

Review of NZIER Report
Assessment of Regulatory Options for
Therapeutic Products

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Executive Summary

This report reviews the New Zealand Institute of Economic Research report ('the NZIER report') to the trans-Tasman working group titled 'Assessment of Regulatory Options for Therapeutic Products' (October 2002). The objective of the review was to establish whether the NZIER report achieved its stated purpose of assessing the need to extend regulation for complementary healthcare products and medical devices and establishing a single regulatory regime across New Zealand and Australia for all therapeutic product using a cost benefit framework.

With respect to the NZIER report's analysis the review found that:

- A generally accepted principle of cost benefit analysis is that weak value judgements should be used in determining whether a policy is to be judged socially beneficial. The NZIER report departed from this principle in several respects. The regulatory options were not the logical outcome of analysis but were predetermined, presumably by officials. The best options may not have been considered while the report did not follow its own advice, namely, that policy makers need to assure themselves that: "The proposals are the best available alternative to meet the stated objectives."
- The NZIER report explicitly stated that most benefits and some costs could not be quantified and that given the costs of compliance it could not determine whether any change from the current regulatory system would generate a net benefit to New Zealand. This decision came down to a value judgement of the additional benefits to consumers' knowledge and health and safety. The report stated that the trade-off was not clear for medial devices and complementary healthcare products. The report advanced a limited number of issues in support of extended regulation, namely: emergence of increased risk due to technological developments and the associated demand for scarce specialist regulators; increased regulatory integration due to globalisation; CER; and the impact of the public health and Accident Compensation Scheme (ACC) on producers and consumers. These "important drivers" were deemed to be impacting on the efficiency and effectiveness of the current regulatory regime.
- No factual evidence was advanced in support of these alleged drivers of the need for additional regulation. The report resorted to unsubstantiated claims

such as the risks are thought to be rising and specialist regulatory staff are becoming more difficult and expensive to recruit. While advanced as a benefit of a Joint Therapeutic Agency (JTA), no explanation was provided as to why the JTA option would not also be adversely affected or why market pressures would not induce an increased supply of skilled people in the medium term.

- While CER should alter market prices of relevant costs and benefits their values measured in opportunity costs should remain unchanged. The NZIER report's assertion that JTA offered an opportunity to develop a new type of trans-Tasman organisation that was an innovative step for CER and the relationship between the two national governments and parliaments was speculative. These views were irrelevant to the 'economic' assessment and suggested the NZIER report was imposing strong value judgements and introducing predetermined bias in favour of the JTA option.
- The NZIER report defined compliance cost broadly but did not measure the production losses, capital costs or most operating costs that the regulation is likely to generate. The analysis of costs was confined largely to quantification of agency costs. The agency cost estimates with respect to alternative options to the Status Quo are suspect and should be independently audited. For example, the agency cost of Medsafe rises from \$1,000 to \$3,652 per status quo activity (265%) which raises questions about the efficiency of the agency and alternative options to those considered. The JTA agency costs are broad brush estimates that do not appear sensible while Tables 8 and 9 do not appear to reconcile with respect to the New Zealand industry's share. In the absence of further explanation the figures contained in Tables 8 to 10 are not credible.
- The NZIER report indicates compliance cost as a percentage of industry turnover. The percentages are likely to be extremely misleading for two reasons. First, production losses, capital cost and most operating costs of compliance are excluded from Tables 9 and 10 estimates. Secondly, industry turnover was guesstimated as the industry was not surveyed.
- The NZIER report generally is of little value to the issue of determining whether there is an economic case for increasing regulation, nor does it provide insight into the best regulatory option should it be in New Zealand's interest to extent

regulation. The NZIER report does provide useful qualitative comments on the impact of regulation in terms of its adverse effects on industry.

1 Introduction

- 1.1 This report provides an independent review of the New Zealand Institute of Economic Research report ('the NZIER report') to the trans-Tasman working group titled 'Assessment of Regulatory Options for Therapeutic Products' (October 2002).
- 1.2 The review was undertaken by Philip Donnelly (refer Appendix 1 for CV) of Philip Donnelly and Associates Limited, economic consultants. The review evaluated whether the NZIER report justified the stated purpose of the report from an economic perspective having regard to the methodology, data and conclusions. The review was undertaken having regard to the accepted principles of cost benefit analysis.

2 Key cost benefit principles

- 2.1 Cost Benefit analysis is a branch of normative economics and is based on the application of weak values judgements ie assumptions that are not controversial and generally accepted. The analyst should avoid imposing own values and generally accept the observed consumption preferences of individuals without imposing moral judgements about its worth. In economics this is called the principle of 'consumer sovereignty', that is individual consumers know best in terms of their purchasing decisions and hence should be allowed, in the absence of externalities on third parties, to make their own choices.
- 2.2 In cost benefit analysis all costs should be measured in opportunity costs which reflect the full monetary and non monetary costs of production. This may require adjustment of market prices where there is good reason to conclude that prices are under or over stated.
- 2.3 A key principle of cost benefit analysis is that there must be a net benefit to society for a project or policy to be judged socially beneficial and in this respect the Kaldor Hicks compensation test should be used. Effectively this test states that for a project or policy to be judged socially beneficial it is necessary for the gainers to secure sufficient by way of benefits such that they compensate the losers and still have some net gain left over.

3 NZIER report's methodology

Purpose

3.1 The NZIER report appropriately adopted a cost benefit framework for its analysis:

“To meet the information requirement for a Regulatory Impact Statement, we use the Cost Benefit Analysis framework.This provides a cost-benefit assessment to assist policy-makers to select the proposal that would yield the greatest net benefit to society.¹

3.2 In this respect the NZIER report stated both broad and narrow purposes. First, in the Executive Summary the purpose was broadly defined as:

“This report assesses the impacts of

- Extending the regulation for complementary healthcare products and medical devices in New Zealand; and
- Establishing a single regulatory regime across New Zealand and Australia for all therapeutic product ,including pharmaceuticals.”²

3.3 Secondly, in the Introduction the purpose was more narrowly defined as:

“This report provides an economic evaluation of the proposal for a joint therapeutic products agency (JTA) to harmonise therapeutic products regulation for Australia and New Zealand, compared to the main alternative options being considered for pharmaceuticals, medical devices and complementary healthcare products.”

3.4 The latter is consistent with the Executive Summary's second bullet point, albeit an expanded version, namely, analysis of the single regulatory trans-Tasman regime compared to the main options being considered.

3.5 The purpose of the analysis was deficient as it was a quantum leap in logic to go from the first to the second stated purpose as the latter does not flow logically from the first. An intermediate step was required if extended regulation was shown to be beneficial, namely, establishing the main alternative options having regard to the findings that justified extending regulation to complementary healthcare products

¹ Refer page 7.

² Refer page 1 executive summary.

and medical devices. From an analytical perspective it was inappropriate for the NZIER report to confine the secondary analysis to preconceived options determined by third parties, presumably officials, that are not logical outcomes of the primary investigation. It begs the question as to whether better outcomes could be achieved by pursuit of other regulatory options (eg contracting out of specific regulatory tasks).

3.6 The NZIER report in fact endorsed this criticism as it stated (the key point is underlined):

“ In deciding whether or not to proceed with:

- Extending the scope and therapeutic products regulation to cover medical devices and complementary healthcare products, and
- A joint therapeutics agency,

Policy-makers need to assure themselves that:

- The proposals are the best available alternative to meet the stated objectives; and
- The proposals deliver net benefits to society, ie improve on the status quo.”

Problem definition

3.7 The NZIER report defines the alleged problem that is facing the Government as follows:

“In pursuing health and trade objectives, the Government is currently faced with three concerns:

- New Zealand’s therapeutic products regulatory framework is inconsistent with that of other developed countries and deemed inadequate in managing public health and safety risks from the use of medical devices and complementary healthcare products;
- Due to the increasing difficulty and cost of attracting and retaining appropriately skilled staff, New Zealand will find it increasingly difficult to meet its regulatory objectives for pharmaceuticals to appropriate standards and within acceptable time frames; and

- Differences in therapeutic product regulation stand in the way of stated policy objectives to remove trans-Tasman trade barriers and integrate the New Zealand and Australian economies under the Trans Tasman Mutual Recognition Arrangement (TTMRA). In relation to the regulation of therapeutic products, the TTMRA has a special exemption that needs to be resolved by 2003.”³

3.8 The NZIER report concludes from this that the first two concerns point to selecting a regulatory arrangement for New Zealand that results in an efficient and sustainable level of risk management in the future, balancing public health and safety and trade benefits with the costs of regulation. To the extent that this is another way of saying that the regulatory option for New Zealand should be based on the outcome that produces the greatest net benefit to society we concur. We disagree if the inference is that some relevant costs and benefits (eg trade with Australia) should be given greater weight than a disinterested economic valuation would otherwise ascribe as this is tantamount to endorsing a policy of cross subsidisation (eg the industry funding Australian trade). It is in breach of one of the fundamental principles of cost benefit analysis, namely, that of imposing weak value judgements and in particular accepting that individual preference counts.

NZIER report’s selection of feasible options

3.9 The NZIER report analyses four options, including two sub-options selected independent of the primary analysis. The ‘preselection of options’ undermines the value of subsequent analysis from an economic perspective. The problem was compounded by lack of consideration of the advantages and disadvantages of different regulatory approaches for pharmaceuticals, complementary healthcare products and medial devices. The NZIER report’s justification for dismissal of this consideration, namely, that “officials deem this not to be a preferred option,” lacks economic conviction and is inappropriate.

Assessment of regulatory impacts

3.10 The NZIER report stated that:

³ Ibid: page 1.

“A cost benefit assessment considers the full impact of proposals on society as a whole, distinguishing in this case between consumers, producers and the Government”

3.11 We agree that cost benefit analysis is the appropriate economic basis for the assessment and that it should consider the full impacts on society. The report goes on to state:

“While some costs, such as regulatory fees and compliance costs have been quantified, some costs and most benefits could not be quantified – such as the impacts of each option on the level of public health and safety risk, or some of the benefits for trade and trans-Tasman relations. This does not mean that the latter are insignificant or do not exist. Instead careful judgement is needed to balance costs and benefits.”

3.12 It is unclear whether “the latter” is referring to ‘benefits’, ‘trade or trans-Tasman relations’ while the reference to careful judgement in balancing costs and benefits is of concern. It implies the application of strong ‘value judgements’ which undermine the fundamental principle of cost benefit analysis, that they should be weak and recognise the principal of consumer sovereignty. The analysis should accept the revealed preferences of consumers (eg the prices paid by consumers) and the analyst should not seek to impose his/her own values. The lack of data on costs and benefits does not justify departure from the weak value judgement principle but rather it suggests even greater awareness. For example, in terms of the subject analysis this means it is reasonable for the analyst to assume that consumers would prefer to be better informed about their purchases/consumption rather than less well informed (a weak value assumption). But it is not acceptable to make assumptions about levels of consumption tradeoffs with respect to risk, a strong value judgement (eg consumers will stop smoking if they are fully informed about the risks of smoking).

3.13 Other than to the extent that it influenced the real value of therapeutic products (ie prices), the benefits of trade in general and trans-Tasman relations in particular were irrelevant to the cost benefit analyse that was undertaken. It was inappropriate for the analyst to give special weight to factors perceived as important by the Government as this was in conflict with the principle of applying

weak value judgements. Special factors should be dealt with outside the cost benefit framework or they be subjected to their own cost benefit analysis.

Conclusions on justification for extending regulation and efficiency drivers

- 3.14 The NZIER report stated that most benefits and some costs could not be quantified. The report was almost silent on whether it is appropriate to extend the regulation for complementary healthcare products as the discussion was confined largely to a limited number of issues that were perceived to provide justification. The issues included technological developments (ie emergence of increasing sophisticated and specialized products), globalization (increasing regulatory integration), Closer Economic Relations (CER) and public health care and accident insurance. The report describes these issues as the important drivers that are impacting on the efficiency and effectiveness of the current regulatory regime, and the costs and benefits of alternative options.
- 3.15 The NZIER report advances these issues as providing support for the Joint Therapeutic Agency (JTA) option. From a cost benefit perspective there is no justification for having special regard to perceived important drivers as this is double counting. If they are relevant they should reflect in the costs and benefits of the main alternative options. For example if specialist staff is becoming more difficult and expensive to recruit this should reflect in option cost. The factor will either be common to all options and cancel out or it will affect some options more than others (eg because more or less specialise staff inputs are required). While specialist staff cost should be measurable, the NZIER report treats this matter (qualitatively) as an implicit benefit of the JTA option but a cost to the other options. No explanation is given as to why the JTA option will avoid the difficulties of recruiting staff with specialist skills. No factual data was provided in support of the claim that there was a scarcity of some specialist regulatory skills, nor was there any comment on whether this was likely to be permanent or short term problem. In the absence of barriers to education, market incentives should induce an increase in the international supply of skills in short supply and overcome the shortage.
- 3.16 Cost benefit analysis should measure relevant costs and benefits in terms of opportunity costs rather than market prices and this may involve the use of shadow

prices in preference to market prices. For example, the analyst should remove tariffs from the value of imported costs (ie use shadow prices in preference to market prices) as tariffs distort real opportunity costs and bias outcomes. In this regard CER is irrelevant to the subject cost benefit analysis, although it could provide reasons why the Government may prefer some regulatory options over others. While CER should alter market prices of relevant costs and benefits their values measured in opportunity costs should remain unchanged. The NZIER report's assertion that: " The proposed Joint Therapeutic Agency offers an opportunity to develop a new type of trans-Tasman organisation that would be governed by two jurisdictions It would be an innovative step for CER ... and in the relationship between the two national governments and parliaments" is speculative and irrelevant to the assessment and indicates a predetermined bias in favour of the JTA option. This is imposing strong value judgements which is inappropriate.

- 3.17 The NZIER report refers to the public health care and accident compensation system (ACC) and the moral hazard they generate, namely, that as a consequence of these systems people do not suffer the full costs of their actions which reduces the incentives to minimise personal costs. There are reduced incentives to ensure therapeutic products are safe, as producers are less legally accountable if something goes wrong, while ACC cover reduces consumer incentives to ensure the safety of products. It is appropriate in cost benefit assessment to consider the distortions the public health and ACC scheme cause as it may be necessary to adjust actual prices.
- 3.18 The NZIER report is suggesting that consumers should pay less for some products and/or consume less if they had to bear the full consequences of their consumption. Therapeutic product producers on the other hand should charge higher prices and/or produce less in the absence of the public health and ACC systems. This implies that there is an element of over production and consumption of therapeutic products under the current regulatory environment and therefore some reduction in current activity would be welfare enhancing as there is over consumption relative to (real) willingness to pay.
- 3.19 This point has some theoretical validity, although the same argument applies to many other products (eg food and drink) and activities (eg sport and recreation),

but in practice the impact should be small. First, making therapeutic consumers fully responsible for the real costs of their consumption is unlikely to have any significant impact on the volume of their consumption as it is irrational to assume people are being reckless because someone else may have to pay for the harm they may inflict on themselves. Harm is more likely to be the result of ignorance than lack of financial incentive. Secondly, producers address risk in several ways including purchase of insurance, adopting institutional structures that give protection to owners (eg companies) and charging higher prices to cover risk of being sued and/or to pay insurance premiums. Excluding pharmaceuticals, the ACC scheme is unlikely to have had a substantial affect on the pricing structure of New Zealand's therapeutics products ie over and above what would prevail in the absence of the public health and ACC systems. This is especially the case with respect to complementary healthcare products as the available information indicates the risk is generally low. It is unlikely that insurance premiums for the producers and distributors of complementary health products and low risk medical devices have been significantly affected. Hence the public health and ACC systems should be given minor weight in terms of the decision to extend regulation to complementary health care products and/or medical devices and/or the selection of regulatory options to control them.

NZIER conclusion on rationale for extending regulation

3.20 The NZIER report referred to a previous report undertaken by the Institute and titled "Regulatory impact analysis: A joint Australian and New Zealand therapeutics goods agency" and stated that the NZIER report builds on the previous report and subsequent work. The earlier report does not justify extending regulation to complementary health care products and medical devices while no additional information was provided in the NZIER report that provided a rational basis for extending regulation to complementary healthcare products or medical devices. The NZIER report and the earlier report explicitly stated that some costs and most benefits could not be quantified. The NZIER report concluded that:

"Given the costs of compliance, whether any change from the Counterfactual is seen to be of net benefit to New Zealand or not depends on:

- A judgement of the additional benefits to consumer health and safety and the value of better information to consumers; and
- A judgement of the value to New Zealand of potential additional trade opportunities, and improved trans-Tasman and international relationships.

This trade-off is not that clear for medical devices and complementary healthcare products, and strongly depends on a judgement of the emerging risk profile, whether added regulation in New Zealand can influence this, and how much society values the risk reduction. No data is available to assess the magnitude of these factors.”⁴

3.21 The NZIER report does not provide any evidence to show that risk is increasing or how regulation can reduce it. Therefore, the report does not realise the primary purpose, namely, to determine the economic justification for extending regulation for complementary healthcare products and medical devices in New Zealand. On this basis the NZIER report concluded that:

“...the decision on whether the regulatory framework needs to be extended involves a qualitative assessment about how well consumers are equipped to deal with the risks, the ability to rectify harm (and the relevance of the precautionary principle), the perceived bias of producers to understate risks or regulators to over regulate, how much risk reduction is valued, and different notions of liberty and responsibility.”⁵

3.22 The probability of an adverse event occurring relative to the compliance cost should have been added to this list. In this respect, comparisons with other readily accepted risk events (eg automotive vehicle travel, sports) would have been helpful to decision-makers. The NZIER report usefully noted that:

“Efficient risk management means that the response is proportionate to the magnitude of that risk, as distinct from risk minimisation. If hurdles are set too high, the social outcome may be worse than if there was no intervention.”

⁴ Ibid: page 47

⁵ Ibid page 47.

4 NZIER evaluation of predetermined options

Compliance cost and measurement

- 4.1 The NZIER report defined compliance cost broadly. The definition included the changes to production processes required by the agency/regulatory regime but left out the loss that may occur as a consequence of producers ceasing production because of excessive compliance cost making production unprofitable. The NZIER report, however, does acknowledge and discuss the potential for this to occur because of the number of small scale producers and the fact that many importers distribute a large number of low volume products. The NZIER report does not attempt to assess the capital cost of compliance, although it does acknowledge that it could cost some manufactures hundreds of thousands to millions of dollars. Nor is any assessment made of the cost of production loss caused by businesses ceasing production.
- 4.2 Logic suggests that the potential production loss could be large as while regulatory cost may be a small percentage of an individual firm's turnover they are likely to be a large percentage of profit. The profit element of production costs varies substantially, industry by industry, firm by firm and product by product. After deducting interest, taxes, depreciation and other compulsory levies, profit is generally a very small percentage of turnover eg on a total industry basis less than 5% of turnover for retail trade and 6% to 8% for manufacturing based on recent industry statistics.⁶ This compared to NZIER's estimates of compliance cost as a percentage of turnover for complementary healthcare product's of 7.7% (Enhanced Medsafe), 7.4% (Unilateral Recognition) and 2.9% (JTA).⁷ NZIER estimates of regulation cost suggest that a significant number of producers could be wiped out by extending regulation, especially as capital and operating costs of compliance were not included in the NZIER report's analysis. Survival should depend on the ability to pass on compliance cost to consumers but the NZIER report notes this will be difficult.

⁶ Refer Business Activity Statistics 1999, Department of Statistics.

⁷ Refer NZIER report , Table 9.

Regulatory Options for New Zealand

- 4.3 The NZIER report discussed four regulatory options that it was asked to consider. The usefulness of the analysis was undermined by the poor quality of most of the data. The options evaluated were as follows:

Option 1: Status Quo: This is continuation of Medsafe as a small agency with regulation confined to existing levels although a register of medical devices may be maintained.

Option 2: Enhanced Medicare: This comprised two options involving expansion of Medicare to regulate pharmaceuticals to stated performance targets, with and without expansion of the regulatory framework to include healthcare products and medical devices.

Option 3: Unilateral recognition: This option recognises the decisions of specified regulators of other countries when deciding to grant pre-market authorisations for the full range of therapeutic products.

Option 4: Joint Therapeutic Product Agency: This option involves a single regulatory regime for pharmaceuticals, complementary health products and medical devices administered by a single regulator for both countries

- 4.4 The NZIER report stated that the analysis was confined to quantification of agency and compliance costs and that other costs such as consumer welfare gains and losses from the impact of regulation on choice were excluded. The analysed costs included the cost to run an agency under each of the four options, business compliance costs and transition costs which were stated as being sketchy. The analysis was at a specific point in time while it was argued that underlying trends were unlikely to be affected much by the different options. Business compliance cost included fees paid by firms, time and wages spent by firms on regulatory affairs and foregone profits due to time delays in obtaining licences.
- 4.5 It is noteworthy that the largest potential cost to business, namely, capital and operating costs of compliance (eg excluding wages and time delays) were excluded from the analysis. These losses are zero for the status quo while for the other options cost will vary according to the regulatory standards that are adopted. We dispute the claim that the trends in costs will be about equal for all options as factors such as the comparative rate of population growth in Australia and New

Zealand should effect the JTA option but not the alternatives. Option 4 is more likely to encourage relocation of New Zealand businesses to Australia as was acknowledged by the NZIER report. The somewhat arbitrary split of costs between Australia and New Zealand is also a factor that could have a significant bearing on cost of option 4 relative to other options. It is an additional risk factor that option 4 introduces from an industry perspective. To assume the trends will be the same for all options was dubious and further analysis is required.

NZIER report's assessment of option costs

- 4.6 Table 6 is an important element in determining the cost of the four options as the cost of agency regulation should be substantially related to this factor. However, no assumptions were made about the impact of various options on the total number of licences as this should vary. Effectively, the cheaper the cost of regulation the larger the number of licences that will need to be processed over time.
- 4.7 Table 8 shows the assumed regulatory agency costs which were provided by Medsafe. The estimates require independent auditing as they appear to be suspect. For example, the 'Enhanced Medsafe' agency \$43 million cost appears excessive. Table 9 shows the pharmaceutical component of this cost as \$29.1 million. The number of activities processed compared to the status quo (8,000) remains the same as the variation relates to improved performance targets consistent with international standards of regulatory practice. The agency cost compared to the Status Quo option, however, increases from \$1,000 to \$3,652 or by 265% per activity. If the estimate is correct it raises issues about the efficiency of Medsafe and options such as contracting out regulatory activities to more efficient regulators (eg Australia) or service providers.
- 4.8 The Unilateral Recognition agency budget also requires explanation as it is considerably more than the Status Quo (\$6.7 million) with respect to the pharmaceutical component. While this option free rides on the work of other countries' agencies, the cost per status quo activity rises from \$1,000 to \$1,838 or by 83%. The NZIER report should have analysed the plausibility of the estimates provided by Enhanced Medsafe as it is inappropriate to accept figures provided by a third party without question. The NZIER report indicated a concern with

Medcare's costing as it noted that the latter's assumption with respect to the ratio of regulatory staff to corporate staff (between 2.25 and 3.25) was too low. NZIER indicated that 4:1 to 5:1 was more usual and undertook sensitivity analysis to test the impact of varying this factor on the cost estimates.⁸ Tables 8 and 9 imply Enhanced Medicare is either a very inefficient organisation or the estimated cost are gross overstatements. Alternatively if they are correct, the JTA cost estimate is suspect.

- 4.9 The forecast JTA agency budget estimate was derived in two ways with similar results. First the Australian Regulatory Impact Statement (2002) assumed the current TGA budget and added a net 15% increase in activity to take account of New Zealand related activities. The second approach was to add Medsafe and TGA status quo budgets together. Table 8 of the NZIER report shows the New Zealand industry's share of the estimated \$68 million JTA agency cost, namely, \$20 million. Australian industry cost falls by the same amount as the New Zealand budget increases (\$12 million). It is noteworthy that the NZIER report Table 8 (\$20 million) and Table 9 figures (\$15.5 million) for the New Zealand industry's share of the JTA cost do not reconcile while there is no explanation for the apparent discrepancy. The figures need to be reconciled.
- 4.10 Table 9 figures require further analysis as they do not appear sensible. With respect to pharmaceuticals, the sum of government cost and regulatory fees falls from the status quo \$8 million to \$6.8 million (\$7.9 million if costs to government are included in the latter) under the joint agency option. Hence higher performance standards are to be achieved at slightly less cost. While it is acknowledged that the JTA option will avoid duplication this estimate appears to be optimistic compared to the \$21.7 million additional cost for Enhanced Medsafe and \$7.3 million for Unilateral recognition. Alternatively, this may confirm previously stated suspicions that the estimates for the latter two options are overstated. Effectively, Table 9 implies savings of \$13.8 million for the JTA option compared to Enhanced Medsafe with respect to regulation of pharmaceuticals to a higher standard than the status quo option. If the Enhanced Medsafe estimate is reasonable, logic suggests the JTA estimate is unrealistic. This is because if there were 100% duplication between New Zealand and Australia with respect to pharmaceuticals, this would

⁸ Refer pages 25 and 26.

enable the entire status quo budget of \$8 million to be saved by the proposed agency. But if the entire New Zealand activity is done away with, no further savings could be realised as effectively it is business as usual for Australian regulation. Hence \$8 million is the maximum potential savings.

- 4.11 The NZIER report refers to direct agency cost savings of between A\$6.5 million to A\$11.5 million based on cessation of duplicated evaluation functions, and voided training costs and future salary increases.⁹ Given the maximum avoided pharmaceutical cost is probably NZ \$8 million (A\$6.6 million) it is difficult to see how economies of scale of such levels can be claimed. There can be no economy of scale savings on activities that become redundant and therefore presumably these savings relate to complementary healthcare products and medical devices. Table 9 indicates considerable cost savings for the JTA option compared to Medsafe and Enhanced Medsafe. As the level of duplication in the case of complementary healthcare products should be relatively small given the likely share of Australian sales in the New Zealand market it is difficult to reconcile the considerable difference between the three options involving increased regulation. The NZIER report refers to avoided training costs, and salary increases but these are not plausible explanations as more people will be needed to handle New Zealand activity. How can these costs be avoided when there is a need to increase total activity?
- 4.12 In summary, in the absence of further explanation, the figures contained in the NZIER report with respect to agency costs are not credible. The estimates for Enhanced Medsafe and Unilateral Recognition options are far too high relative to the JTA option. The method used to estimate the costs of the JTA option was broad brush and an unacceptable basis for policy making.
- 4.13 Estimates are shown in Tables 9 and 10 of compliance cost as a percentage of industry turnovers but the latter was guesstimated. Hence, the percentages are likely to be extremely misleading and no weight should be given to them. The New Zealand industry's turnover should have been surveyed to establish a factual figure. Tables 9 and 10 exclude most of the operating and all of the capital compliance cost of the proposed regulation and regardless of this point are very misleading.

⁹ Refer page 26.

NZIER reports' qualitative assessment of costs and benefits

- 4.14 The NZIER report undertakes a qualitative analysis of the four regulatory options. While acknowledging its low cost, the Status Quo option was dismissed on the grounds that it does not address the concerns of inadequate regulatory capacity, it does not adequately manage the risks from medical devices or complementary healthcare products. In addition, the report notes: that exporters may be disadvantaged if they cannot obtain local export certification; there is a likelihood of increasing delays in pharmaceutical processing; that the regulatory regime is out of step with most other countries; and that potential harm to consumers (which the NZIER report states is thought to be rising) remains unaddressed. Finally, the NZIER report states that the Status Quo is also inconsistent with the Government's objectives for Trans-Tasman economic relations and trade.
- 4.15 While some of the criticisms of the Status Quo raised in the NZIER report may be valid they do not necessarily support the other options evaluated. For example, exporters may be disadvantaged but this does not necessarily mean that the industry should be regulated to their benefit. Other alternatives are available such as an export certification scheme run solely for their purpose. It would be inefficient to regulate the whole industry so as to overcome an export certification problem. Advancing regulation on the basis that it is out of step with most other countries and because the risks are thought to be rising is lacking in proficient analysis. The Status Quo, or any other option not involving the JTA, may be at odds with the Government's objectives for Trans-Tasman economic relations and trade but the purpose of CER was to promote the economic wellbeing of both countries via enhanced trade by reducing bureaucracy rather than enhancing it. It is putting the cart before the horse to suggest that productive New Zealand activity should be sacrificed so as to enhance economic relations between Australia and New Zealand at the regulatory level.
- 4.16 The Enhanced Medsafe option is perceived in the NZIER report to contribute to the Government's health objective as regulation could be extended to complementary healthcare products and medical devices. The main negative factors noted with this option is the substantial \$43.3 per annum compliance cost and the view that it would not support the Government trade objectives or its CER objectives. As previously noted, the estimated compliance cost of this option appears to be very

high. The alleged increasing need for New Zealand exports to be locally certified could be dealt with by less expensive options than increased regulation for the industry as a whole. Previous comments are applicable with respect to CER. Because there is no useful economic evaluation of the justification for extending regulation, the agency cost estimates are dubious and business compliance cost are not fully evaluated. While the NZIER report does not provide any useful contribution to the advantages and disadvantages of this option it does provide some useful analysis of the impact of high cost regulation on industry and consumers. In particular, it correctly notes that a rise in compliance cost would lead to price rises or reduced supply on the margin. Further that the key impact will be on low value/volume products. The report notes with respect to complementary healthcare products that this may lead to a reduction in activity, that this will affect direct and indirect employment and that in this regard there are possibly 100 small cottage-type manufacturers. The report notes that two medium size firms may quit and that registration fees are likely to effect importers more severely than manufacturers. Any price increases will reduce the purchasing power of consumers and funders of healthcare. Most of price impact with respect to pharmaceuticals would be faced by PHARMAC.

- 4.17 The NZIER report notes that this option would meet many of the Government's health objectives at lower compliance costs than Enhanced Medsafe. The perceived disadvantages of this option were that it would not meet CER-related objectives, and that this could disadvantage local manufactures. The report also noted New Zealand may find it hard to get cooperation from other regulators as we would have nothing to offer in return.
- 4.18 As previously stated it is difficult to reconcile the cost of this option given that it essentially free rides on other regulators although the apparent explanation for this is the need for increased market surveillance due to counterfeit imports. Previously comments apply with respect to the other perceived disadvantages in relation to exporters and CER.
- 4.19 The NZIER report noted that while regulatory costs increase compared to the Status Quo, it would achieve safety objectives at lower cost than other options. This is due to perceived economies of scale, the benefits from single application costs for the two markets and the likelihood that current coordination costs will

improve. It was noted that this option would be likely to reinforce the existing trends for pharmaceutical firms to shift activities to Australia. The benefits to New Zealand medical device manufactures would be small in terms of increased trade with Australia, although it would make the latter's manufactures more competitive in the New Zealand market. The report states similar conclusions could be drawn for complementary healthcare products. Other perceived advantages included the ability to offer more to other regulators and greater potential sharing and contributing to CER objectives. In particular it was noted that the JTA option could set a precedent for future development of joint agencies in relation to CER.

- 4.20 The cost estimate for this option relative to the other options is of concern, especially given the cost savings are based on inadequate information. For example, in the absence of information on the overlap in pharmaceutical products between Australia and New Zealand the NZIER report assumed 85%. Similarly, the level of imports of complementary products was based on dubious information, namely: "Our discussions with industry indicated that around 50% of New Zealand's imports of complementary healthcare products are sourced from Australia." No explanation was provided as to why Statistic New Zealand's trade statistics could not be analysed to obtain a factual estimate.

5 Conclusion

- 5.1 The NZIER report did not realise the first purpose, namely, to establish the justification for increasing regulation of therapeutic products on the basis of cost benefit analysis. This is readily acknowledged by the report.
- 5.2 The report dismissed the Status Quo option but did not consider other options other than those supplied, presumably by officials. No industry survey's were undertaken to provide key information on the industry's existing dimensions and therefore it was impossible to assess the scale of impact on the industry and its various components, The agency costs are assumed cost and not based on robust analysis. Preliminary analysis of the data suggests that it is of dubious value. The NZIER report acknowledges the lack of information and that it made guesses as to probably values. The estimates are guesstimates based on inadequate data and should be treated circumspectly. The doubtful value of the data presented in Table 8 to 10 was exacerbated by the lack of information with respect to the major compliance cost for business, namely, capital and operating. The business

compliance cost presented in these tables was speculative and without any foundation.

- 5.3 The NZIER report generally is of little value to the issue of determining whether there is an economic case for increasing regulation, nor does it provide insight into the best regulatory option for New Zealand's interest. The report does provide useful comment on the impact of high cost regulation in terms of the adverse effects on industry.

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