have recommended that this clause be deleted, because we believe the Authority should be liable to court action.

Reporting

The reporting obligations for the Authority contained in the bill are consistent with the expectations for a New Zealand Crown entity. Under clauses 224 to 231 the Board must prepare a statement of intent and an annual report for the Authority before the start of each financial year and provide it to the Ministerial Council. Both documents were to be presented to the House of Representatives and published on the Authority's website.

We believe these provisions were important for the accountability of the Authority. We note too that Standing Orders 335 to 340 provide a process for the financial review of Crown entities and public organisations by subject select committees, and subsequent debate in the House. We would have recommended that the sessional orders discussed above include provision for the House to conduct an annual financial and operational review of the Australia New Zealand Therapeutic Products Authority.

Auditing of the Authority

Under the Agreement, the New Zealand Auditor-General and the Australian Auditor-General were both to be appointed as auditors of the Authority. We would have recommended that clause 232 be amended so that the New Zealand Auditor-General became an auditor of the Authority by virtue of an amendment to the Public Audit Act 2001, rather than by appointment under this bill. We would also have recommended an appropriate amendment, in Schedule 3, to the Public Audit Act.

Regulations under the scheme

Clause 269 provides for regulations to exclude specific products from the scheme, as provided for in article 12 of the Agreement. Clause 269(2)(h) authorises regulations that allow authoritative standards to be used in relation to all or specified products excluded from the scheme. It appears to provide for regulations to incorporate material by reference. We would have recommended that further provisions regarding material incorporated by reference, similar to provisions recommended by the Regulations Review Committee, be inserted into this clause.¹

We note that under clause 269(2)(i), the Minister of Health could prescribe details of the regulatory regime by notice in the *Gazette*. We would also have recommended the insertion of a new clause to require the Minister to be satisfied that the regulations were in the interests of public safety and would ensure the continued quality, safety, efficacy, and performance of the excluded products.

¹ Standard provisions are set down in: Regulations Review Committee, *Inquiry into material incorporated by reference*, 2004 AJHR I.16G.

Clause 271 allows the making of temporary or transitional regulations necessary to fully implement the scheme in New Zealand and ensure a smooth transition. We would have recommended that public consultation requirements be added to this clause.

We believe that regulations made under clause 271 should be subject to sunset provisions in order to explicitly limit the power of the Executive to override primary legislation and to prevent transitional regulations being repeatedly rolled over on expiry. We would therefore have recommended that clause 271(3) be replaced, to state that regulations made under clause 271 must expire no later than five years after their commencement. A five-year time limit is consistent with transition provisions in the Resource Management Act 1991 and the Biosecurity Act 1993, which involved similarly complex regime changes.

Relationship between parts of the bill

As noted earlier, Parts 1 to 5 of the bill were designed to address all matters regarding therapeutic products before they entered the consumer end of the supply chain. Once a product was available to consumers, Parts 6 and 7 would apply.

We believe that clarification of the relationship between Parts 1 to 5 and Parts 6 and 7 would aid interpretation of the bill. We would have recommended the insertion of a new clause into Parts 6 and 7 clarifying that an authority to undertake an activity under Parts 6 and 7 was not the same as an approval under Parts 1 to 5, and vice versa.

Definitions for Parts 6 and 7

Clause 339 defines a number of key terms used elsewhere in Parts 6 and 7. We would have recommended various minor and more substantial amendments to these definitions, often as a result of comment by submitters. The major issues are discussed below, including the need for amendments to definitions that are reflected in subsequent recommended changes to the bill.

Authorised prescriber and collaborative prescribing

Various nursing groups submitted that nurse practitioners should become authorised prescribers. The bill as introduced specifies that dentists, medical practitioners, and midwives fall within the definition of an authorised prescriber. Nurse practitioners are not explicitly referred to. However, the definition also allows for certain groups of health practitioners to be named as authorised practitioners by way of regulations made under clause 502. We believe that these regulations, made on the recommendation of the Minister of Health after full consultation with affected parties, remained the appropriate mechanism for introducing such a change to prescribing rights.

We would have recommended that the definition of “authorised prescriber” also refer to any qualification or training requirements imposed upon authorised prescribers by regulations made under clause 503. This change would ensure the definition of authorised prescriber was consistent with the definition of “designated prescriber”.

We also received a number of submissions addressing the need for a mechanism to authorise collaborative prescribing. Collaborative prescribing allows a non-prescribing health practitioner to prescribe under the supervision of an independent or authorised prescriber. The Minister indicated to us that this issue was to be considered further and

that to allow time for meaningful consultation to take place, the matter would be dealt with by amendment at committee of the whole House stage.

Compounding and dispensing

We would have recommended that compounding and dispensing be treated and regulated under the bill as two separate controlled activities. We would therefore have recommended that the definition of “dispense” be amended to explicitly state that this term does not include the compounding of a medicine.

We would have recommended the insertion of new clauses to reflect the proposal to treat the compounding of scheduled medicines as a separate controlled activity. These provisions would align closely with those for the dispensing of scheduled medicines.

In addition, we would have recommended amending the regulation-making powers in clause 499 to give effect to the changed status of compounding as a separate controlled activity. Regulations for the dispensing of medicines are dealt with in clauses 499(13) to 499(25). We would have recommended the insertion of new clauses to address separate regulation of the compounding of medicines.

We would have recommended amending clauses 361 to 368 so that the restriction on undertaking dispensing was limited to the dispensing of scheduled medicines only. This would ensure that people were not prevented from dispensing non-scheduled medicines that they have compounded themselves.

Dispensary technician

We would have recommended that a definition of “dispensary technician” be inserted into the bill to clarify that a dispensary technician is the holder of a historical, but still valid, qualification. We would have recommended that “Dispensary Assistant Certificate” be deleted from the bill as referring to specific certificates by name and date might create future complexities.

Definitions related to pharmacy practice

We received a number of submissions from representatives of the pharmacy industry, which included suggestions on definitions in clause 339. We would have supported a number of these suggestions and explain our recommendations below.

We would have recommended that subclause (b) in the definition of “pharmacy graduate” be deleted as it was included in the existing Medicines Act as a transitional matter relating to outstanding applications for pharmacist registration under the Pharmacy Act 1970 and no such applications remain outstanding.

We would have recommended the insertion of the words “without limitation” into the definition of “pharmacy practice” to ensure that the definition was not treated as a definitive list. We would also have recommended that the definition include “compounding” as one of the activities a pharmacist undertakes, in order to reflect the new status of compounding as a separately controlled activity, as discussed above.

We would have recommended amendment of the definition of “pharmacy student” to allow the recognition of qualifications of British, Irish, Canadian, and American students engaged in international student practicum arrangements.

We would also have recommended a minor amendment to the definition of “pharmacy technician” and the insertion of a definition for “pharmacy technician student”. We would have recommended that pharmacy technician students be included in the list of people associated with pharmacies who may dispense scheduled medicines in limited circumstances, as detailed in clause 364. They are currently permitted to do so under Medicines Regulations 42(1) and 42(1A).

We would have also recommended the insertion of a new clause to allow updating of the qualifications required for pharmacy technicians to be notified in the *Gazette*. This more flexible mechanism would be intended to avoid future difficulties with specifying the names of qualifications that are likely to change over time.

Prescribe and prescription

The term “prescribe” is not currently defined in the Medicines Act or the Medicines Regulations 1984. We would have recommended that a definition be included in this bill as it represents a controlled activity and other controlled activities are defined. In this bill, “prescribe” means to issue a prescription.

As a consequence of this addition, we would have recommended the insertion of a definition of “prescription” as “a direction that a specified scheduled medicine be dispensed, supplied, or used in a specific way”.

Working day

We would have recommended the insertion of the term “working day” and its definition. Various shorter appeal periods appear in the bill as introduced and do not take account of the days when a District Court is closed during the Christmas and New Year period. We would have recommended amending clauses in the bill to specify the period within which an appeal must be lodged in terms of working days. Examples include clause 477 (appeal against decision in respect of premises) and clause 478 (appeal against decision of licensing authority).

Supply of scheduled medicines other than by wholesale

We would have recommended amending the penalty in clause 347(3)(a) from not exceeding \$100,000 to not exceeding \$40,000. This penalty would apply when a body corporate supplied a pharmacist-only medicine or a pharmacist medicine other than by wholesale, and the recommended change corrects an inconsistency in the bill as introduced.

We would have recommended the deletion of clause 351, which permits an employee working with a prescriber to supply scheduled medicines other than by wholesale in limited circumstances. The clause does not reflect the current position under the Medicines Act. We believe that the status quo should be preserved and that employees of a prescriber should not be given this power.

We believe provisions in the bill authorising employees working with pharmacists or veterinarians to supply scheduled medicines other than by wholesale in limited circumstances should be retained (clauses 352 and 353) but further clarified. In both circumstances the supply should have to occur under the supervision of the pharmacist or veterinarian with whom the employee is working.

We would have recommended deleting clause 352(1)(a) as we do not believe an employee should have to be limited to supplying these medicines only in circumstances where the pharmacist requests their supply. We would have recommended further amendments to subclauses (2), (3), and (4) to clarify the very narrow circumstances in which the authority to supply other than by wholesale would be allowed. Similar amendments would be recommended to clause 353 regarding the authority for a person working with a veterinarian to supply scheduled medicines other than by wholesale in certain circumstances.

Prescribing notices

Under clause 373, a prescribing authority (a health authority that has designated prescribers registered with it) must issue a prescribing notice in the *Gazette* specifying which prescription medicines or which class or description of medicines the registered prescriber can prescribe, and the circumstances in which these prescription medicines can be prescribed. We would have recommended that clause 373(1)(b) be amended to require the notice to specify the circumstances in which a prescription medicine may not be prescribed.

For the avoidance of doubt, we would have recommended that clause 373 also clarify that a prescribing notice is not a regulation for the purposes the Regulations Publications Act 1989 and the Regulations (Disallowance) Act 1989.

The bill as introduced requires a prescribing authority to review a prescribing notice within six months of its issue. Six months may be too short a time to determine what changes might be required. We would therefore have recommended that clause 374 be amended so that prescribing notices must be reviewed periodically at least once every 12 months, and a review could be conducted more frequently if a registration authority considered it necessary.

We would also have recommended amending clause 376 to include provision for the Minister of Health to order a review in the event of a public health or safety concern. We would have recommended that a prescribing authority, if its review concluded that the designated prescribers in the notice should no longer be able to prescribe the prescription medicine or class or description of medicines specified in the notice, must give effect to the results of its review as soon as practicable. This would likely be in the form of the amendment, revocation, or replacement of the original prescribing notice.

Operating pharmacies

Clauses 418 to 428 address certain requirements placed on licences to operate pharmacies. We would not have recommended any substantive changes to these clauses, which mirror the current law on this matter.

Some submitters argued that existing restrictions on majority interest in a pharmacy should be relaxed, so that the majority interest no longer needed to be held by a pharmacist. We do not believe that this bill is the appropriate vehicle to pursue such a significant change in pharmacy ownership. The current ownership provisions have been in place since September 2004 so there has been a relatively short time to assess their effects. In addition, a move to open ownership would require considerable consultation with affected and interested parties which extends beyond the intention of this bill.

Appeals

The bill allows a person to appeal against certain decisions made by a Medical Officer of Health or the licensing authority (Director-General of Health).

Appeal against decision in respect of premises

Under clause 434 a Medical Officer of Health may serve a notice on an owner or occupier of premises in such a condition that there is a risk of medicines stored there being contaminated, deteriorating or becoming dirty. We would have recommended that clause 477, which grants the occupier the right to appeal against such a decision, be amended to also extend the right of appeal to the owner of the premises.

Licensing appeals

We would have recommended the insertion of a new clause to provide that an appeal for a merits review of a decision could be made to the Director-General or to a person designated by the Director-General, where the original decision was made by a delegate of the Director-General. An appeal can be made against various decisions, such as a refusal to grant a licence, the imposition of a condition on a licence, or the suspension of a licence. New clauses could specify the procedures and information required for the review.

This new clause would have avoided recourse to the Courts in the first instance when the original decision is made by a delegate of the Director-General. Where a decision has been made by the Director-General personally, the first appeal would be to the District Court.

Restrictions on xenotransplantation

The bill preserves the current moratorium on xenotransplantation. As in the Medicines Act, xenotransplantation could only be carried out where it was authorised by the Minister of Health or by Order in Council.

We believe that the new definition of xenotransplantation contained in clause 487 is clearer than the current definition in the Medicines Act. It is consistent with the United States Food and Drug Administration definition and is intended to include blood but not bone.

We considered the view that an additional requirement to consider the ethical, spiritual, and cultural issues raised by a xenotransplantation procedure should be included in the matters the Minister of Health must consider before approving the conduct of a xenotransplantation (clause 491). Given that each xenotransplantation clinical trial application requires ethical approval from a health and disability ethics committee, and this review considers cultural and social matters, we do not believe an additional explicit requirement to consider the cultural, social, and spiritual implications of xenotransplantation is necessary. This stance is consistent with the Bioethics Council's

recommendation that health and disability ethics committees consider ethical, spiritual, and cultural issues on a case-by-case basis for each xenotransplantation clinical trial.

Regulations in respect of Parts 6 and 7 of the bill

We would have recommended deleting clause 499(2)(75). This clause as introduced provides for regulations to be made regarding the custody, production, suspension, or revocation of licences required to supply medicines or operate a pharmacy. As these matters are already dealt with in clauses 410, 411, and 416 of the bill, further regulatory powers are therefore unnecessary. They are also issues of considerable importance and it is entirely appropriate that they be addressed in primary legislation.

We would have recommended inserting a new clause dealing with certain requirements to obtain a licence. It would allow a licensing authority to set any test or examination the authority deems appropriate to meet the requirements of holding a licence.

View of National members

Discussion in the Select Committee took place with both New Zealand and Australian officials in regard to exempting complementary medicines from the trans-Tasman regulatory scheme and Treaty. National members believe that this would be the most sensible way to enhance our pharmaceutical regulations yet allow New Zealand small business and consumer demand requirements to be met.

There was a general consensus among all submitters that some regulation would be desirable. The main point of difference was the inclusion of complementary medicines in the trans-Tasman Treaty Agreement.

A “lighter” regulation regime based in New Zealand should be considered to ensure that product labelling and marketing claims are substantiated.

Businesses that appeared before the committee said that this bill would have a dramatic impact on the costs of compliance and the price consumers will pay for their natural health products. They felt that there were cheaper ways of regulating the sector and that this regulation was costly, unnecessary, and bureaucratic. A submitter said that the Government’s own reports say that 60 per cent of natural health products made in New Zealand for New Zealand will be taken off the shelves.

The level of search and seizure power in regard to complementary medicines seems to be well out of line with the potential risk. In other words the powers given are more commensurate with risks associated with dangerous high-level drugs than they are with herbal tea.

Concerns were raised by natural health product suppliers that potential innovation and business opportunity would be lost through unnecessary compliance, with little evidence that risk exists under current law.

Overall the whole purpose of the trans-Tasman regulatory regime and Treaty has been lost with the inclusion of complementary medicines. There is potential that this will add costs to business, could reduce access through regulation, has harsh penalties for non

compliance, could reduce opportunity to enhance NZ business growth and restrict potential health benefits.

View of the non-voting Green member

The committee acknowledges that Sue Kedgley, Green MP, attended meetings of the committee as a non-voting member and her specific comment is as follows:

The Green party agrees that dietary supplements need a better system of regulation, to ensure consumers are confident that they are safe and true to label.

However we believe this should be done by a stand-alone New Zealand agency, based on principles outlined by a Health Committee inquiry into how best to regulate dietary supplements.

We are opposed to their inclusion in the Australia New Zealand Therapeutic Products Agency because we believe the proposed regulatory regime is onerous, and would result in New Zealanders losing their access to some dietary supplements and traditional medicines, a reduction in consumer choice, increased compliance costs and the closure of many small New Zealand businesses. We also have serious constitutional concerns with the proposed regulatory regime, which we believe will undermine the sovereignty of our Parliament.

We are concerned that the select committee had very little information before it about how the agency will operate. Most of the details of how the agency will operate will be set out in Rules and Orders, which will be adopted after the legislation has been adopted.

We are concerned that the Managing Director's wide ranging powers to make regulations will, in practice, enable him or her to determine significant matters of policy and substance that should be the reserve of primary legislation and subject to the full and unlimited scrutiny of the House.

We are concerned at the extensive police powers of search and seizure without a warrant, and the powers of the agency to issue civil penalty and other offences, including instant fines.

We are concerned that if the bill is passed into law, New Zealand will have no direct control over the regulation of therapeutic products except through an extremely limited disallowance regime.

Appendix

Committee process

The Therapeutic Products and Medicines Bill was referred to the committee on 12 December 2006. The closing date for submissions was 7 February 2007. We received and considered 895 submissions from interested groups and individuals. We heard 105 submissions, and hearings were held in Wellington, Auckland, and Christchurch.

We received advice from the Ministry of Health and Te Puni Kōkiri. The Regulations Review Committee reported to the committee on the powers contained in clauses 269, 271, 499, and 503.

Committee membership

Shane Ardern (Chairperson)
Darien Fenton (Deputy Chairperson)
Brian Connell
Sandra Goudie
Hon George Hawkins
Hon Dover Samuels

Peter Brown and Keith Locke were non-voting members of the committee for this item of business.

Steve Chadwick was a substitute member for Hon George Hawkins for much of the consideration of this bill.