Researched Medicines Industry Association of New Zealand Incorporated

Health Select Committee Submission

Improving New Zealand's environment to support innovation through clinical trials

April 2010

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The RMI would like to appear before the committee to present information from our submission in person.

Denise Wood, the RMI Chief Executive Officer, wishes to speak to our submission. She would like to be accompanied by Kevin Sheehy, the RMI Scientific and Technical Manager, and up to two senior delegates of the pharmaceutical industry to provide expert opinion.

This submission, prepared by the Researched Medicines Industry Association (RMI), represents the consensus views of our member companies; the pharmaceutical companies engaged in researching, developing, manufacturing and marketing prescription medicines.

Our Member companies are:

- Abbott Laboratories NZ Limited
- Alcon New Zealand Limited
- AstraZeneca Limited
- Bayer Schering Pharma
- Boehringer Ingelheim NZ Limited
- CSL Biotherapies (NZ) Limited
- Dr Reddy's New Zealand Limited
- GlaxoSmithKline NZ Limited
- Janssen-Cilag (New Zealand) Limited
- Merck Sharp & Dohme (New Zealand) Limited
- Mundipharma New Zealand Limited
- Novartis New Zealand Limited
- Pfizer New Zealand Limited
- Roche Products (New Zealand) Limited
- sanofi-aventis new zealand limited

In preparing this submission the RMI has consulted its members; as well as clinicians involved in running clinical trials in New Zealand, and patient advocacy groups.

A. RMI Recommendations

New Zealand should be aiming to earn over NZ$200 million per year in clinical trials (see Clinical trial trends below). We recommend that the Government establish a clear and comprehensive strategy to simultaneously tackle the numerous difficulties faced by the New Zealand research community. Any attempt to improve only a single aspect of the problem may bring some improvement, but is unlikely to substantially improve New Zealand's appeal as a destination for international clinical research investment.

Many countries have recognised the economic, health and scientific benefits of clinical trials, and are actively competing to attract this research. New Zealand must recognise this competitive environment and improve what it has to offer, if it is to gain a share of these benefits.

The principles that should be followed to improve New Zealand's appeal as a destination for clinical trials are as follows:

1. Improve the administrative efficiency of the approval process, particularly the ethics approval process.
2. Establish career paths for researchers within the health and education systems.
3. Ensure that at least some of the income from clinical trials is used to improve the clinical trials infrastructure.
4. Consider a tax incentive scheme for research and development, providing the structure of this is sustainable long term and it is not removed prior to any positive impact being achieved.
5. Recognise the pharmaceutical industry as a legitimate partner to the Government in bringing clinical trials to New Zealand.

B. New international approach to research

The pharmaceutical industry is currently changing its research and development (R&D) approach from in-house development of products to a more collaborative approach[1]. The new approach uses skills contained in numerous smaller biotechnology companies and clinical research organisations to generate much of the evidence required by regulatory authorities, funders and clinicians.

The new R&D approach enables countries that do not have a substantial pharmaceutical industry to also benefit from the large amounts of money spent on

[1] Lockhart M, Babar, ZU, Garg S, (2010) Evaluation of policies to support drug development in New Zealand, *Health Policy*, in press.

clinical research. The proviso being that these countries need to provide an environment conducive to clinical trials.

Multinational companies are actively competing for research prospects and skilled resources to ensure the success of the pharmaceutical industry into the future.

There are three main factors that contribute to an attractive clinical trials environment, these are:

- **quality**
- **timeliness**
- **cost**

New Zealand currently has some research strengths, including that it has some internationally respected researchers, it should now identify an appropriate niche, and build on its strengths to establish its place as a world class research destination.

There are a number of specific leverage points we consider should be examined in New Zealand to improve this country's attraction as a clinical trials destination. These leverage points are equally relevant to the clinical trials interests of local biotechnology and clinical trials companies as well as multinational corporations. The RMI recommendations are based on attempts to influence these leverage points.

Leverage points:

1. **Improve the speed of application processes to allow rapid trial commencement**
    - mainly ethics and DHB processes
    - regulatory processes are currently reasonably efficient

2. **Develop a critical mass of experienced clinical trials staff**
    - including clinicians and support staff
    - using appropriate career paths
    - possible post-graduate certificate in clinical research

3. **Develop the clinical trials infrastructure**
    - separate business units within DHBs and universities dedicated to clinical trials
    - improve information systems to facilitate communication between all levels of health care

4. **Develop sustainable tax incentives**
    - even minor tax incentives would provide some positive stimulus, given a stable environment

5. **Develop improved relationships with the pharmaceuticals industry**
    - the pharmaceutical industry should be seen as a legitimate partner in order to develop long term strategies in collaboration.

Although it may be tempting to change isolated aspects of the clinical trials environment and hope that the environment improves, the RMI recommends an approach that introduces a package of simultaneous or staged improvements. If only a single aspect is reformed, there is a risk that the overall environment will continue to be unfavourable and that R&D investment will continue to be lost to more competitive countries.

C. Health System Benefits

There are a number of areas where clinical trials lead to substantial improvements in a country's health system. These benefits are particularly important to countries facing the problems of out-migration of graduates and difficulty funding comprehensive health care.

The benefits discussed below make a powerful case for New Zealand to do all it can to host more clinical trials.

Well managed clinical trial income streams provide the opportunity to increase university places for health care professional training. This is one of the reasons for Australia being able to train three medical graduates for every two graduates that New Zealand trains (adjusted for population size)[2].

The opportunity for clinical staff to become involved in research is a major factor in attracting and retaining good quality healthcare staff. High performing staff value the ability to be involved in world class research. Income from clinical trials can also be used to supplement earnings of healthcare professionals, reducing the need for Government funded salary increases in an attempt to retain staff.

The high level of international communication, collaboration, training and support surrounding clinical trials strengthens the ability of researchers to remain abreast of international best practice. Consequently, the researchers are also in a better position to share their information with colleagues and students in educational institutions.

The New Zealand national cancer registry has been identified as an area in particular need of attention; it should accurately reflect national outcomes of treatments and allow estimation of future cancer burdens within the health system. Clinical trials using this database would support improved datasets being developed.

A report on clinical trials in the Dominion Post on 31March referred to a potential downside to clinical trials being that patients may be at risk from receiving no treatment if they were assigned to receive placebo treatment. This statement suggests a misperception of the use of placebos in clinical trials. If there is any risk of

[2] OECD Health at a Glance 2009

harm arising from a person not being on treatment, subjects would be given current standard treatment in addition to a placebo. The appropriate use of placebos would be one of the risks assessed by regulatory and ethics committees.

Subjects in clinical trials also benefit from receiving education about their medical conditions and close supervision, enabling them to better self-manage their conditions after the trials finish.

D. Economic Benefits

Potential New Zealand income

Clinical trials offer substantial economic rewards for those countries that support them.

The estimated cost to bring a single product to the stage of regulatory approval has recently risen to US$ 1.3 billion.

The top ten multinational companies (by R&D spend) spent US$ 58.5 billion on R&D in 2008[3] (see figure 1), and in Australia the pharmaceutical industry spent AU$ 860 million in 2006-2007[4]. Although Australia only contains 0.4 of the world's population, they contribute 3% of the global medical research[5]. With a similarly well trained health workforce; similar patient-to-doctor ratios; and a similarly efficient clinical trials infrastructure, New Zealand should aspire to producing a similarly scaled body of research.

A level of research in New Zealand similar to that in Australia in 2007 (adjusted for population size) would result in an annual spend of NZ$ 223.6 million at current exchange rates.

[3] Scrip Pharmaceutical Company League Tables 2009
[4] Department of Innovation, Industry, Science and Research; Australian Government: Australian pharmaceuticals industry data card (accessed 08 - 04 - 2010) http://www.innovation.gov.au/Industry/Pharmaceuticals/Pages/pharmadatacard.aspx
[5] Department of Innovation, Industry, Science and Research; Australian Government: Pharmaceuticals industry profile (accessed 08 – 04 – 2010) http://www.innovation.gov.au/Industry/Pharmaceuticals/Pages/PharmaceuticalsIndustryProfile.aspx

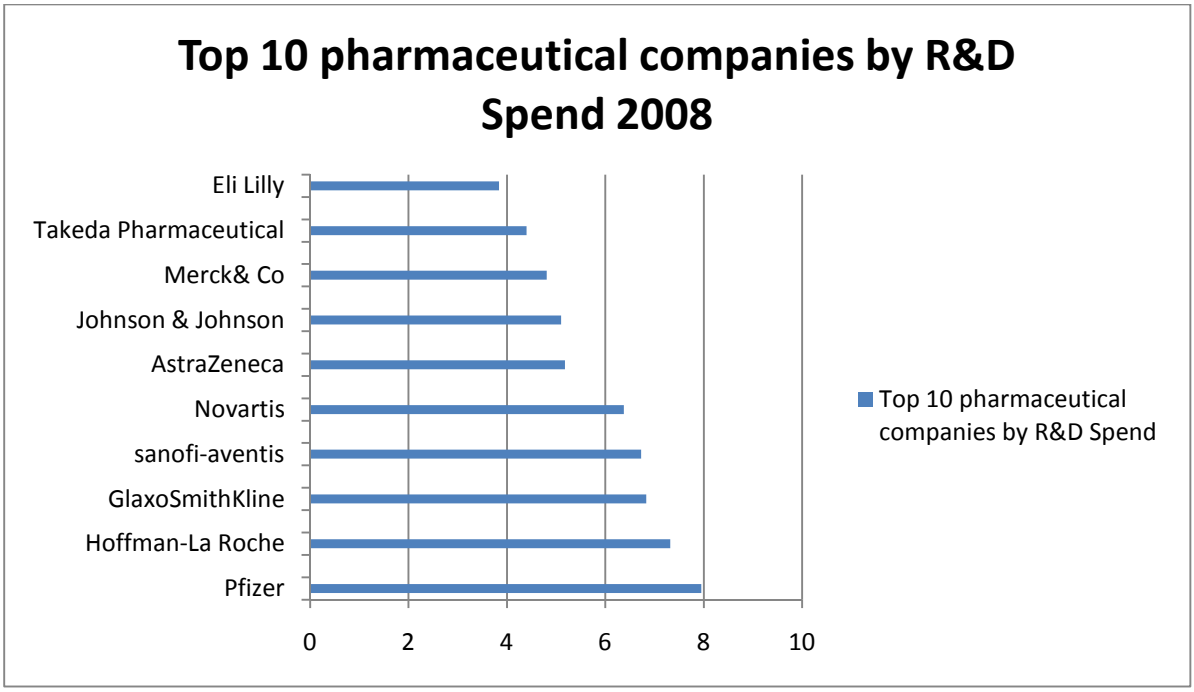

Figure 1: Source Scrip Pharmaceutical Company League Tables 2009

The Dominion Post article referred to above stated that there is between NZ$ 1m - $30m being spent on clinical trials in New Zealand. It is not clear what this figure is based on as it does not appear to be an accurate reflection of the amount actually being spent on clinical trials in New Zealand. The RMI identified that over NZ$ 30 million was spent on R&D in 2009 by only six of our member companies, suggesting that the overall figure is far higher than that reported in the Dominion Post. The actual amount of income New Zealand is receiving from clinical trials is not clear, what is clear however is that it is nowhere near its maximum potential. Further work should be done to establish an accurate picture of the current value of the clinical trials in New Zealand. The RMI would be prepared to support this work in partnership with the Government.

Biotechnology market activity

At the end of 2009 there were 13 biotechnology companies in Australia with market capitalisations in excess of US$ 100 million[6] each, the largest of them having a value of AU$ 19.1 billion. The total value of company acquisitions of Australian biotechnology companies in 2006 was AU$ 4.1 billion[7].

A survey by Statistics New Zealand[8] identified that there were 114 organisations involved in biomedical science and drug discovery in 2009 in New Zealand. These companies depend on international relationships to bring their discoveries to market; and would benefit from a heightened presence of multinational pharmaceutical companies involved in research partnerships.

There are currently five biotechnology companies listed on the New Zealand Stock Exchange[9] , but none of these have reached a NZ$ 100 million market capitalisation threshold besides Fisher and Paykel Healthcare Corporation (currently NZ$ 1.72 billion[10]). There are in addition, three New Zealand biotechnology companies listed on the Australian Stock Exchange.

A particularly successful export strategy pursued in Australia is based on generating Intellectual Property (IP) in biotechnology and developing an income stream from this by licensing it to international pharmaceutical and biotechnology companies.

New Zealand Trade and Enterprise has identified that in order to improve the success of the local biotechnology industry this country needs to build international alliances and attract offshore investment in biotechnology[11].

New Zealand should also develop a patents environment that will support the Government's strategy of developing a knowledge economy based on science and innovation.

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[6] Australian biotechnology sector fact sheet (accessed 09 – 04 – 2010) http://www.innovation.gov.au/Section/AboutDIISR/FactSheets/Pages/AustralianBiotechnologySectorFactSheet.aspx

[7] Thorburn and Hopper, Bioindustry review of Australia http://www.ausbiotech.org/data/downloads/2007%2004%2011%20-%20Highlights%20of%20BioIndustry%20Review%20v1.pdf

[8] Statistics New Zealand, Bioscience survey 2009

[9] Biotechnology Learning Hub, University of Waikato and New Zealand Government: http://www.biotechlearn.co.nz/index.php/themes/new_zealand_views_on_biotech/nz_biotech_companies_on_the_stock_exchange

[10] NZX.com accessed 16h10 12 – 04 – 2010.

[11] New Zealand Trade and Enterprise, Market profile for biotechnology in the Australian market

E. Clinical Trial trends

Internationally, while the numbers of clinical trials have been increasing, New Zealand's relative share of these has been reducing. Recently developing countries are being considered more favourably as destinations for clinical trials; partly due to the improving health systems in these countries, improving efficiency of the systems for approving and running the trials, and relatively low costs. This means that if New Zealand is to achieve its potential, it must improve its attractiveness as a research destination.

Number of clinical trials in NZ compared to Australia

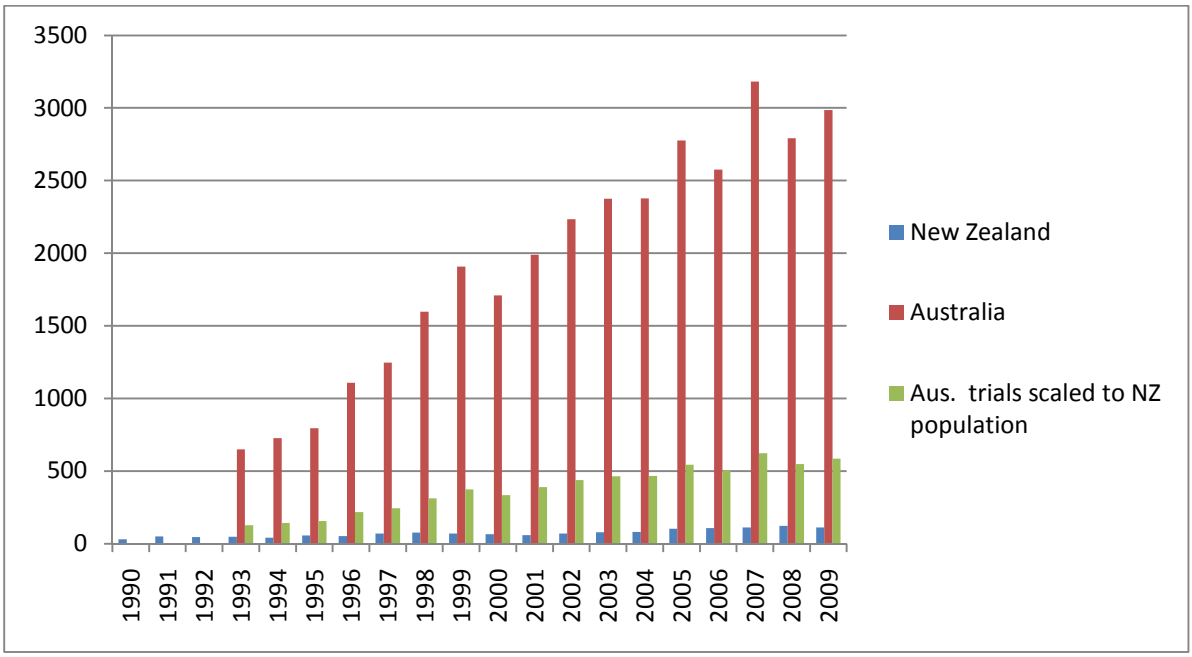

Figure 2: Sources Lockhart M[12] and Medicines Australia[13]

The graph in figure 2 shows numbers of clinical trials notified to the national regulators of each country. This graph clearly indicates that New Zealand is hosting far fewer trials than would be expected compared to Australia (adjusted for population size).

The trends in clinical trials can partly be seen to reflect the strained relationship between the New Zealand Government and pharmaceutical companies in the past (detail in figure 3). The substantial reduction of clinical trials held in New Zealand in the late 1990s and early 2000s correlates with the overly forceful negotiation strategies implemented by PHARMAC. Although the trend reverts to an increase in

[12] Lockhart M, Garg S, Babar, ZU, Evaluation of trends in clinical research in New Zealand: 1989 – 2009, NZMJ In Press

[13] Therapeutic Goods Administration, Australian Government figures provided by Medicines Australia in personal communication

numbers of trials after a few years, comparison with Australia shows that New Zealand has continued to lag behind its potential. In 1993, New Zealand hosted 39% of the number of trials that Australia did (adjusted for population size), but by 2009, this proportion had reduced to only 19%.

Further factors include that New Zealand is geographically remote from most pharmaceutical companies' primary locations and presents a relatively high cost relative to outcomes, counting against it as a location for trials. These factors mean that clinical trial centres in New Zealand must be aware of cost efficiency when competing for clinical trials business.

Number of clinical trials in NZ 1

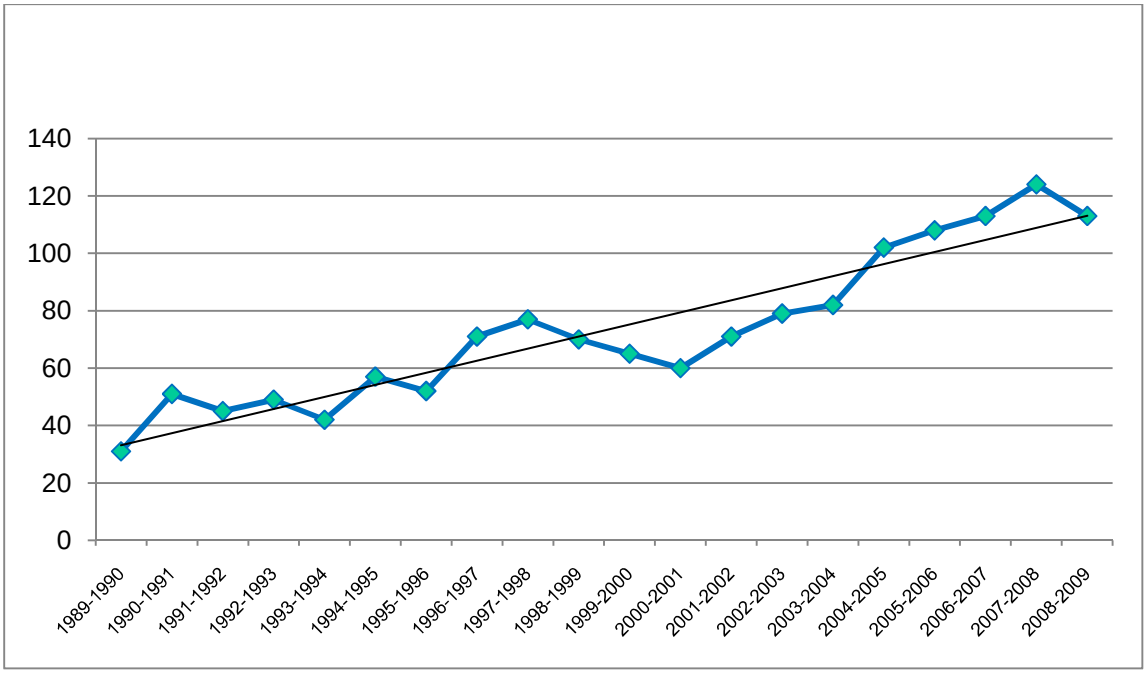

Figure 3: Source Lockhart M, Evaluation of trends in clinical research in New Zealand: 1989 – 2009

F. The current environment in New Zealand

Until recently, successive New Zealand Governments do not appear to have recognised the full economic or health benefits of supporting clinical research. The few incentives that have been created have been short lived and piecemeal, without offering the opportunity for companies to develop long term plans or a critical mass within research.

If New Zealand wants to become an attractive destination for clinical trials, there need to be compelling reasons to overcome the negative aspects of New Zealand being a hostile environment for pharmaceutical companies to market their

medicines. Where companies face the prospect of their products not being funded until they come off patent, the investments in research and benefits listed above are often better placed in other countries.

Currently, the institutions involved in clinical trials often do not see this work as core business; this can be seen in that most DHBs do not include any clinical trials strategy in their annual plans presented to the Ministry of Health.

Two recent papers by Lockhart (in press *Health Policy* and *NZMJ*) have identified a number of policy priorities that the New Zealand Government should consider in improving this country's clinical trials environment.

We have identified specific areas of concern that are currently barriers to New Zealand being an appealing clinical trials environment. These are discussed below.

1. Ethics Committee processes

Ethics approval in New Zealand is a more time consuming step than in many international jurisdictions, and leads to avoidable delays in trial start-up.

A fundamental prerequisite for all clinical trials in humans is ethics approval. This requires the careful consideration of health and social risks posed by a trial, balanced against the expectation that the trial provide some potential benefit to the trial subjects specifically, and humanity in general.

Pharmaceutical companies and researchers recognise ethics requirements as an integral step in planning a trial; and take care to ensure that the balance of risk and benefit is favourable.

Once trials reach the step of ethics application, the companies need the process to proceed expeditiously. Efficient assessment and processing of applications does not need to compromise the careful consideration of the ethics involved.

There are a number of specific problems with the New Zealand ethics approval process, these are:

- No set timeframes within which the Committees are required to provide a response or decision
- Unnecessary delays in secretariat and communications functions
- Return correspondence is often held up until the next meeting before being actioned,
    - and where delegated review of return correspondence is used, there is still a considerable delay
- Under-resourcing
- Inconsistent decisions across regions

- Unpredictable input regarding Maori specific requirements
- Committees are generally run as non-core functions of large bureaucratic organisations
- Committee members are effectively voluntary contributors and as such appear to give the work a lower priority than their main activities.

The performance of ethics committees should be compared to the 14 – 16 day average turnaround (40 day regulated target) for the Standing Committee on Therapeutic Trials (SCOTT) that performs a similarly intensive scrutiny of the scientific rationale of trial protocols. This committee is administered by Medsafe and uses a number of processes that could be applied to the ethics approval process.

Methods of improving ethics committee outputs should include the following:

- Committees should be run on a cost-recovery basis (fee for service) linked to set timeframes for secretariat outputs.
- The Operational Standard should be updated and recognise the competitive nature of the clinical trials environment (this should be compared to the Australian Operational Standard)
- The Operational Standard should make provision for risk-stratified levels of scrutiny (e.g. trials of approved medicines need lower levels of scrutiny due to being associated with lower risk.)
- All committee members should receive training based on an updated Operational Standard.
- Secretariat functions should be adequately resourced.
- Staff should be responsible for meeting predetermined timeframes.
- All committee members should be remunerated at a rate commensurate with the responsibility and time required for the process.
- The Maori requirements for ethics approval should be formalised and standardised to allow companies to plan accordingly rather than face new requests once an application is submitted.
- Maori should have representation at each meeting of each committee, this representation should have delegated authority to conduct the review of Maori requirements for the trial protocol. The Maori review could then be conducted in a similar manner to the health professional review of the medical components .

Australia and Canada have successfully privatised ethics committees with a resultant improvement in efficiency. The New Zealand Government could investigate the feasibility of privatising ethics committees. There is already a well functioning model of a private ethics committee within New Zealand, i.e. the Zenith

Biomedical Ethics Committee[14]. This is a Health Research Council accredited facility with a committee of ten independent members that have medical and lay backgrounds. The main limitation of this committee is that it is not able to accept applications for research done by other institutions.

2. Research staff

New Zealand hospitals and universities should develop clear career pathways for research staff.

New Zealand has reached a point of having so little clinical trial work that researchers and companies report difficulty in finding adequately qualified and experienced staff to run trials. Personnel have at times been brought in from other countries to supplement local staff numbers and expertise.

There are numerous skill sets that are required for clinical trials, some derived from specific training and others gleaned from experience. Once people with these skill sets are employed by a clinical trial facility, and are known to be available, companies will repeatedly approach these facilities for clinical trial placement.

Developing a post-graduate certificate in clinical research should be considered in combination with assessing industry requirements for staff.

In the absence of support and direction, these skill sets are not likely to be developed by individuals or institutions.

The researchers consulted in preparing this paper consider that the Performance Based Research Fund (PBRF) appears to be a poor method of incentivising research. Its funding is allocated retrospectively according to the historic quality of research, and its calculation methods have been criticised for being problematic[15]. There is not currently a method in place to ensure this funding improves incentives for either the researchers whose work contributed to the funding being allocated; or to those candidates looking to do future research. This system appears to simply be a bureaucratic retrospective allocation of baseline funding.

For any research funding to provide true incentives, it should be linked to future research rather than historic performance.

[14] Zenith Ethics Committee website http://wwc.n4system.com/zenTech/Home/Ethics.html
[15] Wiltshire D (2004) http://www2.phys.canterbury.ac.nz/~dlw24/pbrf.html

3. Resourcing and infrastructure

It appears that the DHBs involved in clinical trials do not consider this to be part of their core business, and consequently do not give trials adequate support or resources. Companies bringing clinical trials to New Zealand do not expect their requirements to be subsidised by health system funds, but provide a healthy income stream to the facilities that host them.

We recommend that separate business units are set up in DHBs to ensure that clinical trials are seen as a core function. These business units should be responsible for ensuring that:

- Income from clinical trials is properly accounted for
    - with some income being paid as dividends to DHBs and
    - some income being reinvested in clinical trials infrastructure
- Appropriate resources are provided to support clinical trials
    - human resources, equipment and information technology
- Ongoing business relationships are developed with international clinical trial sponsors
- Databases supporting research requirements are available within DHBs
    - researchers, demographic and disease patterns, health professionals
    - links are developed to national databases such as the national cancer registry
- Clinical trials are run in a cost efficient manner and centres become or remain internationally competitive.

A good example of an efficient clinical trials business model is already being used, the Centre for Clinical Research and effective practice (CCRep)[16]. This centre, an independent charitable research trust linked to Middlemore Hospital, is known for its efficient approach to facilitating clinical trials within its region, and uses a model worth emulating.

Currently the Universities and DHBs hosting trials expect a fixed and unreasonably high portion of the research funds to be dedicated to surcharges for overheads. Clinicians have complained that these surcharges deplete funds available to researchers for actual research. In order to improve the environment, these institutions need to develop an approach that takes into account economies of scale and should consider a reducing scale of surcharge dependent on repeat trials being hosted.

In establishing clinical trials business units, care should be taken to avoid the risk of adding a further layer of bureaucracy and consequently raising overheads. The current global financial environment means that companies are carefully scrutinising

[16] CCRep Fact Sheet http://www.ccrep.org.nz/FilesCont/CCREP%20fact%20sheet%202009%204.pdf

their costs and looking for the most cost competitive environments in which to run trials.

In countries with small populations like New Zealand, strategies are needed to ensure that clinical trials can attain complete enrolment. In New Zealand, poor enrolment at times means that the trials become more expensive on a cost-per-patient basis. Strategies used in Australia and other competitive countries have included public encouragement for people to volunteer as subjects of clinical trials; networks of healthcare professionals and patient advocates that refer to clinical trial centres; General Practitioner engagement to encourage referrals.

4. Economic incentives

The New Zealand Government should develop a business case to explore the feasibility of providing tax incentives for R&D.

The Australian Government has shown consistent support for the clinical trials industry, both in terms of providing tax incentives as well as maintaining strong working relationships with the pharmaceutical industry. The benefits of this approach are reflected in the graph in Figure 2 above. Any support for clinical trials must take into account the long time frames involved in the research cycle, and should therefore remain stable over time.

The Australian *R&D Tax Concession* is a broad-based, market driven tax concession which allows companies to deduct up to 125% of qualifying expenditure incurred on R&D activities when lodging their corporate tax return. A 175% Incremental (Premium) Tax Concession and R&D Tax Offset are also available in certain circumstances[17]. Introduced in 1986, the tax incentives have allowed certainty in planning these typically long term investments in research.

As ongoing innovation depends on income streams from previous innovations, the business model of the pharmaceutical industry and biotechnology firms should not be further undermined by the current provisions in the proposed Patents Bill. There are a number of provisions in the current version of the Patents Bill that reduce the ability of companies in New Zealand to generate adequate income streams to justify the financial risks involved in research.

We see the Government's recent attempts to find a way of funding high cost highly specialised medicines as being a very positive step, and eagerly await the publication of this report. Companies would be more likely to invest in research

[17] AusIndustry, An Australian Government initiative, (accessed 09 – 04 – 2010) http://www.ausindustry.gov.au/InnovationandRandD/RandDTaxConcession/Pages/RDTaxConcession.aspx

where they have some confidence that the products being trialled may ultimately be funded.

5. Relationship building

The New Zealand Government should publicly recognise the pharmaceutical industry as a legitimate partner in bringing research to New Zealand. The pharmaceutical industry has at its core the development of products to enhance people's health and wellbeing. It is also responsible for providing large numbers of "knowledge economy" type jobs in the countries that provide a supportive environment. As long as the public believe that the Government cannot align itself with the aims of the pharmaceutical industry, any attempts to improve the trials environment are likely to be superficial and ineffective.

The Australian Government has become involved in a productive partnership with the industry and this has helped pharmaceuticals become Australia's highest technology related export earner in 2009. The New Zealand Government should explore the possibility of forming a working group such as the combined Australian Government and industry initiative, known as The Pharmaceutical Industry Strategy Group[18].

There are a number of potential public-private-partnerships that should be explored to add value to the New Zealand health and education systems. One model that has successfully been used in New Zealand is the partnering of pharmaceutical companies with centres of research excellence.

Public–private-partnerships could also be expected to reduce some of the pressure off the funding provided by the Health Research Council (HRC), allowing the HRC to achieve more with its current budget.

[18] Pharmaceuticals Industry Strategy Group, Department of Innovation, Industry, Science and Research
http://www.innovation.gov.au/Industry/Pharmaceuticals/Pages/PharmaceuticalsIndustryStrategyGroup.aspx

Conclusions

The RMI has identified numerous potential improvements that should be implemented if New Zealand is to achieve its potential as a destination for international investment in clinical trials.

Although improving each factor independently may contribute to New Zealand's competitiveness, for meaningful impacts to be made these improvements should be implemented as a comprehensive package.

G. Recommendations

We reiterate our recommendations here for clarity:

1. **Improve the speed of application processes to allow rapid trial commencement**
    - mainly ethics and DHB processes
    - regulatory processes are currently reasonably efficient

2. **Develop a critical mass of experienced clinical trials staff**
    - including clinicians and support staff
    - using appropriate career paths
    - possible post-graduate certificate in clinical research

3. **Develop the clinical trials infrastructure**
    - separate business units within DHBs and universities dedicated to clinical trials
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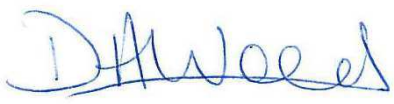
    - the pharmaceutical industry should be seen as a legitimate partner in order to develop long term strategies in collaboration.



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Researched Medicines Industry Association

References

Australian Biotechnology Sector Fact Sheet:

http://www.innovation.gov.au/Section/AboutDIISR/FactSheets/Pages/AustralianBiotechnologySectorFactSheet.aspx

Lockhart M, Babar, ZU, Garg S, (2010) Evaluation of policies to support drug development in New Zealand, *Health Policy*, in press.

Lockhart M, Babar, ZU, Garg S, (2010) Evaluation of trends in clinical research in New Zealand: 1989 – 2009, NZMJ in press.