ACCESS TO INFORMATION AND MEDICINES REGULATION IN NEW ZEALAND

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This article explores a significant issue in the regulatory regime for medicines in New Zealand and around the world: the deficit of information about medicines available to doctors, patients and independent researchers. In New Zealand, while some generic (off-patent) drugs are manufactured domestically, the major suppliers are large multinational companies. Similarly, clinical trials to establish a drug's effectiveness, safety and quality are predominantly undertaken overseas. Much of the information about safety, efficacy and quality of drugs is held and controlled by pharmaceutical companies and regulators. This article proposes ways in which public access to information about medicines can be improved.

I INTRODUCTION

This article examines the regulatory regime for medicines in New Zealand, and the future Trans-Tasman regime that Australia and New Zealand will transition into. It then goes on to explain the issue of hidden data and lack of publicly available information about medicines and clinical trials. In Parts IV and V, it briefly discusses the way that information about medicines is provided by the pharmaceutical industry and explores avenues for making regulatory changes to improve transparency. Finally, this article explores way in which administrative law may also assist in improving transparency in this area.

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A Key Terms

"Medicine" includes any substance or article that is manufactured, imported, sold or supplied for administering to humans for a therapeutic purpose, or an ingredient in the preparation of a therapeutic substance.[1] In this article, the terms "medicine" and "drug" will be used interchangeably. The discussion in this article refers mostly to medicines. However the points made are equally applicable to medical devices.

"New medicine" means any medicine that has not previously been available in New Zealand.[2] The manufacturer must seek New Zealand Medicines and Medical Devices Safety Authority (Medsafe) approval before it markets, manufactures or promotes a new medicine in New Zealand. New medicines tend to be more expensive and protected by patents in contrast to off-patent drugs (generic drugs) such as paracetamol.

"Unapproved medicine" means a medicine that has not received approval at all, or is unapproved for the purpose or dosage it is being prescribed for. This is not a statutory definition, but is the common terminology used to refer to a new medicine or a medicine that is not approved for the dose or use in question. For example, if a medicine approved for adults is prescribed for a child then it is being prescribed for an "unapproved" use.

A "clinical study report" contains the most complete and informative technical information about a drug. These reports are produced by the researchers for every trial on a medicine or medical device and contain vast amounts of information. They detail the experimental methods, results and analysis, and provide appendices that list all the data from every individual involved in a clinical trial.

II THE CURRENT REGIME FOR MEDICINES REGULATION AND THE ANZTPA

This part of the article will précis the regulatory environment for medicines in New Zealand as well as the proposed future scheme under the Australia New Zealand Therapeutic Products Agency (ANZTPA).

The Medicines Act 1981 (the Medicines Act) and Medicines Regulations 1984 (the Medicines Regulations) control the use, approval, manufacture, sale and promotion of pharmaceutical drugs. Medsafe is responsible for pre-market approval and post-market monitoring of medicines.[3] It analyses new medicines for safety, efficacy and quality as well as monitoring reported side effects and continuing to evaluate drugs and medical devices once they are on the market. Medicines are

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1 Medicines Act 1981, s 3(1) and (2).

2 Medicines Act 1981, s 3(3).

3 Medsafe "About Medsafe" (1 July 2014) <www.medsafe.govt.nz>.

usually approved to treat a specific symptom or in a particular dosage.[4] Use of a medicine in a higher dose, for a different purpose, or for a different type of patient (for example, children) requires separate and additional approval.

The evaluation of a medicine in the approval process is based on information supplied to Medsafe by the pharmaceutical company making the application and evidence from other relevant published studies. This includes the clinical study report and data from countries where the drug is already on the market.[5] Medsafe may also request more information from the applicant if it considers it appropriate; this can include an order that further studies be undertaken.[6] Medsafe focuses on information that relates to the specific dosage and use being applied for, although applicants are expected to submit all studies that relate to safety.[7] Failure to disclose all relevant information may result in a penalty imposed under s 36 of the Act.[8]

Unapproved medicine can be prescribed if a doctor believes it is necessary,[9] for example, for rare conditions or to try treatments that are approved overseas. In these instances s 29 of the Medicines Act requires that the Director-General of Health be notified. In prescribing medicine (approved or otherwise) the practitioner must always adhere to professional and ethical standards and seek the informed consent of the patient.[10]

In 2003, Australia and New Zealand signed the Agreement between the Government of New Zealand and the Government of Australia for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products (the Treaty).[11] This Treaty provides for a joint trans-Tasman regulator for medicines and medical devices – the ANZTPA. The Treaty is an attempt to incorporate

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4 Medicines Act 1981, s 21.

5 Such as the USA or Europe. See Medsafe "Quality and Safety of Medicines: Medsafe's Evaluation & Approval Process" (23 April 2013) <www.medsafe.govt.nz>.

6 Medicines Act 1981, s 21(4); Email from Chris James (Manager, Clinical Risk Management, Medsafe) to the author regarding enquiry about Medsafe's powers (11 April 2013); Email from Susan Martindale (Principal Advisor, Regulation, Medsafe) to the author regarding queries about the regulation of medicines (24 April 2013).

7 Email from Susan Martindale (Principal Advisor, Regulation, Medsafe) to the author regarding queries about the regulation of medicines (29 April 2013).

8 Email from Susan Martindale, above n 6.

9 Medicines Act 1981, s 25.

10 Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, sch 1, cl 2 (rights 4, 6 and 7).

11 Agreement between the Government of New Zealand and the Government of Australia for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products (signed 10 December 2003, not yet in force) [Joint Therapeutic Agency Treaty].

medicines regulation into the Australia New Zealand Closer Economic Relations Trade Agreement framework.[12]

The switch to ANZTPA regulation is scheduled for 2016, upon passage of legislation in both countries, thereby implementing the Treaty.[13] The Therapeutic Products and Medicines Bill 2006 (the 2006 Bill)[14] was to be the domestic implementing legislation in New Zealand.[15] However, in 2007 the Bill stalled during the Select Committee phase, the major point of opposition being the inclusion of complementary health products in the scheme.[16] Renewed negotiations in 2011 saw the removal of New Zealand's domestic complementary health products industry from the ANZTPA scheme.[17]

The Treaty provides the overarching rules governing the ANZTPA and powers afforded to it, to be ratified in both countries via implementing legislation. The ANZTPA itself will be given the power to create delegated legislation in the form of "rules" and "orders", which will provide the scheme's regulatory detail. The rules must uphold the primary purpose of safeguarding public health and safety by establishing a regulatory scheme that is consistent with international best practice.[18]

The Ministerial Council (comprised of the Ministers of Health in the two countries) will have the power to make rules pertaining to most aspects of the ANZTPA.[19] The Ministerial Council may also use rules to delegate functions or powers of the Managing Director or the ANZTPA Board.[20] The Agency itself may make orders dealing with more technical and detailed aspects of the framework.[21] The ANZTPA will determine standards for the information provided to consumers

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12 Australia New Zealand Closer Economic Relations Trade Agreement 1329 UNTS 175 (signed 28 March 1983, entered into force 1 January 1983); Joint Therapeutic Agency Treaty, above n 11, preamble.

13 ANZTPA "About ANZTPA" (26 April 2013) <www.anztpa.org>; Joint Therapeutic Agency Treaty, above n 11, art 23.

14 Therapeutic Products and Medicines Bill 2006 (103-1).

15 The Bill passed its first reading by 61 votes to 59: (12 December 2006) 636 NZPD 7067.

16 Therapeutic Products and Medicines Bill 2006 (103-2) (select committee report) at 3; Health Committee *Inquiry into the Proposal to Establish a Trans-Tasman Agency to Regulate Therapeutic Products* (December 2003) at 30, 38 and 48. Note: the Bill was discharged on 24 November 2014, just prior to this publication going to print.

17 John Skerritt and Stewart Jessamine *Description of a Possible Joint Regulatory Scheme for Therapeutic Products under ANZTPA* (ANZTPA, January 2013) [*ANZTPA Discussion Paper*] at 9; John Key "Australia, NZ announce intention on ANZTPA" (press release, 20 June 2011); ANZTPA "Statement of Intent" (27 November 2012) <www.anztpa.org>.

18 Joint Therapeutic Agency Treaty, above n 11, art 2(1).

19 Joint Therapeutic Agency Treaty, above n 11, arts 4 and 9.

20 Joint Therapeutic Agency Treaty, above n 11, art 9(1)(g) and (o).

21 Joint Therapeutic Agency Treaty, above n 11, art 10(1).

and professionals as well as for other matters concerning the quality, safety and efficacy of medicines.[22]

III THE INFORMATION DEFICIT IN MEDICINE

Patients expect medical decisions to be based on scientific evidence. They expect that new drugs be tested in fair, replicable clinical trials before applications are made for market approval. They expect regulators to make fully informed, transparent decisions on the basis of reliable data and information. Finally, they expect that when their doctor is considering a treatment the doctor has access to all the information necessary to weigh up its costs and benefits. However, these things do not always occur. Doctors and independent researchers do not have access to all the information about medicines, only that which is published. This published information can contain bias and conceal data. Medsafe also receives more information than it shares with doctors. In this article, this is termed the "information deficit".

This part of the article outlines the issues concerning access to information and hidden data in New Zealand's current medicines regulation system. Part IV discusses pharmaceutical companies' role in information provision. Part V contains recommendations to address these issues.

A Hidden Data and its Impact on Public Health

A significant number of negative or unflattering clinical trials for medical interventions remain unpublished.[23] This is known as publication bias. It occurs in both industry-funded and academic research. While not necessarily wilful or malicious, many data remain hidden. This can be for a variety of reasons, such as difficulties with and disincentives to publishing trials with inconclusive or negative results in journals, or the discontinuation of a trial or drug development. Regulators, including Medsafe, receive the clinical study report for drugs submitted for approval and consider it in their approval decision. However, in most cases unpublished information is out of the reach of independent researchers and doctors.

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22 *ANZTPA Discussion Paper*, above n 17, at 10.

23 Iain Chalmers "Underreporting Research is Scientific Misconduct" (1990) 263 JAMA 1405; Kirby Lee, Peter Bacchetti and Ida Sim "Publication of clinical trials supporting successful new drug applications: a literature analysis" (2008) 5 PLoS Med 191; Hans Melander and others "Evidence b(i)ased medicine-selective reporting from studies sponsored by pharmaceutical industry: review of studies in new drug applications" (2003) 326 BMJ 1171; F Song and others "Dissemination and publication of research findings: an updated review of related biases" (2010) Health Technol Assess 1; "Written evidence from PLOS (CT20)" in House of Commons Science and Technology Select Committee *Clinical Trials: Written Evidence* (6 March 2013) at 122.

B Examples of the Ramifications of the Information Deficit

The following examples illustrate the impact that publication bias and hidden data can have on public health.[24]

Research shows that 74 clinical trials have been conducted on all the antidepressants that came onto the American market between 1987 and 2004.[25] This represents 12,500 patients worth of data. Thirty-eight of these trials indicated positive results. The other half of the trials indicated that the treatment being trialled was no better than any other treatment, or no better than a placebo. Thirty-seven of the positive trials – all but one – were published in full. However, only three of the trials with negative results were published. The other 22 were never mentioned in the scientific literature and the remaining 11 were written up to make the trial sound successful.[26] The effect of this was to make the drugs appear much more effective and safe than they actually are. The literature is therefore skewed in favour of drugs that may do patients more harm than good. This is the literature which doctors rely on to make their treatment decisions.

Lorcainide was an antiarrhythmic drug developed in 1980, designed to treat patients who had suffered heart attacks. It was trialled in 100 patients: 50 were given Lorcainide and 50 were given a placebo. Of the first 50, 10 patients died. Of the second 50, only one died. It seemed that Lorcainide was a failure; commercial funding was stopped and the drug development discontinued. However, because commercial development stopped early, nothing was published about the trial. Subsequently, other developers had a similar idea, and developed similar antiarrhythmic drugs, which were prescribed all over the world. However, these new antiarrhythmic drugs also caused an increased risk of death in patients who had suffered a heart attack but had not developed an abnormal heart rhythm. By the time this was detected, over 100,000 patients had died unnecessarily. Had the developers of Lorcainide published the results of their trial, doctors would have been a lot more cautious about prescribing antiarrhythmic drugs and those deaths would probably have been prevented.[27]

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24 See also Mark Broatch "Bitter Pills" *The Listener* (New Zealand, 17 November 2012).

25 Ben Goldacre *Bad Pharma: How drug companies mislead doctors and harm patients* (Fourth Estate, London, 2012) at 13.

26 See Chalmers, above n 23, at 1405–1408.

27 AJ Cowley and others "The effect of lorcainide on arrhythmias and survival in patients with acute myocardial infarction: an example of publication bias" (1993) 40(2) Int'l J Cardiol 161; Goldacre, above n 25, at 11.

C Health and Disability Services Consumers' Rights

Patients' rights to be fully informed in making treatment decisions are protected in New Zealand in the Code of Health and Disability Services Consumers' Rights (the Code).[28] Every consumer has the right to have services provided that comply with legal, professional, ethical and other relevant standards.[29] Furthermore, every consumer has the right to have services provided in a manner that minimises potential harm and optimises their quality of life.[30] Patients have a right to information that a reasonable consumer would expect to receive in the circumstances, including an evaluation of the treatment options available that gives an assessment of the expected risks, side effects, benefits and costs of each option.[31]

Without all the information about a treatment, the patient or practitioner cannot make a valid and informed decision.[32] A doctor must be able to access full and accurate information about a drug's safety and efficacy in order to provide quality treatment.[33] When treatment decisions are made in the context of prescribing an unapproved medicine the need for accurate and transparent information to be available to a practitioner becomes even more important.

A practitioner is not in breach of the Code if they have taken reasonable actions in the circumstances (including their own resource constraints) to give effect to the rights in the Code.[34] Therefore the issues that this information deficit causes in light of the Code are not enforceable against practitioners so long as they have made a treatment decision on the basis of all the (published) information available to them. This means that patients have no recourse to enforce their rights to be fully informed via the Code in the particular context of information about pharmaceutical medicines and the effects of the information deficit. Patients are at risk of breaches of the standard of medical care they are entitled to expect because their practitioners cannot provide them with full information about a treatment, despite the practitioner acting exactly as the law and

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28 Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, sch 1, cl 2 (rights 6 and 7).

29 Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, sch 1, cl 2 (right 4(2)).

30 Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, sch 1, cl 2 (right 4(4)).

31 Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, sch 1, cl 2 (right 6(1)(b) and (c)).

32 *Rogers v Whitaker* [1992] HCA 58, (1992) 175 CLR 479 at [9]–[14].

33 For a case study, see Goldacre, above n 25, at 5.

34 Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, sch 1, cl 3.

ethical standards require. The rights protected by the Code are undermined by the lack of transparency that persists in the current system.

D Information and Medsafe

The information that doctors and patients receive from Medsafe is in summary form. Most medicines are accompanied by a "Consumer Medicine Information" pamphlet (CMI) that contains information written for patients. The relevant pharmaceutical company is responsible for producing CMIs but is not legally required to do so. Medsafe does not approve or evaluate CMIs.[35] Data sheets, on the other hand, are required by the Medicines Regulations and contain greater detail and technical prescribing information but are provided to medical practitioners rather than patients.[36]

Medsafe receives published and unpublished data, and information about medicines that are submitted for approval. It can also require that more information be provided and exercises that power routinely.[37] While Medsafe itself undertakes an analysis of the clinical study report, it does not make its analysis public.[38] Medsafe will release some information about a decision where it is required to do so under the Official Information Act 1982 (OIA).[39] However information about safety, quality and efficacy is usually withheld to protect commercial sensitivity.[40]

E Justifications for Restricting Public Access to Clinical Study Reports and Other Unpublished Information

There are three main arguments made for restricting public access to clinical study reports:

- commercial sensitivity;
- protection of trial participants' confidentiality; and
- risk of misinterpretation of large datasets by laypersons or those with a malicious intent.

All of those risks can be resolved while improving transparency.

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35 Medsafe "Consumer Medicine Information" (23 April 2013) <www.medsafe.govt.nz>.

36 Medicines Regulations 1984, cls 51–53.

37 Medicines Act 1981, s 21(4); Email from Susan Martindale, above n 6; Medsafe *New Zealand Regulatory Guidelines for Medicine: Part E: Templates, declarations and checklists* (Ministry of Health, July 2011) at [1.13].

38 Email from Susan Martindale, above n 6.

39 Email from Susan Martindale, above n 6

40 Email from Susan Martindale, above n 6; Official Information Act 1982, s 9(2).

1 Commercial sensitivity

"Commercially sensitive" information involves a trade secret or is information that would unreasonably prejudice the commercial position of the person who supplied it if disclosed.[41] It is important to protect pharmaceutical companies in order to provide incentives for innovation and to allow them to recover the significant costs associated with developing a new drug. However, the threshold for withholding safety and efficacy information about a drug in favour of commercial interests should be very high.

The strong public interest argument for ensuring the safety and efficacy of medicines arguably overrides commercial interests. Details about the molecular structure of a drug or its manufacture are commercially sensitive and should be protected.[42] However, these clinical study report documents do not include information about the composition or preparation of the drug itself, or trade secrets.[43] More relevant in the context of clinical study reports is the commercial impact that negative information in them could have, such as the revelation that a drug is no better than its competitors.

A 2010 decision by the European Ombudsman rebutted the European Medicines Agency's (EMA) assumption that releasing clinical study reports and other unpublished data on anti-obesity medicines would prejudice the commercial interests of the manufacturer.[44] As well as the justifications already discussed above, the EMA argued that the data contained in clinical study reports could be used by competitors to develop a similar product and that competitors would also get information about the long-term clinical development strategy of the manufacturing company.[45] The Ombudsman found that the EMA had failed to elaborate on how the clinical study report would be used by competitors and also that the documents in question did not contain details of the development strategy.

Regardless, redaction is a more suitable way to protect commercial sensitivity than complete non-disclosure. Legislative provisions preventing publication of the clinical study report and unpublished trials before Medsafe has made a decision on market approval are also an option. Such a provision already exists in the Medicines Act with regards to innovative medicines.[46] However,

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41 Official Information Act 1982, s 9(2)(b); Office of the Ombudsmen *Official Information Legislation Guides: Part 5 Common Misconceptions* at 7–8.

42 P Nikiforos Diamandouros *Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency* (European Ombudsman, 24 November 2010) at [75].

43 Diamandouros, above n 42, at [78].

44 Diamandouros, above n 42.

45 Diamandouros, above n 42, at [80]–[83].

46 Medicines Act 1981, s 23B.

following consideration by Medsafe the most appropriate course of action would be to release this unpublished data whether or not approval was given, as the reasons for Medsafe declining to give approval to a particular medicine are also important for patients and doctors.[47]

2 Patient confidentiality

Many protests against disclosing clinical study reports centre on the risk that the individual trial participants will be identifiable and therefore their confidentiality will be breached.[48] This risk, while legitimate, can be addressed. It is a basic requirement of the ethics approval process that the privacy of the individuals in clinical trials is maintained. To that end, individuals are referred to in clinical study reports using identification and test centre numbers.[49] The information linking patients to their numbers is not publicly available. However, it is possible that a combination of physical features described in the clinical study report with regards to an individual patient may be enough to identify that person in some circumstances. In cases where the individual patient data may be enough to identify a patient this can be addressed by redaction. The European Ombudsman noted that because clinical study reports are highly structured documents, which separate individual patient data from other parts of the report, removing private data by redaction does not create an undue administrative burden.[50]

3 Misinterpretation of data and information overload

Concerns have been raised that publicly available clinical study reports, and regulatory information or decisions will be misinterpreted by laypeople causing health scares, or used by competitors to attack the manufacturer. These fears are overblown.

The primary benefit from publication of clinical study reports will be the ability to make unbiased assessments about the efficacy of new drugs. It will also provide data to underpin meta-analyses and systematic reviews by independent researchers. Doctors and other interested parties will then have access to these independent assessments and will be empowered to make better-informed treatment decisions. If a study or academic report is written using clinical study report data that has been interpreted wrongly or "cherry picked" to attack the industry or manufacturer it will not hold much scientific value unless it is substantively true and able to be replicated and tested. In scientific literature the methods must be included in the report, so an analysis using flawed methods or bias will not carry much weight, if any. Additionally, it will have to pass through the peer review process.

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47 Interview with Ron Paterson and Leo Donnelly, Ombudsmen (the author, Wellington, 11 September 2013).

48 Peter Doshi, Tom Jefferson and Chris Del Mar "The Imperative to Share Clinical Study Reports: Recommendations from the Tamiflu Experience" (2012) 9 PLoS Med e1001201.

49 Diamandouros, above n 42, at [86].

50 Diamandouros, above n 42, at [37].

Most laypeople would not be interested in, or able to understand, the level of detail that is included in the clinical study reports. Additionally, most doctors would not attempt or be able to analyse such complex raw data themselves. While it is possible that laypeople may misuse the data and clinical study reports, this is likely to occur rarely. Considerable information is already available to patients and patient groups about medicines, most of which is in scientific journals and involves complex scientific concepts. However, these are not regularly misinterpreted or misused by patients or other parties to create health scares.

4 Positive Reasons for Disclosure

The most significant argument for disclosure of clinical study reports and other unpublished trial data is that there is a substantial public interest in the transparency of data on medical interventions. As discussed above, publication bias and hidden data presents a significant challenge to public health and creates unnecessary risk for patients. The competing interests at stake are commercial and financial considerations that should be secondary to safeguarding public health and protecting patient faith in the regulatory system. Making all information available allows for independent assessment of the data and promotes fully informed treatment decisions. The developers of a drug also have an ethical imperative to publish all the data they glean from clinical trials because patients often agree to participate in clinical trials to help further medical knowledge.[51] Non-disclosure of the results of that trial undermines the sacrifices and philanthropy of the participants and may create disincentives for others to participate in future studies.[52]

IV INFORMATION AND THE PHARMACEUTICAL INDUSTRY

Pharmaceutical companies provide limited information to patients and doctors, and this information is often tailored to project a positive image of a drug while downplaying its negative aspects.

A Flawed Trials and Hidden Data

Industry-funded trials that are reported in academic journals are significantly more likely to show positive results and overstate the benefits of a drug than independent trials or studies.[53] This is caused by a number of factors:

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51 "Written evidence from PLOS (CT20)", above n 23, at 122; "Written evidence submitted by Glyn Moody (CT22)" in House of Commons Science and Technology Select Committee *Clinical Trials: Written Evidence* (6 March 2013) at 131.

52 Doshi, Jefferson and Del Mar, above n 48.

53 Florence T Bourgeois, Srinivas and Kenneth D Mandl "Outcome Reporting Among Drug Trials Registered in ClinicalTrials.gov" (2010) 153 Annals of Internal Medicine 158; JE Bekelman, Y Li and CP Gross "Scope and Impact of Financial Conflicts of Interest in Biomedical Research: a systematic review" (2003) 289 JAMA 454; Sergio Sismondo "Pharmaceutical company funding and its consequences: a qualitative systematic review" (2008) 29 Contemporary Clinical Trials 109; Goldacre, above n 25, at 80; Joel Lexchin

- Publication bias, whereby positive results are more likely to be published than negative or neutral results. This problem is not limited to industry-funded publications.
- The medicine is sometimes compared to an alternative that the researcher knows is worse – such as a placebo or a competitor drug at a very low dose – rather than the current best treatment for the condition.[54]
- Patients in clinical trials are sometimes selected carefully so that they are more likely to show improvement during the trial.[55]
- Trials may be stopped early or extended beyond the initial end date. This distorts the experimental design and may bias the results in ways unknown to the reader.[56]

Because of the economic incentive connected to the success of a newly developed medicine, it is unsurprising that industry-funded trials are often written up and publicised in a way that emphasises the positive aspects of a medicine while downplaying or concealing unflattering results. This makes it all the more important to release the clinical study reports and other unpublished data to allow independent assessment of the data collected in clinical trials.

B Medical Writing

As part of their drug development and marketing process, pharmaceutical companies employ medical writers – institutions or freelancers that specialise in writing up clinical trials and "publication strategy" services.[57] Medical writers meet with senior members of a company's drug development team and clinical researchers to work on manuscripts, posters, presentations about the new medicine, and to discuss the journals that will be targeted for publication.[58]

A medical writer will produce several draft manuscripts to submit to targeted journals and send these drafts to external authors – usually credible academics who have agreed to co-author the

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and others "Pharmaceutical industry sponsorship and research outcome and quality: systematic review" (2003) 326 BMJ 1167.

54 DJ Safer "Design and Reporting modifications in industry-sponsored psychopharmacology trials" (2009) 190 J Nerv Ment Dis 583; Goldacre, above n 25, at 180.

55 PM Rothwell "External validity of randomised controlled trials: To whom do the results of this trial apply?" (2005) 365 The Lancet 82; Goldacre, above n 25, at 177.

56 Paul S Mueller and others "Ethical Issues in Stopping Randomized Trials Early Because of Apparent Benefit" (2007) 146 Annals of Internal Medicine 878; D Bassler and others "Stopping Randomized Trials Early for Benefit and Estimation of Treatment Effects: Systematic Review and Meta-regression Analysis" (2010) 303 JAMA 1180; Goldacre, above n 25, at 181.

57 Linda Logdberg "Being the Ghost in the Machine: A Medical Ghostwriter's Personal View" (2011) 8 PLoS Med e1001071; New Zealand-based medical writing companies include: ADIS International; SGS New Zealand; Rata Communications; Biowrite Solutions; and Quintiles.

58 Information received from a confidential source in the medical industry with background as a medical writer.

articles or act as "key opinion leaders" by presenting information about the drug to colleagues.[59] The medical writing industry promotes itself as "quality control", assisting busy researchers to write up the results of their trials. However, the process of medical writing for pharmaceutical company-funded trials is not independent from the company itself. Pharmaceutical companies have first input as to content, full control over the presentation of data and the writing process, and therefore the key message of these publications.[60] For example, a former medical writer interviewed for this article recalled a series of manuscripts they worked on for a large pharmaceutical company in which data points from individual patients that indicated unfavourable interpretation of the results were selectively omitted from graphs to be used in poster presentations or PowerPoint presentations.[61]

The association of an external expert "author" lends articles and trial reports an air of independence and academic weight, especially when the contribution of the medical writer or input of the sponsor company is undisclosed. Many of the more reputable medical journals now demand transparency about the origins and authorship of reports that are submitted to them for publication.[62]

While ensuring declaration of medical writing assistance is a very positive change, there are three issues that it does not resolve:

- Declaration of medical writing assistance for new articles does not affect the literature published for the last few decades on which doctors still rely for most medicines that they prescribe. Much of this literature was produced by medical "ghost writers" but attributed solely to independent academics.[63]
- The process by which the article is written is not declared. The extent to which the manufacturer drove the key message is therefore unknown to the reader.
- Less reputable journals are not so rigorous. It has been reported that pharmaceutical companies emphasise speed over quality in their publication strategies, happy to target smaller, less reputable journals to claim and cite published articles for promotional

59 Logdberg, above n 57.

60 Information received from a confidential source in the medical industry with background as a medical writer.

61 Information received from a confidential source in the medical industry with background as a medical writer.

62 International Committee of Medical Journal Editors "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" (August 2013) <www.icmje.org>.

63 Logdberg, above n 57; Xavier Bosch, Bijan Esfandiari and Leemon McHenry "Challenging Medical Ghostwriting in US Courts" (2012) 9 PLoS Med e1001163; Jeffrey R Lacasse and Johnathon Leo "Ghostwriting at Elite American Medical Centers in the United States" (2010) 7 PLoS Med e1000230; Information received from a confidential source in the medical industry with background as a medical writer.

materials.[64] It is therefore possible that undisclosed medical "ghost writing" may still occur in these articles.

In the United States, it has now been suggested that academics who put their names to articles that are predominantly written and analysed by ghost writers without disclosing those facts can be found guilty of fraud.[65] While it is unlikely that many New Zealand-based academics are acting as guest authors or key opinion leaders, it is still desirable that the practice of medical writing without disclosure be considered fraudulent and punished if it is discovered.

There is a strong medical writing industry in New Zealand. Most medical writers, while usually highly qualified, do not hold medical degrees or qualifications in statistical interpretation.[66] They are usually educated in research or biomedical science. A former medical writer interviewed for this article, who does have medical training, stated that their eventual reason for leaving the profession was that the things asked of them as a medical writer sometimes came into conflict with their professional ethical obligations as a doctor. The example given was that they were often asked to present data in a way that concealed negative aspects of the drug, thereby misleading patients and doctors who would eventually read their manuscripts. This could create outcomes that were damaging to the best interests of patients. The interviewee expressed doubt that someone trained in medicine could ethically act as a medical writer due to the conflicts of interest involved.

There are some guidelines for medical writers created by various industry associations.[67] However, there are no official guidelines and no official recognition of the industry in New Zealand. Full regulation of the medical writing industry would be difficult, expensive and ineffective due to the fragmented nature of the profession and the number of freelance writers. However, it is still desirable that the Ministry of Health publish a set of best practice guidelines or a similar document pertaining to the medical writing industry. While small, this step may increase transparency and more clearly enunciate the ethical issues involved in medical writing to those members of the industry.

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64 Information received from a confidential source in the medical industry with background as a medical writer.

65 Simon Stern and Trudo Lemmens "Legal Remedies for Medical Ghostwriting: Imposing Fraud Liability on Guest Authors of Ghostwritten Articles" (2011) 8 PLoS Med e1001070; Bosch, above n 63.

66 Information received from a confidential source in the medical industry with background as a medical writer. See for example Medical Writer "Qualifications and Skills" (19 November 2014) <www.medicalwriter.org.uk>.

67 Adam Jacobs and Elizabeth Wagner "Commentary: European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications" (2005) 21 Current Medical Research and Opinion 317. The Australasian Medical Writers Association subscribes to the Media, Entertainment & Arts Alliance Code of Ethics.

Although the peer review process gives reasonable assurances with regard to the quality of the methodology and results analysis presented in an article, it is not an effective solution to the concerns surrounding medical writing. There is disparity between different reviewers with respect to the attention placed on each article they are given. Additionally, the reviewer, while able to critique the immediate analysis in the article, will have no way of knowing the extent to which the sponsor has influenced the initial selection of data used in the article, and hence the overall message.[68] It is unrealistic to hold the peer review process out as a solution to the issues of bias and hidden data in academic articles.

V MAKING CHANGES

The public health impact of the information deficit is significant. Doctors cannot make fully informed treatment decisions, which exposes patients to unnecessary risks and breaches patients' right to give informed consent to treatments. Participants in clinical trials cannot be sure that the experiments done on them will contribute to the scientific literature. The following sections explore legal options for reversing, combating and preventing the information deficit.

The proposed solutions are twofold:

(1) Create a statutory duty to register the existence of all clinical trials undertaken in New Zealand or on New Zealand citizens on the Australia New Zealand Clinical Trials Register (ANZCTR) and require that the sponsor of the trial update the register with the results of the clinical trial within a reasonable time after completion.
(2) Include a requirement in the ANZTPA regulatory framework that the Agency maintain a publicly available database of all information submitted to it for drugs that are approved for market. This information should include complete clinical study reports and the regulatory analysis.

These solutions assume that the relevant domestic ANZTPA implementation legislation and subsequent entry into force of the Treaty will progress as planned by 2016. However, they should alternatively be considered for the Medicines Act reform that would have to occur if the trans-Tasman agency does not proceed.

There are also administrative law options for doctors, patients or independent researchers wishing to access information from the regulator. These will continue to be available with regards to medicines under the trans-Tasman framework, although the exact functioning of these administrative law components in the ANZTPA context is yet to be established. The avenues explored are:

- the Official Information Act 1987;

68 Information received from a confidential source in the medical industry with background as a medical writer.

- the Ombudsman; and
- the Regulations Review Committee.

A The ANZTPA Regime

The entirely new regulatory environment created for the ANZTPA presents an opportunity to create a transparent, thorough, patient-focused regulatory scheme for Australia and New Zealand. To be truly effective, the Agency must ensure that it receives all necessary information from applicants for drug approval as well as provide patients, doctors and independent researchers with the information they need to make fully informed decisions. These proposals will not make Australasia uncompetitive nor will they stymie innovation and drug development. In fact, they will bring the ANZTPA in line with international practice. In Europe and the United States steps towards greater transparency and effective information access are also being taken.[69]

1 Information provided to the Agency

Medsafe currently receives all information held by the applicant about a medicine submitted for approval, including clinical study reports, and also ensures that more studies are done if necessary. The same situation will apply in the ANZTPA scheme and the Agency will also be able to require other parties to provide relevant information.[70] Failure to provide information for an approved product may result in regulatory action such as the suspension or cancellation of an approval.[71] These provisions are a great improvement and must be rigorously enforced.

The 2006 Bill gave the ANZTPA power to issue "information requirement notices" (to be defined in the rules).[72] It also provided for significant enforcement options, including penalties of up to five years' imprisonment for submitting materially false or misleading information.[73] Additionally, the holder of a product licence for a therapeutic product would be required, on becoming aware of adverse-effect information, to give written notice to the Agency of that information.[74] If the proposed provisions are enacted and properly enforced they will create a robust information-gathering system, allowing the ANZTPA to demand full clinical study reports and trial data.

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69 House of Commons Science and Technology Select Committee *Clinical Trials: Written Evidence* (6 March 2013); Food and Drug Administration Amendments Act 121 Stat 904 § 801.

70 *ANZTPA Discussion Paper*, above n 17, at 39.

71 *ANZTPA Discussion Paper*, above n 17, at 39.

72 Therapeutic Products and Medicines Bill 2006 (103-1), cl 78.

73 Therapeutic Products and Medicines Bill 2006 (103-1), cls 74(4) and 79(5).

74 Therapeutic Products and Medicines Bill 2006 (103-1), cl 76(1).

2 Information provided by ANZTPA to the public

Data protection is important, especially in relation to medicines that are innovative and have not yet received approval. However the current protection that is given globally to data held by the industry has come at too high a price for public health. It is important to normalise a situation in New Zealand where manufacturers and regulators are encouraged proactively to disclose all information about the safety, quality and efficacy of medicine. Medsafe's mission statement is "to enhance the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit".[75] The Treaty indicates that the Agency's primary concern will also be safeguarding public health and safety.[76] Protection of public health and safety, and ensuring public confidence in the regulatory system are factors that incline towards greater openness and sharing of information.[77]

Data protection and disclosure are not mentioned in the Treaty, leaving such matters to be decided by rules. The ANZTPA Discussion Paper only deals with data protection briefly; it states that the ANZTPA will not be able to use protected information about an existing approved medicine when evaluating an application for a new medicine.[78] "Protected information" will include information about the active ingredient of the existing medicine if that information is not in the public domain. "Use" was not defined in the Discussion Paper and could be interpreted extremely broadly. Information will be protected for a period of five years from when an innovative existing medicine receives approval. Information will also be protected if the drug's sponsor has not given ANZTPA permission in writing to use it. However, arguably it does not indicate an intention to prohibit use of the clinical trial data, such as by disclosing it on a database. These data protection provisions should be interpreted as concerning only information relating to active ingredients and the composition of the medicine.

If the ANZTPA is to be a regulator that operates according to international best practice, it must provide transparency and release all the information, published and unpublished, that it receives from applicants for medicines approval. This article proposes that ANZTPA create and maintain a searchable and accessible database containing all information it holds about medicines submitted for approval. Legislation is the most effective means for establishing this scheme, and would serve to normalise greater disclosure and transparency.[79]

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75 Medsafe "About Medsafe" (10 May 2013) <www.medsafe.govt.nz>.

76 Joint Therapeutic Agency Treaty, above n 11, preamble and art 2.

77 Interview with Ron Paterson and Leo Donnelly, Ombudsmen (the author, Wellington, 11 September 2013).

78 *ANZTPA Discussion Paper*, above n 17, at 22.

79 "Evidence submitted from the Editor and Deputy Editor of the British Medical Journal (CT23)" in House of Commons Science and Technology Select Committee *Clinical Trials: Written Evidence* (6 March 2013) at 136.

This proposed ANZTPA database would initially involve significant resources and time if retrospective populating is authorised, as large amounts of information currently held by Medsafe and the Therapeutic Goods Association (TGA) would require uploading. However once a database is established and properly populated the exercise should involve simply uploading new data that is received, as required, after approval is granted. Correspondingly, the costs should drop away. It is desirable that the information be retrospectively added to the database as most drugs currently on the market were approved several years ago. Information about those medicines is just as important to patients as information about newly approved drugs.

This article does not advocate disclosure of any information about products before they have been approved for the market. This would be unreasonable and would considerably damage commercial interests.[80] However, once approval has been granted or declined the ANZTPA should be mandated to publicly release the information it receives, with appropriate redaction. There is a definite public interest in publishing the reasoning behind Medsafe's decisions and risk/benefit analysis including for those drugs that are declined approval.[81] Those drugs might still be prescribed to patients as unapproved medicines.

B Clinical Trial Register

In addition to provisions requiring greater transparency from regulators, legislation should be put in place that requires all trials carried out in Australia or New Zealand to be registered on the Australia New Zealand Clinical Trials Register (ANZCTR), which already provides a framework for voluntary trial registration. This would allow patients and doctors to be better informed of all the data that has been collected on a drug, not just that which is published.

1 Registration

The responsibility for the initial registering of clinical trials should fall on the ethics committee responsible for approving the trial. This would involve listing the new trial on the ANZCTR and entering basic details such as the sponsor's identity, what is being tested and how many participants are involved. All this information will be provided by the applicant and would therefore not require much extra time or work for the ethics committees to populate the ANZCTR website. Alternatively, it could be a condition of approval that the applicants register the trial before ethics approval is granted. To avoid any doubt, a provision in the ANZTPA implementing legislation or a rule requiring registration of all trials could be enacted. This would be desirable to ensure clarity and to empower the ethics committees with enforcement capabilities.

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80 "Written evidence of Sir Alasdair Breckenridge (CT12)" in House of Commons Science and Technology Select Committee *Clinical Trials: Written Evidence* (6 March 2013) at 64.

81 Interview with Ron Paterson and Leo Donnelly, Ombudsmen (the author, Wellington, 11 September 2013).

Responsibility to update the register with the results of clinical trials should rest with the sponsor and researcher of each trial. Most of the information that the ANZTPA receives will be about drugs that were trialled in different jurisdictions, as relatively few clinical trials are conducted in New Zealand and Australia. Furthermore, not all clinical trials undertaken are for new medicines, and are often testing or focused on improving current medicines. It is therefore impractical to expect that the ANZTPA assume responsibility for uploading the results of these trials, although it should have the power to enforce any breaches. In light of the dependence that Australia and New Zealand have on overseas regulators and manufacturers and the small number of trials undertaken in the jurisdiction, the ANZTPA should have a separate statutory obligation to maintain a public database of the information it receives in applications, as discussed above.[82]

2 Legislative provision for the register

Many experts giving written evidence to the United Kingdom Science and Technology Select Committee in March 2013 stated that regulation was needed to ensure that all clinical trial results are published.[83] This section of this article examines possible legislation for the enactment of a system for compulsory clinical trial registration.

The first jurisdiction to require registration of clinical trials by law was the United States. The Food and Drug Administration Amendments Act 2007 requires that all interventional clinical trials for regulated drugs and devices undertaken in the United States must be registered on clinicaltrials.gov database and that all results for those trials must be put on the database within 12 months after completion.[84] If a trial reaches its completion before the drug is approved for use, then the deadline for posting results is no more than 30 days after approval is given.[85] Violations are met with a fine of up to US$10,000 followed by a further US$10,000 for every day the violation is not remedied after a 30-day grace period.[86] For government-funded studies that fail to register, the penalty is a withholding of grant funds.[87] However apparent lack of enforcement has meant that

82 See above at *Part V: A The ANZTPA Regime*.

83 G Antes and Iain Chalmers "Under-reporting of clinical trials is unethical" (2003) 361 Lancet 978; Iain Chalmers, Paul Glasziou and Fiona Godlee "All trials must be registered and the results published: academics and non-commercial funders are just as guilty as industry" (2012) 346 BMJ f105; "Written Evidence Submitted by Sir Iain Chalmers (CT11)" in House of Commons Science and Technology Select Committee *Clinical Trials: Written Evidence* (6 March 2013) at 57; "Written Evidence Submitted by Dr Ben Goldacre (CT55)" in House of Commons Science and Technology Select Committee *Clinical Trials: Written Evidence* (6 March 2013) at 294; "Written Evidence Submitted by Professor Lesley Stewart (CT15)" in House of Commons Science and Technology Select Committee *Clinical Trials: Written Evidence* (6 March 2013) at 75.

84 Food and Drug Administration Amendments Act 121 Stat 904 § 801.

85 Food and Drug Administration Amendments Act 121 Stat 904 § 801.

86 Food and Drug Administration Amendments Act 121 Stat 904 § 801.

drug developers have been able to evade their obligations to register their clinical trials and results.[88] By 2012, only one in five trials conducted since the legislation came into force had been registered within the legislative deadline.[89]

Similar legislation for a mandatory clinical trial register and proper enforcement of the registration of trials will improve accessibility to information about medicines and guarantee that participants in clinical trials make meaningful contributions to the development of our knowledge about medical interventions. Given that the ANZCTR framework already exists, this legislation does not require an entirely new scheme to be created, merely the upgrading of a pre-existing structure. Legislating for a mandatory clinical trial register would also be a move that aligns the Australasian regime with those in the United States and Europe.

3 Implications

There are potential risks associated with a public database for clinical trial data. As is the case whenever the risk profile of a system is changed, the behaviour of those being regulated may alter. Companies might elect to avoid undertaking certain trials which risk exposing an unfavourable aspect of their drug if they know that all the unpublished information that they must share with the regulator will be made public.[90] It may seem more attractive for companies to withhold information from the regulator and risk the punishment of being found in breach of their obligations.[91]

There is also the threat of loss of competitiveness and consumer variety if regulations become too constraining and costly. The Australian and New Zealand markets are small, even when combined. Pharmaceutical companies primarily target markets in North America and Europe. Therefore there is a risk that by making the regulatory environment too restrictive, applications for medicines approval will be seen as commercially unviable and decline. Should this occur, New Zealand and Australian consumers will not be able to access the newest and best medicines. It seems, therefore, that the Australasian regulatory environment may be constrained to follow North America and Europe with regards to disclosure requirements and transparency.

There is a definite move towards transparency and greater disclosure in the Northern Hemisphere markets. The United States has legislated for compulsory clinical trial registration, the United Kingdom is undertaking a select committee inquiry into hidden data, and the European Union is moving towards practices that promote greater transparency and disclosure. It is important

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87 Food and Drug Administration Amendments Act 121 Stat 904 § 801.

88 Goldacre, above n 25, at 52.

89 Andrew P Prayle, Matthew N Hurley and Alan R Smyth "Compliance with mandatory reporting of clinical trial results on ClinicalTrial.gov: cross-sectional study" (2012) 344 BMJ d7373.

90 Opinion given by a confidential source in the government medicines/health area.

91 Opinion given by a confidential source in the government medicines/health area.

to manage the risks discussed in this section to ensure competitiveness is maintained in the Australasian market. However, by 2016, when the ANZTPA is scheduled to begin, it is likely that there will have been a further international shift towards greater transparency and disclosure. Creating a culture in which unpublished information is routinely made available and transparency is the norm is vital. While Australasia should be mindful of the situation in the Northern Hemisphere, this should not prevent it from making some progress towards greater disclosure in this area.

VI ADMINISTRATIVE LAW: ALTERNATIVE METHODS FOR OBTAINING INFORMATION

This Part explores the options provided by administrative law for patients, doctors and independent researchers to access unpublished information on the safety and efficacy of drugs. The options investigated are: use of the OIA, seeking assistance from the Ombudsman, and lodging a complaint with the Regulations Review Committee (RRC). These public law tools can be employed under the present Medicines Act regime and will continue to be available when the ANZTPA takes over. The ANZTPA will be accountable in a similar way to a regulatory agency established by domestic legislation.[92] New Zealand's systems may require some modification in respect of their application to the ANZTPA. The following sections describe the current law.

A Official Information Act 1982

The OIA will apply to information held by ANZTPA and can be used at present to request official information held by Medsafe.[93] It is unclear how often Medsafe receives OIA requests about medicines approval; the agency has made one OIA release in the past two years, and six between 2005 and 2011.[94] These releases involved information about the approval process taken for a particular medicine, adverse reaction information and investigations, and one Intensive Medicines Monitoring Programme report.

In general, OIA requests asking for safety, efficacy or quality information will likely be declined for reasons of commercial sensitivity.[95] Each request will necessarily have to be decided in its own context and on the balance of all the factors in the OIA. This section will provide a general discussion on some specific factors that will feature in this balance and what they indicate about the likelihood of success if a researcher were to request the release of the full clinical study report for an approved medicine from Medsafe.

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92 Joint Therapeutic Agency Treaty, above n 11, art 8.

93 Therapeutic Products and Medicines Bill 2006 (103-1), cl 170.

94 Medsafe "Recent Official Information Act Releases" (17 April 2013) and "Archive of Official Information Act Releases" (13 April 2013) <www.medsafe.govt.nz>.

95 Email from Susan Martindale, above n 7.

The underlying principle of the OIA is the presumption that information should be made available unless there is good reason to withhold it.[96] None of the conclusive reasons for withholding information under s 6 apply in the context of information held about medicines. Therefore the only section relevant to justifications for refusing to release information is s 9.

1 Section 9(2)(a)

Section 9(2)(a) provides for the withholding of information to protect the privacy of natural persons. As discussed in Part IV above, patient confidentiality and protection against release of identifying information in clinical study reports is important. However, clinical study reports do not generally contain identifying features for individual patients. That information can also be effectively redacted. Justifying a refusal to provide clinical study reports and other safety information under s 9(2)(a) would generally be unsuccessful.

2 Section 9(2)(b)

Section 9(2)(b) of the OIA allows information to be withheld if releasing it would disclose a trade secret or unreasonably prejudice the commercial position of the person who supplied the information. This is a high threshold.[97] Part IV broadly discussed these considerations and should be referred to in relation to the OIA discussion. Clinical study reports may contain commercially sensitive information in the sense that information suggesting the drug does not have a favourable risk profile, or may not be any better than a competitor or generic drug, would be likely to negatively affect the manufacturer's commercial position.[98] However, finding information is commercially sensitive alone is not sufficient reason for withholding it.[99]

There is precedent in the veterinary context holding that information about the active ingredient and chemical composition of a new medicine will be commercially sensitive and able to be withheld using s 9(2)(b).[100] The Hazardous Substances and New Organisms Act 1996 (HASNO) provides a procedure for dealing with OIA requests and information that might be withheld about veterinary medicine.[101] The Medicines Act does not have any similar provisions, apart from possibly section 23B protecting confidential supporting information about innovative medicines for a particular period. This would colour the consideration of an OIA request and indicates that a greater

96 Official Information Act 1982, s 5.

97 David McGee *Requests for Information Regarding the production of* The Hobbit *and film Production Generally* (New Zealand Ombudsman, 31 January 2013) at 12–13.

98 Interview with Ron Paterson and Leo Donnelly, Ombudsmen (the author, Wellington, 11 September 2013).

99 Office of the Ombudsmen, above n 41, at 7–8; McGee, above n 97, at 12–13.

100 *Wyeth (NZ) Ltd v Ancare New Zealand Ltd* [2010] NZSC 46, [2010] 3 NZLR 569.

101 *Wyeth (NZ) Ltd v Ancare New Zealand Ltd*, above n 100, at [14] and [45]; Hazardous Substances and New Organisms Act 1996, pt 5.

significance will be placed on protection of information received about innovative medicines. However, in the context of all other medicines the Medicines Act has no such prescriptions for dealing with OIA requests. This makes the veterinary medicines context distinguishable.

Given that the Medicines Act, as the primary statute, will colour OIA considerations, if the ANZTPA rules and legislation include specific data protection provisions these may well alter the arguments made in this section with regards to the commercial sensitivity of the data received by ANZTPA. If the rules were enacted with an express procedure for handling OIA requests, similar to that in HASNO, this would affect the outcome of an OIA consideration. It is hoped that, as outlined above, the ANZTPA legislation will take a pre-emptively accessible approach to releasing official information.

Arguably, information about safety and efficacy does not reach the same commercially sensitive threshold as information about the composition and active ingredient of a medicine. While some of the content in clinical study reports may be considered commercially sensitive, it may not be enough to constitute "unreasonable prejudice" to the commercial position of the manufacturer.

3 Section 9(2)(ba)

A regulator might also be able to use s 9(2)(ba) to justify withholding information. This paragraph protects information that a person has been compelled to provide under an enactment. An applicant is compelled to provide Medsafe with all the information they hold on the safety, efficacy and quality of their drug. Making that information publicly available could be considered likely to prejudice the supply of similar information. There might be a greater incentive for pharmaceutical companies to risk a fine and breach their statutory disclosure obligations if they know that the information that they provide may become publicly available. This would damage the public interest by hindering Medsafe or the ANZTPA's ability to assess new medicines knowing that all necessary information is before them.

There are also natural justice requirements at stake if manufacturers are effectively compelled to disclose clinical information about their products. They are required to provide all information to the regulator, including sensitive information that they might not normally wish to disclose, and then would have no option but for this information to be publicly displayed. However, the opportunity for redaction can lessen these risks to companies, as does the requirement that information is only made public after a decision has been made about their application. A manufacturer is not compelled to give Medsafe any information unless they wish to sell their drug to the New Zealand public. Any medicine entering the market must be safe and reasonably effective. If a drug does not meet those standards, the patients consuming it have a right to be fully informed of its shortcomings as much as they do its benefits.

4 Public interest

Even if the grounds discussed above are established, information must be disclosed if the public interest outweighs the justification for withholding it.[102] The Medicines Act is relevant in determining what the public interest involves in this context.[103] The Medicines Act does not include a purpose or principles section. However the 2006 Bill has the key objective of safeguarding public health and the safety of New Zealanders.[104] The primary purpose of the Treaty is also to safeguard public health.

In the area of pharmaceutical drugs and medical devices, there is a high public interest in disclosure. As emphasised in Part IV, hidden data and publication bias have a significant negative impact on public health and can pose serious risks for patients. Doctors and patients cannot make effective and fully informed health decisions if they do not have access to all the unpublished information about medicines.[105] Additionally, independent researchers would be able to conduct further investigations and meta-analyses, which would improve medical understanding and knowledge. These factors create a compelling argument in favour of access to official information. Arguably, all but the strongest arguments under s 9(2)(a), (b) or (ba) would be overridden by the public interest.

5 Ombudsman

The ANZTPA will be subject to the Ombudsmen Act 1975 and the Australian Ombudsmen Act 1976 (Cth), with both offices co-operating in their investigations.[106] In Europe, the Ombudsman has been a champion for open access to information about drugs and clinical trials in the context of a maladministration complaint against the European Medicines Agency.[107] However it does not appear that the New Zealand Ombudsman has ever been asked to assist with a matter relating to pharmaceutical drugs and information access of the nature discussed in this article.

The Ombudsman could provide a cost effective avenue for accessing clinical study reports and other unpublished data. Additionally, because the Ombudsman's investigations are carried out in private, there is no danger of premature public disclosure of information that should be kept confidential'.[108] The Ombudsman currently has jurisdiction to investigate complaints against

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102 Official Information Act 1982, s 9(1); see also McGee, above n 97, at 26.

103 GDS Taylor and JK Gorman *Judicial Review: A New Zealand Perspective* (2nd ed, Lexis Nexis, Wellington, 2010) at 304.

104 Therapeutic Products and Medicines Bill 2006 (103-1) (explanatory note).

105 See above at *Part IV Information and the Pharmaceutical Industry*.

106 Therapeutic Products and Medicines Bill 2006 (103-1), cls 154–155.

107 Diamandouros, above n 42.

108 Ombudsmen Act 1975, ss 18 and 21.

Medsafe as it is a part of the Ministry of Health.[109] However in the context of information access it is likely that the most common exercise of the Ombudsman's jurisdiction will be the express function given under the OIA to investigate a refusal to release information.[110]

6 Regulations Review Committee

The RRC examines all legislative instruments, investigates complaints and examines proposed regulation-making powers.[111] Six of the eight states of Australia have an RRC-equivalent, but none allows public complaints, as is the practice in New Zealand. This raises the question of whether the ANZTPA will remain subject to RRC oversight and whether, if so, Australian and New Zealand citizens can lay complaints about any Ministerial Council Rules or Orders with the RRC.

A legislative instrument cannot be reviewed on its merits. However a complaint can be based on grounds relating broadly to the relationship between regulation and the relevant Act, or on procedural grounds.[112] The most relevant ground for challenging a rule would be that it is not in accordance with the general objects and intentions of the statute under which it is made.[113] All rules must give effect to the objectives of the Treaty – to facilitate public health and create a regulatory scheme which accords with international best practice.[114] An official clinical trials register and better public access to information is current international best practice. Furthermore, public health is better facilitated by allowing doctors and researchers to access unpublished data.

There may therefore be grounds for complaint if any future rules hinder such information access and publication of clinical trial data. It would be highly unsatisfactory if the ANZTPA were to be immune from the regulations complaints process, especially because it is a body with legal personality in Australia only and because the regulation of medicines and medical devices is such a crucial part of the public health system in both countries.

In addition to complaints, public participation in regulatory decision making is possible via participation in organisations like patient interest groups. However, there is a risk that larger industry players will have a louder voice, given the comparative power and resources available to

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109 Ombudsmen Act 1975, sch 1, pt 1.

110 Official Information Act 1982, s 28.

111 Cabinet Office *Cabinet Manual 2008* at [7.79]–[7.78]; Standing Orders of the House of Representatives 2011, SO 314.

112 Standing Orders of the House of Representatives 2011, SO 315(2).

113 Standing Orders of the House of Representatives 2011, SO 315(2)(a).

114 Joint Therapeutic Agency Treaty, above n 11, art 9.

most pharmaceutical companies in the Australasian market.[115] This may dilute the impact of patient groups, making the formal complaints process more important in the context of pharmaceutical regulation.

VII CONCLUSION

This article has provided an overview of the current and proposed future legislative structures that regulate medicines and medical devices in New Zealand. It has done so in light of the deficit in information relating to safety and efficacy data for medicines and medical devices. While this analysis is relevant to Medsafe, especially the administrative law discussion, most of its application will be in the context of the ANZTPA scheme.

The key propositions in this article are:

- The ANZCTR should become a mandatory clinical trials registry for all trials done in Australia and New Zealand, with ethics committees and trial sponsors holding responsibility for populating the register. Sufficient enforcement powers and resourcing should be enacted to ensure the efficacy of this scheme.
- The ANZTPA should be placed under a statutory duty to make all the unpublished information it holds about medicines publicly available.
- Generally speaking, the arguments for preventing disclosure of official information containing clinical study reports and other unpublished raw data would not outweigh the significant public interest in disclosure.
- Administrative law "tools" such as OIA requests, RRC complaints, and use of the Ombudsman may assist in facilitating disclosure of trial data and clinical study reports held by Medsafe or the ANZTPA.

The ANZTPA project is an opportunity to implement substantial changes in the way that medicines are regulated in New Zealand and Australia to remedy the information deficit and protect public health and welfare. At the time of going to print, the Therapeutic Products and Medicines Bill 2006, which gave effect to the Australia/New Zealand Treaty on therapeutic products, was discharged, meaning that New Zealand will need to redraft and reconsider how it will implement the Treaty and the new Trans-Tasman regime. The conclusions listed above should be considered and implemented where possible in the context of the future ANZTPA scheme in order to create a more transparent system aligned with the emerging international best practice.

Australia and New Zealand are constrained to follow the larger European and North American markets with regards to disclosure requirements and transparency or risk creating a regulatory

115 Discussed in the context of electricity regulation in Mark Bennett and Joel Colon-Rios "Public Participation in New Zealand's Regulatory Processes" in Susy Frankel and Deborah Ryder (eds) *Recalibrating Behaviour: Smarter Regulation in a Global World* (LexisNexis, Wellington, 2013) 181 from 214.

environment that is seen by the industry as overly burdensome and therefore unviable. However, this does not mean that any attempt to improve transparency and disclosure in the Australasian market should be abandoned. The ANZTPA scheme is scheduled to come into force in 2016, by which time there will have been further progress made internationally which Australasia should ensure it remains consistent with.

Bitter experience has shown that the information deficit in relation to medicines and medical devices has grave impacts.[116] This is not something that patients are aware of, yet it directly impacts their right to be fully informed before making a treatment decision. Additionally, it affects decisions to publicly fund medicines and distorts the medical literature on which doctors rely. Legislative change is one aspect that is required to remedy this situation. It is important to create a culture of transparency and openness amongst government regulators that facilitates better-informed treatment decisions and improved public health and safety.

116 See for example Goldacre, above n 25, at 5; and Broatch, above n 24.