PROFESSIONAL STANDARDS COMMITTEE INQUIRY

Constituted under Part 8 of *the Health Practitioner Regulation National Law (NSW)* to hold an Inquiry into a Complaint in relation to:

Dr David George Richardson
MED0001024567

Date/s of Inquiry:	8 December 2016, 22 and 23 February 2017
Committee members:	Mr Robin Handley (Chairperson) Professor Donald Chisholm Dr Simon Cowap Honorary Associate Professor Paul Macneill
Appearance for Health Care Complaints Commission:	Mr Benjamin O'Donnell of Counsel, instructed by Ms Jaimee Dinihan, Legal Officer
Appearance for Dr David George Richardson:	Mr Gary Gregg of Counsel, instructed by Ms Louise Watson of DibbsBarker
Date of decision:	17 March 2017
Decision	The Committee made findings of unsatisfactory professional conduct and determined to caution Dr Richardson and impose the conditions on his registration set out on page 19 and 20 below.
Publication of decision:	Refer to page 21 of this decision for details of non-publication directions.

SUMMARY

The NSW Health Care Complaints Commission (HCCC) commenced an investigation into Dr David George Richardson's conduct following a report into the dispensing practices of a pharmacist. Evidence from this report led the HCCC to be concerned about Dr Richardson's prescribing practices, in particular, that he had prescribed hormone medication for certain patients, without the requisite authority for doing so, without first referring them for specialist advice, and without a recognised therapeutic purpose.

As a result of its investigation into Dr Richardson's conduct, on 12 May 2016 the HCCC lodged complaints with the Medical Council of NSW alleging that Dr Richardson was guilty of unsatisfactory professional conduct. Such complaints require an inquiry by a Professional Standards Committee.

Having examined the evidence, the Committee found that Dr Richardson's conduct constituted unsatisfactory professional conduct and made orders for the protection of health and the safety of the public.

BACKGROUND

1. Dr Richardson, who is now aged 63, graduated with the degrees of MBBS (Honours) from Sydney University in 1978. In 2001, he completed a Diploma of Nutritional Medicine at Swinburne University.

2. After initially serving as a Hospital Intern and then a Hospital Resident/Registrar, in 1982 Dr Richardson founded the Galston Medical Centre. In 1990, he developed an interest in menopause and hormone replacement therapy for men and women and, in addition to managing a busy general practice, sought to develop a more specialised general practice using a variety of treatments.

3. In 2001, Dr Richardson acquired a further general practice in Asquith, now called the Royston Clinic, which he developed over the next 10 years. In 2010, he decided to focus on his more specialised interests, sold the Royston Clinic, and established a new more specialised practice in Richmond, which he described in his curriculum vitae as focusing on "effective, evidence based treatment of people who often 'fall between the cracks' of General Practice, and who may not be fully serviced by specialist medicine". In his Statement dated 2 November 2016, Dr Richardson described himself as "a general practitioner who specialises in integrative medicine".

4. The five complaints that are the subject of this inquiry arose out of an investigation by the Pharmaceutical Services Unit (PSU) into the conduct of a pharmacist who was suspected of illicitly supplying anabolic steroids. The report of the PSU investigation for the Pharmacy Council identified a number of prescriptions provided by Dr Richardson for which he did not hold the appropriate authority. This led to an investigation by the HCCC which confirmed that Dr Richardson did not have authority pursuant to s 37 of the *Poisons and Therapeutic Goods Regulation 2008* to prescribe Clomiphene, a non-steroidal fertility medicine commonly used to stimulate the pituitary gland to secrete hormones, for example to induce ovulation in women.

5. Dr Richardson had prescribed Clomiphene for five male patients, whom he considered to have an androgen deficiency, over a period of about three weeks in early 2014. In each case, Dr Richardson prescribed Clomiphene for the patient on one occasion only. The prescription dates were: 24 February 2014, 27 February 2014, 3 March 2014, 6 March 2014 and 18 March 2014. In April 2014, the PSU contacted Dr Richardson to ask him whether he had the requisite authority to prescribe Clomiphene. He responded that he did not have such an authority and was not aware of the need to do so. Dr Richardson has not prescribed Clomiphene since. Dr Richardson had first treated one of the patients in 2008; the others in 2012/2013. The relevant period that is the subject of this inquiry is 1 January 2012 to 31 December 2014.

6. The HCCC notified Dr Richardson of its investigation into his prescribing Clomiphene by letter dated 22 April 2015. Dr Richardson responded to the complaints by letter dated 17 June 2015, stating that he had believed that the restrictions on prescribing Clomiphene under the 2008 Regulation only applied to prescriptions for female patients. He said that as soon as he was made aware that this was not the case, he stopped prescribing Clomiphene. He acknowledged that he had prescribed Clomiphene without referring the patients in question for specialist advice but noted, once again, that he had believed that the restrictions on prescribing Clomiphene only applied in respect of female patients. Dr Richardson also referred to "peer review articles" which he claimed supported the efficacy and safety of his prescribing Clomiphene for androgen therapy in men.

7. By letter dated 7 October 2015, the HCCC notified Dr Richardson of its proposing to refer the matter to its Director of Proceedings for determination whether to prosecute a complaint before the Medical Council, notifying Dr Richardson of its grounds for so doing and inviting his response. Dr Richardson's solicitors replied by letter dated 6 November 2015, attaching a detailed response from Dr Richardson into his treatment of each of the five patients who were the subject of the complaints.

8. On 12 May 2016, the HCCC lodged five complaints with the Medical Council alleging that Dr Richardson was, in each case, guilty of unsatisfactory professional conduct as defined in s 139B of *the Health Practitioner Regulation National Law (NSW)* (the National Law). In particular, in each of the five complaints it is alleged that Dr Richardson:

   (a) engaged in conduct "that demonstrates the knowledge, skill or judgment possessed, or care exercised, by the practitioner in the practice of the practitioner's profession is significantly below the standard reasonably expected of a practitioner of an equivalent level of training or experience" (s 139B(1)(a));
   (b) engaged in "improper or unethical conduct relating to the practice or purported practice" of medicine (s139B(1)(l)); and
   (c) contravened a provision of the National Law by failing to keep adequate medical records, thereby contravening clause 7 and Schedule 2 of the *Health Practitioner Regulation National Law Regulation 2010* (the 2010 Regulation) (s 139B(1)(b)), then in effect.

9. The relevant provisions of the National Law and the 2010 Regulation, together with other relevant provisions, are set out in **Attachment 1**.

10. In reaching our decision, the Committee had regard to oral evidence given by Dr Richardson and the HCCC's expert witness Dr Norman Walsh, and to the documents produced by the parties. We applied the standard of proof of reasonable satisfaction and in doing so we were mindful of the gravity of the allegations and the consequences for Dr Richardson if we were to find them proven.

11. The Committee initially convened to hear this matter on 8 December 2016. At that hearing, Dr Richardson's counsel, Mr Gary Gregg, objected to Dr Cowap sitting as a member of the Committee on the ground that there was a reasonable apprehension of bias arising from Dr Cowap's disclosed acquaintance with the HCCC's expert witness, Dr Walsh. Having heard submissions from the parties on this issue, the Committee adjourned to consider the objection.

12. On the hearing being resumed, Dr Cowap declined to recuse himself and the Committee determined that the hearing should continue. However, Mr Gregg sought a further adjournment to discuss this with his client and subsequently informed the Committee of his intention to file proceedings in the Supreme Court seeking an order that Dr Cowap be removed as a member of the Committee. For this reason, the Committee decided to adjourn the hearing pending the outcome of the Supreme Court application.

13. In the Supreme Court on 9 February 2017, Justice White dismissed Dr Richardson's Notice of Motion and Summons, awarding costs to the Medical Council: *Richardson v The Medical Council of NSW* [2017] NSWSC 105. In his judgment, Justice White stated that the degree of social interaction disclosed by Dr Cowap, described by Dr Cowap as "very slight" and comprising his meeting Dr Walsh on one social occasion:

    to a fair-minded lay observer, could not give rise to a reasonable apprehension that Dr Cowap might not bring an impartial mind to the resolution of the issues [at paragraph 19].

14. Moreover, referring to statements by Dr Cowap as to how he would approach the evidence, His Honour did not accept that a lay observer could reasonably apprehend from those statements that if Dr Cowap were called upon to decide between Dr Walsh's evidence on the one hand, and that of another independent expert witness on the other, that he would not approach the matter impartially [at paragraphs 26 – 28].

15. The Committee reconvened the hearing on 22 February 2017.

ISSUES

16. The five complaints, each one relating to a different patient, and the particulars or details of those complaints are set out in full at **Attachment 2**. In a statement dated 2 November 2016, Dr Richardson disputed most of the particulars of each complaint but admitted in each case that he had not obtained an authority under s 37 of the *Poisons and Therapeutic Goods Regulation 2008* for prescribing Clomiphene, and that he did not refer the patient for specialist advice before prescribing the medication although he

said he did not consider such a referral to be necessary.

17. In a letter dated 28 November 2016, Dr Richardson's solicitors confirmed these admissions emphasising that Dr Richardson does not admit that he is guilty of unsatisfactory professional conduct. The Committee notes that in his statement dated 2 November 2016, Dr Richardson also stated:

> *I acknowledge that my record keeping has been lacking in some incidences [sic] and I will continue to improve this. In consultation, my first priority is to give one hundred per cent of my attention to the patient. If I am running extremely late, I may not get to typing the notes until the end of the session and this may mean my notes are overly brief. I recognise this and will continue to work in spite of time constraints to improve the detail in the patients' records. In particular, I am ensuring records of physical examination in clinical notes are accurate and complete.*

18. The Committee notes s 171(2) of the National Law, which states:

> *No inquiry need be held into the complaint if the relevant health practitioner admits the subject-matter of the complaint in writing to the Committee.*

Particulars of Complaint One

Between 1 January 2012 and 31 December 2014 the practitioner prescribed medication for Patient A as set out in Schedule A:

- *(a) without an appropriate therapeutic purpose;*
- *(b) in quantities in excess of recognised therapeutic standards as to what was medically appropriate in Patient A's circumstances;*
- *(c) without obtaining an authority under section 37 of* the Poisons and Therapeutic Goods Regulation 2008*;*
- *(d) without conducting an appropriate assessment of Patient A prior to prescribing medication;*
- *(e) without referring Patient A for appropriate specialist advice with respect to endocrine or andrology issues.*

19. Dr Richardson admits particular (c) but does not admit particulars (a), (b), and (d). With respect to particular (e), he acknowledges that he did not refer the patient to a specialist but says that he did not consider this necessary.

Particulars of Complaint One A

Between 1 January 2012 and 31 December 2014 the practitioner failed to keep adequate medical records in relation to Patient A in contravention of clause 7 and Schedule 2, Clause 1 of the Health Practitioner Regulation National Law Regulation 2010 *("the Regulation") in that he failed to record an appropriate medical assessment in terms of history and physical examination*.

20. Dr Richardson does not admit this complaint.

Particulars of Complaint Two

Between 1 February 2013 and 31 July 2014 the practitioner prescribed medication for Patient B as set out in Schedule B:

- *(a) without an appropriate assessment of Patient B prior to prescribing medication;*
- *(b) without referring Patient B for appropriate specialist advice with respect to endocrine or andrology issues before prescribing clomiphene;*
- *(c) without an appropriate therapeutic purpose;*
- *(d) in quantities in excess of recognised therapeutic standards as to what was medically appropriate in Patient B's circumstances;*
- *(e) without obtaining an authority under section 37 of the* Poisons and Therapeutic Goods Regulation 2008*.*

21. Dr Richardson admits particular (e) but does not admit particulars (a), (c), and (d). With respect to particular (b), he acknowledges that he did not refer the patient to a specialist but says that he did not consider this necessary.

Particulars of Complaint Two A

Between 1 February 2013 and 31 July 2014 the practitioner failed to keep adequate medical records in relation to Patient B in contravention of clause 7 and Schedule 2, Clause 1 of the Health Practitioner Regulation National Law Regulation 2010 *("the Regulation") in that he failed to record sufficient definite and recognised clinical findings to support a diagnosis of "androgen deficiency".*

22. Dr Richardson does not admit this complaint.

Particulars of Complaint Three

Between 1 March 2012 and 30 November 2014 the practitioner prescribed medication for Patient C as set out in Schedule C:

- (a) *without an appropriate assessment of Patient C prior to prescribing medication;*
- (b) *without referring Patient C for appropriate specialist advice with respect to endocrine or andrology issues;*
- (c) *without an appropriate therapeutic purpose;*
- (d) *in quantities in excess of recognised therapeutic standards as to what was medically appropriate in Patient C's circumstances;*
- (e) *without obtaining an authority under section 37 of* the Poisons and Therapeutic Goods Regulation 2008*;*
- (f) *without responding appropriately to actual and/or potential adverse effects of the prescribed drugs on Patient C.*

23. Dr Richardson admits particular (e) but does not admit particulars (a), (c), (d) and (f). With respect to particular (b), he acknowledges that he did not refer the patient to a specialist but says that he did not consider this necessary. The HCCC did not press particular (f) at the hearing.

Particulars of Complaint Three A

Between 1 March 2012 and 30 November 2014 the practitioner failed to keep adequate medical records in relation to Patient C in contravention of clause 7 and Schedule 2, Clause 1 of the Health Practitioner Regulation National Law Regulation 2010 *("the Regulation") in that he failed to record sufficient definite and recognised clinical findings*.

24. Dr Richardson does not admit this complaint.

Particulars of Complaint Four

During the course of 2014 the practitioner prescribed medication for Patient D as set out in Schedule D:

(a) without conducting an appropriate assessment of Patient D prior to prescribing medication;
(b) without referring Patient D for appropriate specialist advice with respect to endocrine or andrology issues;
(c) without an appropriate therapeutic purpose;
(d) in quantities in excess of recognised therapeutic standards as to what was medically appropriate in Patient D's circumstances;
(e) without obtaining an authority under section 37 of the Poisons and Therapeutic Goods Regulation 2008*;*
(f) and inappropriately withdrew antidepressant medication.

25. Dr Richardson admits particular (e) but does not admit particulars (a), (c), (d) and (f). With respect to particular (b), he acknowledges that he did not refer the patient to a specialist but says that he did not consider this necessary. The HCCC did not press particular (f) at the hearing.

Particulars of Complaint Four A

During the course of 2014 the practitioner failed to keep adequate medical records in relation to Patient D in contravention of clause 7 and Schedule 2, Clause 1 of the Health Practitioner Regulation National Law Regulation 2010 *("the Regulation") in that he failed to record sufficient and appropriate history and clinical examination findings.*

26. Dr Richardson does not admit this complaint.

Particulars of Complaint Five

Between 1 January 2008 and 31 December 2014 the practitioner prescribed medication for Patient E as set out in Schedule E:

(a) without conducting appropriate assessments of Patient E prior to prescribing medication;
(b) without referring Patient E for appropriate specialist advice with respect to endocrine or andrology issues;

(c) without an appropriate therapeutic purpose;
(d) in quantities in excess of recognised therapeutic standards as to what was medically appropriate in Patient E's circumstances;
(e) without obtaining an authority under section 37 of the Poisons and Therapeutic Goods Regulation 2008*;*

27. Dr Richardson admits particular (e) but does not admit particulars (a), (c), and (d). With respect to particular (b), he acknowledges that he did not refer the patient to a specialist but says that he did not consider this necessary.

Particulars of Complaint Five A

Between 1 January 2008 and 31 December 2014 the practitioner failed to keep adequate medical records in relation to Patient E in contravention of clause 7 and Schedule 2, Clause 1 of the Health Practitioner Regulation National Law Regulation 2010 *("the Regulation") in that he failed to record an adequate history or physical examination findings.*

28. Dr Richardson does not admit this complaint.

Summary of the Issues

29. The particulars set out above give rise to six issues for the Committee:

i. Did Dr Richardson prescribe Clomiphene without obtaining an authority under section 37 of the *Poisons and Therapeutic Goods Regulation 2008*? Dr Richardson admits this particular.
ii. Did he prescribe medication for the five patients who are the subject of these complaints without having conducted an appropriate assessment?
iii. Did he prescribe medication for the patients without referring them for appropriate specialist advice with respect to endocrine/andrology issues?
iv. Did he prescribe medication for the patients without an appropriate therapeutic purpose?
v. Did he prescribe medication for the patients in quantities in excess of recognised therapeutic standards as to what was medically appropriate in the patients' circumstances?
vi. Did he fail to keep adequate medical records in relation to each of the patients in contravention of clause 7 and Schedule 2, Clause 1 of the *Health Practitioner Regulation National Law Regulation 2010* in that he failed to record an adequate history or physical examination findings?

THE EVIDENCE

Dr Walsh

30. The HCCC's expert witness Dr Walsh, who gave evidence at the hearing, provided four reports for these proceedings dated 7 September 2015, 15 September 2016, 25 November 2016 and 5 January 2017. The Committee declined to take into account Dr Walsh's report dated 15 September 2016 because some of his comments involved what the Committee considered to be intemperate language indicating that he had not complied with the general

duties of an expert witness to the Committee set out in NCAT [NSW Civil and Administrative Tribunal] Procedural Direction 3 on Expert Witnesses: in particular paragraphs 11, 12 and 13 which address the overriding duty of an expert witness to assist the tribunal impartially and not as an advocate for a party.

31. Dr Walsh's evidence was that Dr Richardson failed to conduct an appropriate assessment of the five patients who are the focus of this inquiry in that he failed to perform an appropriate physical examination – for example, there is no evidence of his having examined the testes or having considered secondary sexual characteristics such as the distribution of body hair or musculature - and had prescribed androgens for two patients who had admitted to having formerly used steroids illegally. Dr Walsh said good practice would be not to prescribe androgens for patients with a history of illegal steroid use: such a person should be referred to an andrologist.

32. Dr Walsh said there is no appropriate therapeutic purpose for prescribing Clomiphene for a man since it is only indicated for the treatment of women. Clomiphene can only be prescribed by an endocrinologist or gynaecologist: in his report dated 7 September 2015, he stated that Dr Richardson should, in any event, have referred the patients for such appropriate specialist advice. However, in cross-examination at the hearing, he acknowledged that he is not aware of any regulations or guidelines requiring referral to a specialist. Nevertheless, in his view, complicated or complex cases should be referred to a specialist, although he acknowledged that this is a matter of judgment for a General Practitioner (GP).

33. Dr Walsh said the quantity of Clomiphene prescribed by Dr Richardson was excessive and, in any event, he had ignored the listed indication for prescribing androgens for a man since the patients' testosterone levels were not below the normal range: they did not have a chronic androgen deficiency. In so finding, Dr Walsh relied on Pharmaceutical Benefits Scheme (PBS) criteria for testosterone prescribing published in April 2015, which he said are treated as guidelines for prescribing testosterone in Australia. These PBS criteria recommend that a patient should see a specialist before treatment is started and state that no PBS subsidy is available if the patient's testosterone level has not fallen below 6 nmol/l, in which case the patient will have to pay the full cost of the treatment. The pre April 2015 version of the PBS criteria, relevant at the time Dr Richardson prescribed Clomiphene, specified a level of 8 nmol/l. In cross-examination, Dr Walsh said that in his first report he had employed a threshold of 8.9 nmol/l although he acknowledged that he had not specified this.

34. In his report dated 25 November 2016, Dr Walsh referred to the International Society of Andrology's recommended threshold for androgen therapy of 8 nmol/l but noted that the Endocrine Society of the USA recommends the lower limit of the normal range for such treatment in healthy young men as 9.8 to 10.4 nmol/l although some US experts favour a more stringent level of 6.9 nmol/l. In oral evidence, Dr Walsh acknowledged that the normal range for a particular hormone specified in the results of a pathology test should not be interpreted as the accepted range because the normal range used by one pathology laboratory may differ from that used by another laboratory.

35. In his report dated 5 January 2017, Dr Walsh noted that total testosterone must be measured fasting and as near to 8.00 am as possible as this is the peak period for testosterone production during the day. Many of Dr Richardson's tests were conducted some hours from this time potentially making the results falsely low. Moreover, some tests were conducted non-fasting. Non-fasting specimens collected after 8.00 am can be up to 25% lower that their true value.

36. Dr Walsh was critical of Dr Richardson's medical records, which he said failed to provide evidence of appropriate medical assessment in terms of history, physical examination and clinical findings of the kind necessary for patients suffering from hormonal disorders or deficiencies.

37. In summary, Dr Walsh's opinion was that Dr Richardson's conduct was significantly below that expected of a practitioner of an equivalent level of training or experience and invited his strong criticism.

Dr Richardson

38. The Committee took into account the correspondence between Dr Richardson and the HCCC, his statement in these proceedings dated 2 November 2016, and his oral evidence at the hearing. He said that his practice, which specialises in integrative medicine, is to concentrate on more complex medical problems that are generally not well-served by most doctors – patients "with a combination of psychological, social, hormonal, nutritional, lifestyle and other medical factors" [statement paragraph 2]. At the hearing, he said he sees a lot of patients with mental health problems such as depression, anxiety, Post Traumatic Stress Disorder (PTSD), and Chronic Fatigue Syndrome. He refers many of his patients to psychologists for treatment. He also gives nutritional advice having regard to food sensitivities. His patients have other GPs whom they see for other day-to-day health problems.

39. Dr Richardson said he has between 12,000 and 15,000 patients. However, many of these he sees intensively for a short period and thereafter only for periodic review. He estimated that his treatment of only approximately 1 to 2% of these patients involves androgren therapy. Currently, he has about 20 to 30 patients having such treatment. He has been prescribing androgens for patients since the late 1980s/early 1990s.

40. Dr Richardson said that in order to determine whether a man has an androgen deficiency, he looks to see whether he has symptoms or signs of such a deficiency before referring him for pathology tests. Dr Richardson takes a careful history of the patient having first asked him to complete forms requiring information about personal details and medical history and, at the relevant time, a questionnaire headed 'Male Hormone Checklist' asking questions about the person's symptoms. Dr Richardson said he goes through the forms with the patient to ascertain the person's medical history and also undertakes a general physical examination including assessing musculature and the amount of body hair. Dr Richardson acknowledged that at the relevant time he had stopped doing a testicular examination because, in his experience, this has not proved particularly useful in what are usually otherwise fairly healthy, young men. Since the commencement of these proceedings, he has recommenced undertaking a testicular examination.

41. Where a patient has had pathology tests organised by another doctor, Dr Richardson said he will try and obtain copies of such test results and of any prior specialist reports. (Two of the five patients in question had previously seen an endocrinologist: patient C at Concord Hospital and patient E, an endocrinologist whose name the patient could not remember). Dr Richardson said he has found that pathology tests for younger men rarely record a testosterone level below 6.9 nmol/l. Before he undertakes any drug treatment with a patient, he will explore other ways of dealing with the problem, for example through counselling, and encouraging lifestyle changes by addressing nutrition, exercise etc. If such treatment fails to achieve any improvement in the patient's condition, only then will Dr Richardson consider drug treatment. If he does issue a testosterone prescription, he will inform the patient that initially it is for a trial period – usually of three months – at the end of which he will discuss with the patient his ongoing symptoms, such as energy level, libido etc, often running through the question on the 'Male Hormones Checklist' form, together with new pathology results. In answer to a question from Professor Chisholm, Dr Richardson acknowledged that before issuing a testosterone prescription, he should also probably arrange a pathology test for his patients' Prolactin level.

42. Dr Richardson said he already had general measures in place at the relevant time in 2012-2014 to ensure that body-builders and steroid abusers were not treated by him. When a person phones to try and make an appointment to see him, his staff first explore the caller's reasons for wanting to see Dr Richardson, spending about 10 minutes with them on the phone asking a series of questions designed to screen out the likes of body-builders and those just trying to get a prescription for steroids. He has developed a form for use in this screening process, kept under review with input from his staff, and recently updated. He has three trained staff currently undertaking this telephone interview, who prepare a summary on the basis of which he will make a decision as to whether or not to see the person. If he agrees to see the person, at the time of the first appointment, a staff member will spend about 45 minutes with the person completing the personal details, medical history and 'Male Hormone Checklist' forms, and will then accompany the person in to see Dr Richardson to present the information gathered before leaving the person with Dr Richardson for the remainder of the interview.

43. Dr Richardson said he works collaboratively with his patients, reviewing them as required. They are all complex patients. Having discussed their history and made a physical examination, he will draft a treatment plan with the patient in point form, giving them a copy to take away. Where required, he will also give the patient a prescription. He often spends at least an hour with the patient on the first consultation. He acknowledged that he finds it difficult paying attention to the patient while at the same time making notes in the course of their discussion. Sometimes, if he is running late with appointments, it is tempting to leave making a record of the discussion until the end of the day. However, he is now making an effort to keep abreast of his record keeping, writing more notes in the course of, or immediately after, interviews rather than later and, additionally, recording significant negative answers to questions, something he used not to do. Dr Richardson said he is using the 'Best Practice' guide to record keeping and believes his record keeping has improved.

44. Dr Richardson described how he went to the Kingswood Compounding Pharmacy in early 2014 to obtain an anti-fungal treatment for his cats. In the course of talking with the pharmacist, the pharmacist told him that the restriction on prescribing Clomiphene did not apply when the Clomiphene was compounded by a pharmacist, rather than being a proprietary medicine, and was prescribed for males. Dr Richardson said he later checked the wording of cl 37 of the *Poisons and Therapeutic Goods Regulation 2008* but found it said nothing about gender and nothing about the compounded medication.

45. Having researched the use of Clomiphene and found that it had been used to treat low testosterone levels in men since at least 1976, and believing he could rely on the pharmacist's advice, over a period of just over 3 weeks in February/March 2014, Dr Richardson issued scripts for Clomiphene to five patients. He acknowledged that he should have sought further advice before doing so, had been foolish, and regretted this. When he learnt from the PSU that he was not authorised to prescribe Clomiphene, he immediately stopped prescribing it and informed the five patients for whom he had prescribed it, where appropriate giving them prescriptions for alternative medications such as Sustanon, which he could prescribe.

46. Dr Richardson said he has been prescribing androgen medications since the late 1980s/early 1990s and considers he is well able to assess the safety of relevant drugs and whether it is a reasonable to prescribe a particular drug for a particular patient. He does not agree that it was necessary for him to consult an endocrinologist before prescribing Clomiphene. He said he reads the relevant literature, spending a part of his working day keeping up to date with new research and publications, which he reads online.

47. With regard to the level of testosterone at which androgens should be prescribed, Dr Richardson noted that very few young men have testosterone levels below 6.0 nmol/l, the April 2015 PBS criterion. He said the general recommended threshold is about 8.0 nmol/l, but what is appropriate depends on the range of symptoms as well as the pathology of the particular patient. Generally, in younger men, Clomiphene is a safe medication. He noted that none of the five patients for whom he prescribed Clomiphene had suffered any harm as a result and none of them had complained about the treatment. Indeed, one of them did not have his prescription filled. In relation to two of the five patients who admitted to prior illegal use of steroids, both consulted him having tried steroids in order to address problems associated with lack of energy and low libido, but wanting to explore further treatment under medical supervision. Neither was a body-builder. In relation to the patient who experienced cardiac problems, Dr Richardson said it was at his suggestion that the patient stop taking androgens until specialist advice on his cardiac condition had been sought. That specialist's advice was that the cardiac condition was genetic and unrelated to his testosterone therapy.

48. Dr Richardson said that since the investigation by the HCCC, he has made changes to his procedures, now categorising male patients by their age. He no longer treats patients under 40 with androgen therapy. Where a patient is over 50, he will not treat him with androgen therapy unless at least two fasting tests record testosterone levels of below 8 and he has symptoms and signs of androgen deficiency. If Dr Richardson has any doubts about a patient, he will refer the patient to an endocrinologist.

FINDINGS

49. The Committee found Dr Richardson to be a sincere doctor who is committed to achieving the best results for his patients. We are satisfied that he acted in what he considered to be the interests of the five patients who are the subject of the complaints. He has admitted to making a foolish mistake in prescribing Clomiphene when he was clearly not authorised to do so under cl 37 of the *Poisons and Therapeutic Goods Regulation 2008.* While he does not admit a breach of the requirement to keep adequate medical records, he does admit that his record keeping "has been lacking in some instances". The Committee considers that it is the inadequacy of his record keeping that is in part responsible for some of the allegations made against him, which are reflected in the particulars of the five complaints.

50. Turning to the six issues summarised in paragraph 29 above, the Committee's findings are as follows:

i. Did Dr Richardson prescribe Clomiphene without obtaining an authority under clause 37 of the Poisons and Therapeutic Goods Regulation 2008?

Dr Richardson admits this particular. There is no dispute that he was in breach of the Regulation. The Committee finds this particular to be proven. We note his admission that he acted foolishly but that he only issued five prescriptions for Clomiphene over a period of just over three weeks. On learning that he did not have the requisite authority, he immediately ceased prescribing Clomiphene and notified the five patients concerned that he was doing so, making alternative arrangements for them. He has said that he has no intention of prescribing Clomiphene again.

ii. Did he prescribe medication for the five patients who are the subject of these complaints without having conducted an appropriate assessment?

Mr O'Donnell submitted that Dr Richardson failed to make an appropriate physical assessment of the five patients, for example to measure the testicular size of four of the five patients, and has a tendency, perhaps unconscious, to jump to the conclusion that androgen therapy is required. Mr Gregg noted Dr Richardson's evidence that he did conduct a physical examination of his patients but did not always record this fully.

The Committee finds this particular to be proven. While Dr Richardson's evidence is that he conducted a physical examination of the five patients, it appears that in the case of four of the patients he did not conduct a testicular examination and it is not clear from his medical records what was otherwise the extent of his medical examination. For example, one patient had no observations at all recorded, only two patients had their weight recorded and three patients had their blood pressure recorded, one twice. The Committee considers this grossly deficient. We also consider that Dr Richardson should have arranged a test of his patients' Prolactin levels where he considered the Testosterone level low and where the Luteinising Hormone [LH] level was near or below the lower limit of normal.

iii. Did he prescribe medication for the patients without referring them for appropriate specialist advice with respect to endocrine or andrology issues?

Dr Richardson's evidence is that while his patients had complex problems, he did not consider it necessary to refer them for specialist advice. In the case of two of the patients, they had (patient C) or were alleged to have (patient E) previously consulted an endocrinologist. Having researched the medical literature on Clomiphene, Dr Richardson considered it a safe medication for younger men and, having long experience of using androgen therapy, he considered it unnecessary to refer the five patients for assessment by an endocrinologist before commencing them on androgen therapy.

Mr O'Donnell pointed to Dr Richardson's evidence that he deals with complex cases and submitted that such cases warrant specialist advice, particularly in the case of the two patients who admitted to prior steroid use. Mr Gregg referred to Dr Richardson's evidence that before prescribing androgen medication, he explored other lifestyle options, such as improving their nutrition and exercise regimes. Having done so, Dr Richardson took into account the patients' symptoms, signs and repeat pathology before prescribing androgen therapy. In the case of the two patients who admitted to prior use of steroids, Mr Gregg noted Dr Richardson's evidence that those patients, whom he considered not to be body-builders, sought treatment from Dr Richardson so that for the future their androgen medication could be trialed in a supervised environment.

The Committee is not satisfied that this particular is proven. We accept Dr Richardson's evidence that he is experienced in androgen therapy. The medical literature on the use of Clomiphene provided to the Committee – a number of journal articles, some published by prestigious institutions, of which Professor Chisholm has informed himself – establishes that Clomiphene has been used for the treatment of testosterone deficiency with beneficial results for some years and without serious adverse effects. We are satisfied that Dr Richardson took care in prescribing it and note that none of the five patients suffered any adverse effects.

iv. Did he prescribe medication for the patients without an appropriate therapeutic purpose?

Mr O'Donnell submitted that if Dr Richardson did not make a proper assessment of the patients and failed to obtain specialist advice, then he should be taken not to have prescribed medication with an appropriate therapeutic purpose. Mr Gregg rejected this. He submitted that the only reason for Dr Richardson prescribing Clomiphene was for a therapeutic purpose.

The Committee is satisfied that Dr Richardson acted in what he considered to be the best interests of the five patients who are the subject of the complaints. We are not satisfied that he prescribed Clomiphene for a non-therapeutic reason such as body-building. We note that the restriction on prescribing Clomiphene is related to the significant risks of ovarian hyperstimulation or multiple pregnancies in women. Neither of these risks apply to men and we

are not aware of any serious adverse effects reported in men, although acknowledging that the amount of data available in the literature is limited.

We are not therefore satisfied on the evidence before us that Dr Richardson prescribed Clomiphene for the five patients who are the subject of these complaints without an appropriate therapeutic purpose. This particular is, therefore, not proven.

v. *Did he prescribe medication for the patients in quantities in excess of recognised therapeutic standards as to what was medically appropriate in the patients' circumstances?*

Mr O'Donnell noted that there is debate globally about the appropriate standard for androgen treatment for men suffering from low levels of testosterone. He said in Australia, the PBS criteria seem to have been used as the *de facto* standard. Mr Gregg noted this debate but rejected the suggestion that the PBS criteria should be treated as guidelines. The PBS document makes clear that a doctor may prescribe testosterone treatment without complying with the PBS criteria, in which case the treatment will not attract the PBS subsidy and the patient will pay the full cost of treatment. He noted that the PBS document states that "the PBS criteria reflect a more conservative approach to using public money for health intervention".

The Committee notes Professor Chisholm's advice that where there are other signs and symptoms suggestive of androgen deficiency, some endocrinologists might commence a trial of testosterone treatment at a testosterone level above the PBS criterion but clearly below the reference range. As noted above, the reference range may differ between laboratories but a lower cut-off, of around 10.4 nmol/l, which is cited by the American Endocrine Society, might be considered reasonable. This in respect of a fasting sample taken, preferably twice, as close to 8.00am as possible.

The Committee is not satisfied that this particular is proven. We recognise that there is an ongoing debate about the appropriate testosterone level at which testosterone treatment may be commenced due to an absence of satisfactory long term clinical trial results for patients treated for testosterone levels at around the 7 to 10 nmol/l range. However, when treating patients in this range, it would be appropriate to regard the intervention as a trial and to carefully document parameters of response – which was not always done by Dr Richardson.

vi. Did he fail to keep adequate medical records in relation to each of the patients in contravention of clause 7 and Schedule 2, Clause 1 of the *Health Practitioner Regulation National Law Regulation 2010* in that he failed to record an adequate history or physical examination findings?

Mr O'Donnell noted admissions by Dr Richardson that he did not always record all the information obtained in his initial interview with the patient, including in his physical examination, such as the patient's weight. Mr O'Donnell submitted that it is clear from a review of Dr Richardson's records that they are inadequate and fail to meet the required standard.

Mr Gregg acknowledged that when Dr Richardson's records in respect of the relevant period are reviewed, there are minor deficiencies when considered overall. However, it should be recognised that making notes during the course of an hour long interview, while at the same time listening to what the patient is saying, is challenging. Since the relevant time, Dr Richardson has consciously sought to improve his record keeping both in the systems employed in his practice and his efforts to keep notes while interviewing the patient or immediately after.

The Committee is satisfied that this particular of the complaints is satisfied. In addition to Dr Richardson's inadequate record of his patients' histories and of his findings on physical examination, when providing androgen treatment at testosterone levels that were not unequivocally low, he should have recorded that he discussed with the patient any uncertainties associated with the treatment, its pros and cons, and that he identified target symptoms and a time when the therapy would be reviewed and, if ineffective, ceased. Thus, it is clear from Dr Richardson's admissions, Dr Walsh's evidence, and a review of Dr Richardson's records, that Dr Richardson's record keeping during the relevant period was deficient and that he failed to meet the required standard.

Summarising the above, the Committee finds that in respect of each complaint, the particulars relating to the first two and the last issues identified in paragraph 16 above are proven.

DOES DR RICHARDSON'S CONDUCT AMOUNT TO UNSATISFACTORY PROFESSIONAL CONDUCT?

51. It is necessary for the relevant provisions of the National Law and their application to be briefly explained. Section 139B of the National Law states relevantly:

Meaning of "unsatisfactory professional conduct" of registered health practitioner generally

(1) Unsatisfactory professional conduct of a registered medical practitioner includes each of the following:

(a) Conduct significantly below reasonable standard

Conduct that demonstrates that the knowledge, skill or judgment possessed, or care exercised, by the practitioner in the practice of practitioner's profession is significantly below the standard reasonably expected of a practitioner of an equivalent level of training or experience.

(b) Contraventions of this Law or regulations

A contravention by the practitioner (whether by act or omission) of a provision of this Law, or the regulations under this Law or under the NSW regulations, whether or not the practitioner has been prosecuted for or convicted of an offence in respect of the contravention.

52. The phrase "significantly below" is not defined in the National Law. However, in the Second Reading Speech when the National Law's predecessor, the *Medical Practice Act 1992* (which contained a similar definition of unsatisfactory professional conduct), was introduced to Parliament, it was stated that:

The first main purpose of the bill is to refocus the Health Care Complaints Commission (HCCC) on investigating serious complaints about health service

providers. To achieve this, Commissioner Walker recommended that unsatisfactory professional conduct be redefined so that only significant instances involving lack of skill, judgment, or care will result in an investigation or disciplinary action. ….. the reference to 'significant' in that context may refer to a single act or omission that demonstrates a practitioner's lack of skill, judgment or care, or it may refer to a pattern of conduct. In any individual case, that will depend on the seriousness of the circumstances of the case.

53. The word 'significant' has been described as meaning "not trivial, of importance, or substantial": *Re A Medical Practitioner and the Medical Practice Act* [40010 of 2007].

54. The Commission bears the onus of establishing that Dr Richardson is guilty of 'unsatisfactory professional conduct', the standard of proof required being the civil standard of reasonable satisfaction, subject to the requirement for the Committee to be 'comfortably satisfied' given the seriousness of the consequences for Dr Richardson should the Committee make findings adverse to his professional standing: *Briginshaw v Briginshaw* (1938) 60 CLR 336.

55. The Committee's findings in respect of the particulars of the complaints are set out above. We are 'comfortably satisfied' from those findings that Dr Richardson is guilty of unsatisfactory professional conduct pursuant to s 139B(1)(a) in so far as he prescribed medication for the five patients who are the subject of these complaints without having conducted an appropriate assessment. We find that his conduct in this regard demonstrated that his knowledge, skill or judgment was significantly below the standard reasonably expected of a practitioner of an equivalent level of training or experience.

56. We also find that Dr Richardson's prescribing Clomiphene without authority, in breach of the *Poisons and Therapeutic Goods Regulation 2008*, demonstrated that his knowledge, skill or judgment was significantly below the standard reasonably expected of a practitioner of an equivalent level of training or experience.

57. Further, we find Dr Richardson is guilty of unsatisfactory professional conduct pursuant to s 139B(1)(b) in so far as he breached the NSW Regulations – clause 7 and Schedule 2 of the *Health Practitioner Regulation National Law Regulation 2010* - by failing to meet the required standard for medical records.

ARE ORDERS OR DIRECTIONS WARRANTED?

58. Having found that Dr Richardson is guilty of unsatisfactory professional conduct, the Committee must consider whether to exercise its powers under Part 8 Division 3 Subdivision 3 of the National Law and, in particular, whether to exercise its powers under s 146B(1). This states relevantly:

146B General powers to caution, reprimand, counsel etc [NSW]

(1) A Committee may do one or more of the following in relation to a relevant health practitioner the subject of a complaint referred to it-

(a) caution or reprimand the practitioner;

(b) direct that the conditions, relating to the practitioner's practising of the practitioner's profession, it considers appropriate be imposed on the practitioner's registration;

(c) order that the practitioner seek and undergo medical or psychiatric

treatment or counselling (including, but not limited to, psychological counselling);

(d) order that the practitioner complete an educational course specified by the Committee;

(e) order that the practitioner report on the practitioner's practice at the times, in the way and to the persons specified by the Committee;

(f) order that the practitioner seek and take advice, in relation to the management of the practitioner's practice, from the persons specified by the Committee.

59. Section 3A of the National Law states the objectives of the National Law as it applies in NSW:

In the exercise of functions under a NSW provision, the protection of health and the safety of the public must be the paramount consideration.

60. It is well-established that the role of the Committee in exercising its powers is protective of the public interest and not focused on punishment of the individual concerned, notwithstanding that orders made may be punitive in effect: *Lee v Health Care Complaints Commission* [2012] NSWCA 90, per Basten JA at [20].

61. During the course of the hearing, having heard the evidence and submissions from the parties on that evidence, the Committee informed the parties of its tentative findings and of the orders it was considering, and allowed an adjournment to enable them to formulate any further submissions with regard to how the Committee should exercise its powers. Counsel then addressed the Committee on those submissions.

Submissions

62. Mr O'Donnell submitted that where conditions are imposed on a doctor's registration, it is appropriate that the doctor be reprimanded rather than cautioned, especially where a doctor has issued prescriptions without the authority to do so. He submitted that a condition should be imposed on Dr Richardson's registration requiring him to undertake a medical records course. Further, that there should be a condition limiting his prescribing testosterone medication, with a discretion for the supervising endocrinologist to determine the ongoing duration of this condition. Finally, Mr O'Donnell submitted that there should be a condition that Dr Richardson undergoes an audit six months from the date of the decision and thereafter 12 monthly, with the auditor reporting to the Medical Council. Audits should continue until the Council is satisfied that there has been an improvement in Dr Richardson's practice.

63. Mr Gregg submitted that a caution was appropriate in this case and that the conditions on Dr Richardson's registration proposed by the Committee were more than adequate to protect the public. Mr Gregg noted that the five Clomiphene prescriptions issued by Dr Richardson were during a three week period only in circumstances where Dr Richardson has admitted making an error of judgment, which he immediately acknowledged and took steps to address. He has not prescribed Clomiphene since then. It is now more than two years since the relevant period, there have been no other complaints made against Dr Richardson and, given the Committee's tentative findings, a reprimand would be punitive rather than protective of the public. He said Dr Richardson would willingly undertake a medical records keeping course. He

submitted that a condition limiting Dr Richardson's prescribing androgen medication should only be in respect of male patients, which were the focus of the complaints. Finally, he said Dr Richardson would willingly submit to an audit of his medical records 12 months from the date of the decision.

Consideration

64. The Committee decided that, in all the circumstances of this case, a caution was appropriate rather than a reprimand. We note that no other complaints have been made against Dr Richardson and that he only issued five Clomiphene prescriptions over a period of just over three weeks. He ceased issuing such prescriptions immediately on being informed that he was not authorised to do so, acknowledging his mistake and taking steps to make alternative arrangements for the five patients. He admits to his error of judgment in relying on the advice of a pharmacist. We also note Dr Richardson's co-operation in willingly undertaking the necessary steps to rectify his practise. As stated above, we found Dr Richardson to be a sincere doctor who, notwithstanding the problems identified in the course of these proceedings, is committed to achieving the best results for his patients.

65. The Committee is, however, of the view that conditions on Dr Richardson's registration are necessary for the protection of the public in order to guard against the repetition of the deficiencies highlighted in these proceedings. We note Dr Richardson's willingness to undertake further education in medical records keeping, to accept the limitation on his prescribing outlined by Mr Gregg and to accept audits on his practice. We do not consider that the more stringent conditions proposed by Mr O'Donnell are warranted.

DETERMINATION AND ORDERS

The Committee has therefore determined to exercise its powers under s146B of the National Law as follows:

1. To caution Dr Richardson, and

2. To impose the following conditions on his registration:

(1) To complete within 6 months of 17 March 2017 'MIPS Health Records online module' organised by Medical Indemnity Protection Society Limited. The practitioner must:

a. within 2 months of 17 March 2017 provide evidence to the Medical Council of NSW of his enrolment in the above-mentioned course;
b. within 2 months of completing the above-mentioned course, provide documentary evidence to the Council that he has satisfactorily completed the course;
c. bear responsibility for any costs incurred in meeting this condition.

In the event that 'MIPS Health Records online module' is unavailable, the practitioner must propose to the Council for approval a similar course to be undertaken in accordance with the requirements of this condition no later than 2 months from 17 March 2017.

(2) For a minimum period of 2 years from 17 March 2017, the practitioner shall not prescribe or dispense to any new or existing male patient androgens or other

medications primarily aimed at modifying androgen levels, other than DHEA, without:

(a) an initial assessment of that patient by an endocrinologist nominated by the practitioner and approved by the Medical Council. The endocrinologist must be a currently practising Fellow of the Royal Australian College of Physicians who has reviewed the patient's records and the practitioner's proposed treatment plan and,

(b) thereafter an annual review comprising a re-referral of the male patient to the same endocrinologist or a documented telephone discussion between the practitioner and the approved endocrinologist to discuss continuing treatment. The practitioner shall not prescribe androgens or other medications aimed at modifying androgen levels without the agreement of the endocrinologist who conducts the initial or follow up assessment.

(c) documentary evidence of the assessment by the approved endocrinologist, or subsequent telephone discussion about the patient in the patient's medical record.

(d) If the approved endocrinologist is unavailable, the patient must be assessed by another endocrinologist (who has been approved by the Council). The practitioner must provide this endocrinologist with all correspondence and advice provided by the original endocrinologist.

(3) To submit to an audit of the medical records of 20 randomly selected patients who have received treatment in his medical practice in the past year by a person or persons nominated by the Medical Council. These records are to include the records of five male patients randomly selected from those who are currently undergoing androgen therapy, or all such patients if their number is less than five. This process shall be conducted as follows:

(a) the audit is to be held within 12 months from 17 March 2017 and will be conducted at least annually for a minimum period of two years or as determined by the Council;

(b) the auditor(s) is to assess the practitioner's compliance with good medical record keeping standards, legislative requirements and compliance with the other conditions set out above. The auditor(s) should pay particular regard to the practitioner's:

- prescribing practice in respect of hormone therapy,
- recording of history and physical examination, and to
- evidence that he has discussed his treatment plan with the patient and, where appropriate, outlined criteria to assess its efficacy.

(c) the practitioner is to authorise the auditor(s) to provide the Council with a report of their findings;

(d) the practitioner is to meet all costs associated with the audit and any subsequent reports.

(4) To authorise and consent to any exchange of information between the Medical Council of NSW and Medicare Australia and Pharmaceutical Services for the purposes of monitoring compliance with these conditions.

NB. Conditions (2) and (3) will only be discharged on there being a satisfactory outcome to the second annual audit provided for in condition (3). In the event that the outcome of the second audit is not satisfactory, these conditions will

remain in place until such time as there is a satisfactory outcome from the annual audit as determined by the Medical Council.

APPEAL AND REVIEW RIGHTS

Dr Richardson has the right to appeal this decision to the NSW Civil and Administrative Tribunal.

An appeal must be lodged with the Tribunal within 28 days of the date of these written reasons.

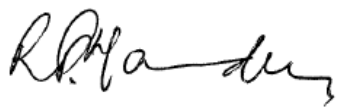
Dr Richardson also has the right to seek a review by the Medical Council of NSW of the Committee's order to impose conditions. Should Dr Richardson's principal place of practice be anywhere other than NSW at the time of seeking a review of conditions, Dr Richardson may make an application for review to the National Board.

NON-PUBLICATION ORDER

The non-publication order made on 14 February 2017 in respect of Patients A, B, C, D and E continues so that the name and address and any identifying features of those persons in this written statement of decision are not to be published.

DISTRIBUTION OF DECISION

We will provide a copy of this written statement of our decision to Dr Richardson, the Commission, the National Board, and to the complainant.



Mr Robin Handley
Chairperson

17 March 2017

(Date)

Attachment 1

Health Practitioner Regulation National Law (NSW) No 86a

Section 139B Meaning of "unsatisfactory professional conduct" of registered health practitioner generally [NSW]

(1) **"Unsatisfactory professional conduct"** of a registered health practitioner includes each of the following-

(a) Conduct that demonstrates the knowledge, skill or judgment possessed, or care exercised, by the practitioner in the practice of the practitioner's profession is significantly below the standard reasonably expected of a practitioner of an equivalent level of training or experience.
(b) A contravention by the practitioner (whether by act or omission) of a provision of this Law, or the regulations under this Law or under the NSW regulations, whether or not the practitioner has been prosecuted for or convicted of an offence in respect of the contravention.
(c) A contravention by the practitioner (whether by act or omission) of-
(i) a condition to which the practitioner's registration is subject; or
(ii) an undertaking given to a National Board.
(d) A contravention by the practitioner (whether by act or omission) of a decision or order made by a Committee or the Tribunal in relation to the practitioner.
(e) A contravention by the practitioner of section 34A(4) of the *Health Care Complaints Act 1993* .
(f) Accepting from a health service provider (or from another person on behalf of the health service provider) a benefit as inducement, consideration or reward for-
(i) referring another person to the health service provider; or
(ii) recommending another person use any health service provided by the health service provider or consult with the health service provider in relation to a health matter.
(g) Accepting from a person who supplies a health product (or from another person on behalf of the supplier) a benefit as inducement, consideration or reward for recommending that another person use the health product, but does not include accepting a benefit that consists of ordinary retail conduct.
(h) Offering or giving a person a benefit as inducement, consideration or reward for the person-
(i) referring another person to the registered health practitioner; or
(ii) recommending to another person that the person use a health service provided by the practitioner or consult the practitioner in relation to a health matter.
(i) Referring a person to, or recommending that a person use or consult-
(i) another health service provider; or
(ii) a health service; or
(iii) a health product;
if the practitioner has a pecuniary interest in giving that referral or recommendation, unless the practitioner discloses the nature of the interest to the person before or at the time of giving the referral or recommendation.
(j) Engaging in overservicing.
(k) Permitting an assistant employed by the practitioner (in connection with

the practitioner's professional practice) who is not a registered health practitioner to attend, treat or perform operations on patients in respect of matters requiring professional discretion or skill.
(l) Any other improper or unethical conduct relating to the practice or purported practice of the practitioner's profession.

(2) For the purposes of subsection (1)(i), a registered health practitioner has a **"pecuniary interest"** in giving a referral or recommendation-

(a) if the health service provider, or the supplier of the health product, to which the referral or recommendation relates is a public company and the practitioner holds 5% or more of the issued share capital of the company; or
(b) if the health service provider, or the supplier of the health product, to which the referral or recommendation relates is a private company and the practitioner has any interest in the company; or
(c) if the health service provider, or the supplier of the health product, to whom the referral or recommendation relates is a natural person who is a partner of the practitioner; or
(d) in any circumstances prescribed by the NSW regulations.

(3) For avoidance of doubt, a reference in this section to a referral or recommendation that is given to a person includes a referral or recommendation that is given to more than one person or to persons of a particular class.

(4) In this section-
"benefit" means money, property or anything else of value.
"recommend" a health product includes supply or prescribe the health product.
"supply" includes sell.

Section 146B General powers to caution, reprimand, counsel etc [NSW]

(1) A Committee may do one or more of the following in relation to a relevant health practitioner the subject of a complaint referred to it-

(a) caution or reprimand the practitioner;
(b) direct that the conditions, relating to the practitioner's practising of the practitioner's profession, it considers appropriate be imposed on the practitioner's registration;
(c) order that the practitioner seek and undergo medical or psychiatric treatment or counselling (including, but not limited to, psychological counselling);
(d) order that the practitioner complete an educational course specified by the Committee;
(e) order that the practitioner report on the practitioner's practice at the times, in the way and to the persons specified by the Committee;
(f) order that the practitioner seek and take advice, in relation to the management of the practitioner's practice, from the persons specified by the Committee.

(2) If the relevant health practitioner is not registered, a direction may still be given under this section but has effect only so as to require the conditions concerned to be imposed when the health practitioner is registered.

(3) If a Committee acting under this section makes an order or directs that any condition be imposed on a health practitioner's registration, the Committee may order

that a contravention of the order or condition will result in the health practitioner's registration in the health profession being cancelled.

(4) The order or condition concerned is then a
"critical compliance order or condition" .

Health Practitioner Regulation (NSW) Regulation 2010 (in effect at the time the complaints were lodged; repealed with effect from 1 September 2016).

Clause 7 Records relating to patients

(1) A medical practitioner or medical corporation must, in accordance with this Part and Schedule 2, make and keep a record, or ensure that a record is made and kept, for each patient of the medical practitioner or medical corporation.
(2) A contravention of subsection (1) by a medical practitioner does not constitute an offence but may constitute behaviour for which health, conduct or performance action may be taken.
(3) …
(4) …

Schedule 2, Clause 1 Information to be included in record

(1) A record must contain sufficient information to identify the patient to whom it relates.
(2) A record must include the following:
(a) any information known to the medical practitioner who provides the medical treatment or other medical services to the patient that is relevant to the patient's diagnosis or treatment (for example, information concerning the patient's medical history, the results of any physical examination of the patient, information obtained concerning the patient's mental state, the results of any tests performed on the patient and information concerning allergies or other factors that may require special consideration when treating the patient),
(b) particulars of any clinical opinion reached by the medical practitioner,
(c) any plan of treatment for the patient,
(d) particulars of any medication prescribed for the patient.
(3) The record must include notes as to information or advice given to the patient in relation to any medical treatment proposed by the medical practitioner who is treating the patient.
(4) A record must include the following particulars of any medical treatment (including any medical or surgical procedure) that is given to or performed on the patient by the medical practitioner who is treating the patient:
(a) the date of the treatment,
(b) the nature of the treatment,
(c) the name of any person who gave or performed the treatment,
(d) the type of anaesthetic, if any, given to the patient,
(e) the tissues, if any, sent to pathology,
(f) the results or findings made in relation to the treatment.
(5) Any written consent given by a patient to medical treatment (including any medical or surgical procedure) proposed by the medical practitioner who treats the patient must be kept as part of the record relating to that patient.

Poisons and Therapeutic Goods Regulation 2008

Clause 37 Authority required to prescribe certain restricted substances

(1) This clause applies to the following restricted substances:
acitretin
clomiphene
cyclofenil
dinoprost
dinoprostone
etretinate
follitropin beta
isotretinoin for oral use
luteinising hormone
tretinoin for oral use
urofollitrophin (human follicle stimulating hormone)
(2) A person must not prescribe a restricted substance to which this clause applies unless the person holds an authority under Part 8 to prescribe the substance.
(3) This clause does not apply to the prescription of a substance:
(a) by a veterinary practitioner, or
(b) by a person who is authorised by the Permanent Head of the Commonwealth Department of Health to issue a prescription for the substance.
(4) A person who issues a prescription that authorises the supply of a substance to which this clause applies must ensure:
(a) in the case of a prescription that is issued in accordance with an authority under Part 8 that was granted to a particular person (by means of an instrument in writing given to the person), that the prescription is endorsed with the reference number shown on the authority, or
(b) in any other case, that the prescription is endorsed with words that clearly indicate that the prescription has been issued under this clause.
Maximum penalty: 15 penalty units.

Attachment 2

The **Health Care Complaints Commission** of Level 13, 323 Castlereagh Street, Sydney, NSW, having consulted with **the Medical Council of New South Wales** in accordance with sections 39(2) and 90B(3) of the *Health Care Complaints Act 1993* and section 145A of the *Health Practitioner Regulation National Law (NSW) (the National Law');*

HEREBY COMPLAINS THAT

Dr David Richardson, 266 Crooked Lane, NORTH RICHMOND NSW 2754 being a medical practitioner registered under the National Law ("the practitioner"),

COMPLAINT ONE

Is guilty of unsatisfactory professional conduct under section 139B(1)(a) and/or (1) of the National Law in that the practitioner has:

(i) engaged in conduct that demonstrates the knowledge, skill or judgment possessed, or care exercised, by the practitioner in the practice of medicine is significantly below the standard reasonably expected of a practitioner of an equivalent level of training or experience; and/or

(ii) engaged in improper or unethical conduct relating to the practice or purported practice of medicine.

PARTICULARS OF COMPLAINT ONE

Patient A

1. Between 1 January 2012 and 31 December 2014 the practitioner prescribed medication for Patient A as set out in Schedule A:
    (a) without an appropriate therapeutic purpose;
    (b) in quantities in excess of recognised therapeutic standards as to what was medically appropriate in Patient A's circumstances;

(c) without obtaining an authority under section 37 of the *Poisons and Therapeutic Goods Regulation 2008;*

(d) without conducting an appropriate assessment of Patient A prior to prescribing medication;

(e) without referring Patient A for appropriate specialist advice with respect to endocrine or andrology issues;

COMPLAINT ONE A

Is guilty of unsatisfactory professional conduct in that he has contravened a provision of the National Law.

PARTICULARS OF COMPLAINT ONE A

Between 1 January 2012 and 31 December 2014 the practitioner failed to keep adequate medical records in relation to Patient A in contravention of clause 7 and Schedule 2, Clause 1 of the Health Practitioner Regulation National Law Regulation 2010 ("the Regulation") in that he failed to record an appropriate medical assessment in terms of history and physical examination.

COMPLAINT TWO

Is guilty of unsatisfactory professional conduct under section 139B(1)(b) of the *National Law* in that the practitioner has contravened the National Law in that the practitioner has;

(i) engaged in conduct that demonstrates the knowledge, skill or judgment possessed, or care exercised, by the practitioner in the practice of medicine is significantly below the standard reasonably expected of a practitioner of an equivalent level of training or experience; and/or

(ii) engaged in improper or unethical conduct relating to the practice or purported practice of medicine.

PARTICULARS OF COMPLAINT TWO

Patient B

2. Between 1 February 2013 and 31 July 2014 the practitioner prescribed medication for Patient B as set out in Schedule B:
    (f) without an appropriate assessment of Patient B prior to prescribing medication;
    (g) without referring Patient B for appropriate specialist advice with respect to endocrine or andrology issues before prescribing clomiphene;
    (h) without an appropriate therapeutic purpose;
    (i) in quantities in excess of recognised therapeutic standards as to what was medically appropriate in Patient B's circumstances;
    (j) without obtaining an authority under section 37 of the *Poisons and Therapeutic Goods Regulation 2008.*

COMPLAINT TWO A

Is guilty of unsatisfactory professional conduct in that he has contravened a provision of the National Law.

PARTICULARS OF COMPLAINT TWO A

Between 1 February 2013 and 31 July 2014 the practitioner failed to keep adequate medical records in relation to Patient B in contravention of clause 7 and Schedule 2, Clause 1 of the Health Practitioner Regulation National Law Regulation 2010 ("the Regulation") in that he failed to record sufficient definite and recognised clinical findings to support a diagnosis of "androgen deficiency".

COMPLAINT THREE

Is guilty of unsatisfactory professional conduct under section 139B (1)(a) and/or (1) of the National Law in that the practitioner has:

(i) engaged in conduct that demonstrates the knowledge, skill or judgment possessed, or care exercised, by the practitioner in the practice of

medicine is significantly below the standard reasonably expected of a practitioner of an equivalent level of training or experience; and/or

(ii) engaged in improper or unethical conduct relating to the practice or purported practice of medicine.

PARTICULARS OF COMPLAINT THREE

Patient C

3. Between 1 March 2012 and 30 November 2014 the practitioner prescribed medication for Patient C as set out in Schedule C:

(g) without an appropriate assessment of Patient C prior to prescribing medication;

(h) without referring Patient C for appropriate specialist advice with respect to endocrine or andrology issues;

(i) without an appropriate therapeutic purpose;

(j) in quantities in excess of recognised therapeutic standards as to what was medically appropriate in Patient C's circumstances;

(k) without obtaining an authority under section 37 of the *Poisons and Therapeutic Goods Regulation 2008;*

(a) without responding appropriately to actual and/or potential adverse effects of the prescribed drugs on Patient C.

COMPLAINT THREE A

Is guilty of unsatisfactory professional conduct in that he has contravened a provision of the National Law by failing to keep adequate medical records in relation to Patient C.

PARTICULARS OF COMPLAINT THREE A

Between 1 March 2012 and 30 November 2014 the practitioner failed to keep adequate medical records in relation to Patient C in contravention of clause 7 and Schedule 2, Clause 1 of the Health Practitioner Regulation National Law Regulation

2010 ("the Regulation") in that he failed to record sufficient definite and recognised clinical findings.

COMPLAINT FOUR

Is guilty of unsatisfactory professional conduct under section 139B of the *National Law* in that the practitioner has:

(i) engaged in conduct that demonstrates the knowledge, skill or judgment possessed, or care exercised, by the practitioner in the practice of medicine is significantly below the standard reasonably expected of a practitioner of an equivalent level of training or experience; and/or

(ii) engaged in improper or unethical conduct relating to the practice or purported practice of medicine.

PARTICULARS OF COMPLAINT FOUR

Patient D

4. During the course of 2014 the practitioner prescribed medication for Patient D as set out in Schedule D:
   (a) without conducting an appropriate assessment of Patient D prior to prescribing medication;
   (b) without referring Patient D for appropriate specialist advice with respect to endocrine or andrology issues;
   (c) without an appropriate therapeutic purpose;
   (d) in quantities in excess of recognised therapeutic standards as to what was medically appropriate in Patient D's circumstances;
   (e) without obtaining an authority under section 37 of the *Poisons and Therapeutic Goods Regulation 2008;*
   (f) and inappropriately withdrew antidepressant medication.

COMPLAINT FOUR A

Is guilty of unsatisfactory professional conduct in that he has contravened a provision of the National Law.

PARTICULARS OF COMPLAINT FOUR A

During the course of 2014 the practitioner failed to keep adequate medical records in relation to Patient D in contravention of clause 7 and Schedule 2, Clause 1 of the Health Practitioner Regulation National Law Regulation 2010 ("the Regulation") in that he failed to record sufficient and appropriate history and clinical examination findings.

COMPLAINT FIVE

Is guilty of unsatisfactory professional conduct under section 139B of the *National Law* in that the practitioner has:

(i) engaged in conduct that demonstrates the knowledge, skill or judgment possessed, or care exercised, by the practitioner in the practice of medicine is significantly below the standard reasonably expected of a practitioner of an equivalent level of training or experience; and/or

(ii) engaged in improper or unethical conduct relating to the practice or purported practice of medicine.

PARTICULARS OF COMPLAINT FIVE

Patient E

5. Between 1 January 2008 and 31 December 2014 the practitioner prescribed medication for Patient E as set out in Schedule E:
   (f) without conducting appropriate assessments of Patient E prior to prescribing medication;
   (g) without referring Patient E for appropriate specialist advice with respect to endocrine or andrology issues;
   (h) without an appropriate therapeutic purpose;

(i) in quantities in excess of recognised therapeutic standards as to what was medically appropriate in Patient E's circumstances;
(j) without obtaining an authority under section 37 of the Poisons and Therapeutic Goods Regulation 2008;

COMPLAINT FIVE A

Is guilty of unsatisfactory professional conduct in that he has contravened a provision of the National Law.

PARTICULARS OF COMPLAINT FIVE A

Between 1 January 2008 and 31 December 2014 the practitioner failed to keep adequate medical records in relation to Patient E in contravention of clause 7 and Schedule 2, Clause 1 of the Health Practitioner Regulation National Law Regulation 2010 ("the Regulation") in that he failed to record an adequate history or physical examination findings.