HEALTH CARE COMPLAINTS COMMISSION

Statement of Decision

Mr Samuel Cohen, Institute of Hair Regrowth and Beauty (IHRB)

1. Background

1.1 On 16 August 2010 a complaint was received at the Commission. This complaint concerned the provision of services by Mr Samuel Cohen who is the operator and proprietor of the Institute of Hair Regrowth and Beauty (IHRB). IHRB is situated at Suite 1, Level 5, 105 Pitt Street, Sydney.

1.2 The complainant had been a previous client of Mr Cohen and paid $3,700 cash for a hair replacement treatment program which included a "money back guarantee" if not satisfied. After nine months treatment the complainant was not satisfied with the results and requested a refund which was not forthcoming. He also complained about allergic reactions to the "Topical Solution" supplied by IHRB. He then commenced legal action against IHRB which culminated in a hearing date being set at the Consumer Trade and Tenancy Tribunal (CTTT) for 15 September 2010. Mr Cohen paid a refund in full a week prior to the commencement of proceedings and the CTTT closed the case.

1.3 Over a period of time the complainant came into contact with a number of other clients of IHRB who were also dissatisfied with the quality of treatment they received. This contact was initiated through a website titled "IHRB my story". Through this website, the complainant came into contact with two further complainants. One of these complainants had also instigated legal proceedings against IHRB which were settled out of court. All complainants experienced side effects as a result of applying the topical solutions provided by IHRB which required medical treatment.

1.4 On 2 September 2010, the second complainant attended IHRB for a consultation with Mr Cohen and alleges he was supplied with proscar, loniten and 15% minoxidil topical lotion without any prescription. These are prescription only medications. The medication allegedly supplied had no prescribing doctor details and no client details. The complainant states that no warnings or any kind of advice as to the possible side effects of the drugs was provided by Mr Cohen.

1.5 The complainant stated he paid for the medication via EFPTOS. He states that when he first visited IHRB in 2007, he was asked by Mr Cohen to get a doctor's prescription before certain medications could be provided to him. However, he claims that, as he became a regular client, he was provided with proscar and loniten by Mr Cohen without a doctor's prescription.

1.6 On 20 September 2010 the third complainant provided a statement to the Commission.

2. The Complaint

2.1 The complainants alleged that Mr Cohen was in possession of and selling medications either with or without prescriptions at his business premises. They allege that these medications, identified as the drugs proscar, loniten and minoxidil, are sold to clients:

1. Without a doctor's prescription.
2. Without medicine information sheets.
3. Without any discussions of or reference to the risks or potential side effects involved in taking the medication.

Office address
Level 13
323 Castlereagh Street
SYDNEY NSW 2000

Post address
Locked Mail Bag 18
STRAWBERRY HILLS
NSW 2012

Toll Free in NSW 1800 043 159
T (02) 9219 7444
F (02) 9281 4585
E hccc@hccc.nsw.gov.au

W www.hccc.nsw.gov.au
ABN 62 909 056 262
DX 11617 SYDNEY DOWNTOWN

It is a contravention of the Poisons and Therapeutic Goods Act 1966 (PTGA) for non qualified persons to dispense these medications. The complainants also alleged that Mr Cohen was endangering the health of his clients by encouraging the reapplication of his "topical solution" after they had suffered an allergic reaction, and by recommending medication such as loniten, which is not approved for hair growth by the Food and Drug Administration (FDAUSA) and the Therapeutic Goods Administration (TGA Australia)

3. Issues

3.1 The following issues were investigated concerning Health Services provided by Mr Cohen at IHRB. Whether or not:

i) Mr Cohen was unlawfully supplying medications to clients of IHRB contrary to the Poisons and Therapeutic Goods Act 1966.

ii) Mr Cohen was dispensing medications to clients for whom it was not prescribed, using medication obtained from the prescriptions of other clients.

iii) Mr Cohen had been retaining client prescriptions for significant periods of time and then arranging bulk dispensing of medication.

iv) Mr Cohen deliberately altered two client prescriptions.

v) Mr Cohen supplied prescription medications to clients who had not been assessed or provided with a prescription by a medical practitioner.

vi) Mr Cohen was recommending loniten tablets, a prescription medication, to clients as a hair regrowth medication knowing that it is not approved in Australia by the TGA.

vii) Mr Cohen endangered the health and safety of clients by supplying medications without medicine information sheets and advising them to reapply prescribed "topical solution" after they had experienced adverse side effects.

4. Respondent

4.1 Mr Cohen is the operator and proprietor of the Institute of Hair Regrowth and Beauty (IHRB). He started the business in December 2002. He has no formal qualifications in medicine or health. He states that he has forty years experience in the hair regrowth industry and this experience has established his expertise in this field.

5. Investigation

5.1 On 9 September 2010 investigators from the Commission attended the residence of the first complainant and obtained numerous documents and medications from him. These medications were proscar, loniten and minoxidil. Some of the minoxidil medication had been obtained by him from his own consultations with Mr Cohen dating from 11 September 2008. An unopened plastic bottle containing 100 x 10 mg loniten tablets, a 30 x 5 mg packet of finasteride tablets and a bottle of 100 ml minoxidil topical solution of 15% concentration were also obtained. These items were allegedly supplied to the second complainant on 2 September 2010 by Mr Cohen.

5.2 On 20 September 2010 a statement was obtained from the third complainant, a previous IHRB client, in which he described his experiences with Mr Cohen. He also provided commission investigators with photographs of himself taken in July 2007 when he suffered from a second allergic reaction to the medication provided to him by Mr Cohen. He states, that after his first adverse reaction, Mr Cohen advised him that it was safe to reapply the minoxidil topical solution and later recommended that he take loniten.

5.3 On 22 September 2010, during the execution of a search warrant conducted in the presence of Mr Cohen, police and commission investigators located and obtained a large quantity of medications including minoxidil solutions, proscar and loniten. This included 48 bottles of minoxidil which Mr Cohen stated had been supplied the day before by a pharmacist with whom he had a business relationship. In addition, a further 77 bottles of minoxidil solution were found. These bottles were located in several boxes which were labelled according to the concentration of minoxidil the bottles contained. The bottles did not have client names on them. Proscar and loniten were also obtained. These items were correctly labelled with client names and prescribing doctor details.

5.4 Documentation was also obtained relating to the ordering, purchasing and sale of these medications by Mr Cohen to multiple clients. 117 client prescriptions were also located as well as client record cards displaying medication supply and treatment details.

5.5 During the execution of the warrant Mr Cohen provided responses to various question asked where he outlined his business processes. He stated:

- He obtains the medication from a pharmacist
- He obtains the prescriptions from IHRB clients
- Has his office assistant attend the Pharmacy and present the scripts and she returns with the medication
- He then supplies the medication via post to the clients.

5.6 On 22 September 2010 the Commission also attended a dispensing and compounding pharmacy. HCCC investigators served a notice on the pharmacist and obtained dispensing records for minoxidil, proscar and loniten. Investigators were also accompanied by an officer from the Pharmaceutical Services Branch of NSW Health (PSB)

5.7 At the premises the PSB officer located a large quantity of compounded medication, namely 24x100ml bottles of minoxidil of varying concentration. The minoxidil was labelled "made in accordance with IHRB specifications".None of the bottles contained client details and the pharmacist did not have prescriptions for these medications.

5.8 On 24 September 2010 Commission investigators executed a search warrant at the pharmacy concerned.

5.9 During the search Commission investigators located a folder which contained 47 prescriptions and ordering records from IHRB. Computer records and sales records for medication sold to Mr Cohen were also obtained.

5.10 The prescriptions obtained were cross referenced with IHRB client cards and dispensing records, specifically in respect to minoxidil, proscar and loniten.

5.11 On 27 September 2010 the Commission made an interim prohibition order in relation to Mr Cohen and IHRB. The duration of the order was for a period of 8 weeks, valid until 22 November 2010 providing that Mr Cohen:

- Must not alter or amend any prescriptions in his possession.
- Must not order any schedule 2 or schedule 4 medication from a pharmacy or a person licensed to dispense such medication.

- Must not sell any schedule 2 or schedule 4 medication.

5.14 On 22 October 2010 a statement was obtained from the second complainant. He stated that he was sold proscar and loniten without a doctor's prescription by Mr Cohen. He stated that he had previously suffered acute side effects from taking proscar and the topical solution which led to him attending hospital.

5.15 The pharmacist was interviewed by commission investigators on 27 October 2010

5.16 Mr Cohen was interviewed by commission investigators on 12 October 2010. Mr Cohen also gave evidence before me on 10 December 2010.

6. The Evidence

Issue I- Whether Mr Cohen was unlawfully supplying medications to clients of IHRB contrary to the Poisons and Therapeutic Goods Act 1966.

6.1 NSW Health Pharmaceutical Services Branch (PSB) issue guidelines with regard to schedule 2 and schedule 4 medications. These guides are summaries and should be used in conjunction with the PTGA and the Poisons and Therapeutic Goods Regulation 2008 (PTG Reg). The relevant sections of the Act, Regulations and guidelines are as follows:

- Schedule 2 medications are - Substances which are dangerous to life if misused or carelessly handled, but which should be available to the public for therapeutic use or other purposes without undue restriction.
- Retail sale only by authorised practitioners. Pharmacists and persons licensed as "poisons sellers" (country stores remote from pharmacy).
- Wholesale sale of therapeutic substances may be made only by persons licensed or authorised to do so under the Poisons and Therapeutic Goods Regulations

- Schedule 4 medications are - Substances which in the public interest should be supplied only upon the written prescription of a medical practitioner, nurse practitioner authorised to prescribe the substance , midwife practitioner authorised to prescribe the substance, dentist, optometrist authorised to prescribe the substance or veterinary practitioner. **Schedule 4 medications are restricted substances.**

6.2 Specific requirements are made for record keeping and the writing and filling of prescriptions to ensure that they are not inappropriately obtained, and that the client is appropriately instructed in the use of the drug.

6.3 The PTGA contains the following definitions.

6.4 **Sell**- includes dealing in, agreeing to sell, or offering or exposing for sale, or keeping or having in possession for sale, or sending, forwarding, delivering or receiving for sale or on sale, or authorising, directing, causing, suffering, permitting or attempting any of such acts or things.

6.5 **Supply** includes:
a) Sell, dispense and distribute
b) Supply, whether by free of charge or otherwise, by way of sample or advertisement
c) Agree or offer to sell or distribute
d) Keep or have in possession for sale, dispensing or distribution
e) Send, forward, deliver or receive for sale, dispensing or distribution

6.6 PTGA 1966 Section 10

Prohibition on supply of certain substances otherwise than by wholesale

(1) A person who supplies otherwise than by wholesale any substance specified on schedule 1,2,or 3 of the poisons list except under, and in accordance with the conditions of, a general suppliers licence or a general suppliers authority issued under the regulations is guilty of an offence.

Maximum penalty: 15 penalty units or imprisonment for 6 months, or both

(2) A person who supplies a restricted substance (a schedule 4 medication) otherwise than by wholesale is guilty of an offence.

Maximum penalty

(a) 20 penalty units or imprisonment for 2 years, or both, if the restricted substance involved in the offence is of a kind prescribed by the regulations for the purposes of this section, or

(b) 15 penalty units or imprisonment for 6 months, or both, in any other case.

6.7 Proscar, loniten and minoxidil mixed with retin A are restricted substances

6.8 Minoxidil is listed in the PTGA as a schedule 2 substance if it is of a concentration of 5% or below. If minoxidil is in excess of 5% concentration or if it is compounded with additional substances which are schedule 4 or above, it becomes a schedule 4 substance.

6.9 Minoxidil (trade names Rogaine, Regaine, Avacor, Loniten (orally), is a vasodilator medication known for its ability to slow or stop hair loss and promote hair regrowth.

6.10 Common side effects of minoxidil include[1] burning or irritation of the eye; itching; redness or irritation at the treated area; unwanted hair growth elsewhere on the body. Users should seek medical attention if they experience the severe side effects. Severe allergic reactions include rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue; chest pain; dizziness; fainting; fast heartbeat; sudden, unexplained weight gain; swollen hands or feet.

6.11 Finasteride (commercial name of proscar and propecia) is used in the treatment of benign prostatic hyperplasia (BPH), and male pattern baldness (MPB). Finasterides are schedule 4 substances under the PTGA 1966.

6.12 Side effects of finasteride include[2] impotence, abnormal ejaculation, decreased ejaculatory volume, abnormal sexual function, gynecomastia, erectile dysfunction, ejaculation disorder and testicular pain. Resolution occurred in men who discontinued therapy with finasteride due to these side effects and in most men who continued therapy.

---

[1] Monthly Index of Medical Specialities(MIMS) Full Prescribing Information
[2] Monthly Index of Medical Specialities(MIMS) Full Prescribing Information

6.13 Retin A is a schedule 4 medication. If this substance is compounded with another substance, such as minoxidil of any concentration, it results in the compounded substance being a schedule 4 substance.

6.14 Retin A is mixed with minoxidil because this increases the absorption of the minoxidil which in turn, should make the minoxidil more effective when applied to the scalp.

6.15 Loniten is indicated as an adjunctive therapy for clients with severe refractory hypotension which has failed to respond to extensive multiple therapies. Warnings [3]- if used alone loniten can cause a significant retention of salt and water, producing dependent oedema puffiness of face, eyes and hands. Loniten is not approved by the Food and Drug Administration (FDAUSA) or Therapeutic Goods Administration (TGA) for hair growth in Australia. Loniten is a schedule 4 medication.

6.16 Mr Cohen provides a preformatted letter to clients who sign up for his services. This letter is for the attention of a general practitioner confirming that the client has enrolled on IHRB's hair regrowth program. The letter outlines a request to the practitioner to prescribe a "Topical Solution" which comprises of 0.0025 retin A in 5% minoxidil. It also requests a prescription for finasteride as a booster. The letter further states that the medication is listed by the Food and Drug Administration (FDAUSA) and TGA as a treatment for hair loss and, if the practitioner considers the client suitable, a prescription can be completed by the practitioner.

The TGA approves minoxidil and finasteride (propecia) for hair loss treatment. Finasteride is only approved in 1 mg doses. The use of the active ingredient minoxidil[4] in combination with any products which inflame the scalp, for example topical retinoids such as retin A, is not recommended due to the possibility of enhanced minoxidil absorption and consequently, increased potential for adverse reactions. This advice is not included in the preformatted letters provided to general practitioners by Mr Cohen.

6.17 The client then returns in person to IHRB or forwards the prescriptions to Mr Cohen. Upon receipt of the prescriptions Mr Cohen orders the compounding of the solutions from a pharmacist. The requests for medication are performed on occasions via an email message, telephone call or by a written order to the pharmacist, signed by Mr Cohen.

6.18 Prescriptions obtained from IHRB and the pharmacy were for minoxidil solutions mixed with retin A, loniten and proscar.

6.19 A number of client cards, 581 in total, were obtained from IHRB premises. These cards provide details of prescriptions received and medication supplied by Mr Cohen to his clients over a number of years.

6.20 The pharmacist compounds the topical solution to the requirements of Mr Cohen which in the case of minoxidil is between 5% and 17% concentration depending on the order, with retin A added. These "Topical Solutions" are compounded according to IHRB specifications and the solution includes a number of other herb extracts which are added. These ingredients are over and above what has been written on the doctor's prescriptions.

---

[3] Monthly Index of Medical Specialities(MIMS) Full Prescribing Information
[4] Monthly Index of Medical Specialities(MIMS) Full Prescribing Information

6.21 Minoxidil up to 15% concentration was located at Mr Cohen's business premises during the search warrant on 22 September 2010. The minoxdil bottles did not have any client names on them. There were no warning and advisory information sheets or expiry dates on the bottles.

6.22 Documentation obtained at the pharmacy on 24 September 2010 indicates that prescriptions are not presented to the pharmacist at the point they are compounded and then dispensed. In his interview with Commission investigators on 27 October 2010 the pharmacist confirmed this. The pharmacist states that he has dispensed schedule 4 medication to Mr Cohen without being in possession of the prescription and at times, he admitted that he was not sure if the prescriptions were ever forthcoming from Mr Cohen.

6.23 Emails and IHRB letters for orders of medication signed by Mr Cohen and addressed to the pharmacist were obtained by Commission investigators from the pharmacy during the search warrant. The orders placed were for minoxidil solutions mixed with retin A. References are made in the letters to Mr Cohen being in possession of prescriptions for the orders.

6.24 On 12 October 2010 Mr Cohen was interviewed by Commission investigators. He states that the 48 bottles of minoxidil located at IHRB premises during the search warrant were without client names due to excessive crystallisation of the topical solutions. These bottles had been supplied to Mr Cohen on the 21st September 2010. Mr Cohen states that the pharmacist was not compounding the topical solutions with his added herb extracts correctly and a number of clients were sending bottles back to Mr Cohen. Mr Cohen states that he was waiting to see if the topical solutions would stop crystallising before he put client names on the bottles, in case he had to return them all to the pharmacist.

6.25 Mr Cohen stated that he had been supplying medication to his clients over a number of years. He states that he was not familiar with the PTGA 1966 and was unaware that he was not authorised to supply schedule 2 and schedule 4 medications to his clients. He stated that he had since made himself familiar with the legislation. Mr Cohen states that since he had been appointed as an agent for his clients, he believed he was entitled to act in this way. He does not dispute that he was not complying with the legislation and regulations, but stated his actions were accepted practice within the hair growth industry

Issue II- Whether Mr Cohen was dispensing medications to clients for whom it was not prescribed, using medication obtained from the prescriptions of other clients.

6.26 Mr Cohen stated that his client cards, which the commission obtained, were just like a doctor's medical record. Mr Cohen states that what he means by this is that he records on the cards all important details such as consultations, medication he has supplied to the client, progress of the client's treatment in terms of hair regrowth, and also details of any adverse reactions to the medication the client has experienced. Commission investigators asked Mr Cohen questions about a number of his clients. These questions addressed the entries Mr Cohen made on their client cards and his supply of schedule 4 medications to them. These clients are referred to below:

6.27 Client 1-first attended IHRB on 25 November 2009. He obtained a prescription for minoxidil and retin A on 2 December 2009 and Mr Cohen made a record in the client card that he received the prescription on 4 December 2009. On 16 December 2009

the client was supplied with 11 bottles of minoxidil solution. The prescription is not actually dispensed by the pharmacist until 9 August 2010.

- Client 2- first attended IHRB on 16 September 2009.He obtained a prescription on 17 October 2009. The client card depicts he was supplied 11 bottles of minoxidil on 4 November 2009. The prescription was not dispensed by the pharmacist until 21 May 2010.

- Client 3- first attended IHRB on 4 September 2009. He obtained a prescription on 14 September 2009. Mr Cohen made a record in the client card that he received the prescription on 17 September 2009. The client card depicts that the client was supplied minoxidil in September, October, November and December 2009 (single bottle dosages). He was also supplied minoxidil in March and April 2010. The prescription was not dispensed by the pharmacist until 7 May 2010.

- Client 4- first attended IHRB on 18 October 2007. He obtained a prescription for minoxidil and retin A on 5 October 2009. Mr Cohen made a record on the client card that he received the prescription on 6 October 2009. The client card shows the client was supplied minoxidil in October and November 2009 amounting to 5 bottles. He was then supplied 1 bottle in February 2010 and 1 bottle in April 2010. The prescription was not dispensed by the pharmacist until 11 May 2010.

- Client 5- first attended IHRB on 15 July 2009. He obtained a prescription on 22 July 2009 for minoxidil and retin A (including proscar and loniten) Mr Cohen made a record in the client card that he received the prescription on the 23 July 2009. On 31 July 2009 the client card shows the client was supplied 10 bottles of minoxidil. The prescription was not dispensed by the pharmacist until 19 April 2010.

- Client 6- first attended IHRB on 25 November 2009. He obtained a prescription for minoxidil and retin A on 2 December 2009. Mr Cohen made a record in the client card that he receives the prescription on 4 December 2009. On 16 December the client card depicts he supplied with 11 bottles of minoxidil to the client. The prescription was not dispensed by the pharmacist until 9 August 2010.

- Client 7- first visited IHRB 11 February 2008. He obtained a prescription for proscar on 21 February 2008. Mr Cohen made a record in the client card that he received this prescription on 25 February 2008. The client card depicts he supplied the client with proscar on 5 June and 14 June 2008 and 14 May 2009. E mails from Mr Cohen to the client refer to the supply of a pack of proscar for free on 5 June 2008. The original prescription for the proscar was located during the warrant conducted by the police. It has never been dispensed.

6.28 Mr Cohen admitted to the Commission that on the occasions cited above he dispensed medication to clients for whom it was not prescribed. He did this by using medication he obtained from other clients prescriptions. He states that this occurred only occasionally and he only ever did this when he knew a prescription for the medication had already previously been prescribed for the client by a doctor. Mr Cohen stated that he never supplied medication to a client when a prescription had not previously been written by a doctor. Mr Cohen states that he also supplied his clients with bottles of minoxidil which were returned by previous clients. If the bottles had the previous clients name on them he would peel the label off. So long as the bottles had not passed their expiry date he would supply them to other clients. Mr Cohen stated that most of the medication was basically the same.

6.29 Mr Cohen's evidence was initially that such conduct was rare, and when individual examples were put to him he maintained that it was not his common practice.

Issue III- Mr Cohen has been retaining client prescriptions for significant periods of time and then arranging bulk dispensing of medication.

6.30 Out of a total number of 47 IHRB client prescriptions obtained from the pharmacy, on average it took six months from the time of them being written to the time of being dispensed by the pharmacist.

6.31 On 6 May 2010 the pharmacist admitted in interview to dispensing the following prescriptions to Mr Cohen for IHRB clients:

- 400 x 10 mg loniten tablets. This was a repeat prescription dispensed all at once. The prescription was written on 6 August 2009 and the IHRB client card indicates that the client was sent one pack of loniten by Mr Cohen on 23 April 2010. No further loniten had been supplied up until 22 September 2010.
- 400 x 10 mg loniten & 180 5 mg finasteride tablets (proscar). This was a repeat prescription dispensed all at once. The prescription was written on 19 August 2009.
- 180 x 5 mg finasteride tablets (proscar). This was a repeat prescription dispensed all at once. The prescription was written on 29 September 2009.

6.32 The pharmacist states that Mr Cohen requested that the above items be dispensed but did not provide any reasons for why the repeats should be dispensed as well. These transactions on 6 May 2010 supplied Mr Cohen with 800 loniten and 360 finasteride tablets.

6.33 In addition to the above, a prescription of a confirmed IHRB client for loniten (100 x 10 mg tablet x 5 repeats) dated 12 December 2009 was obtained at IHRB premises. On the client card there is an entry that states that the male was sent one pack of loniten on 12 December 2009. According to the card, the client has not been supplied any further loniten by Mr Cohen. This prescription has not been dispensed. A potential 500 loniten tablets are available on this prescription. A prescription for minoxidil and retin A obtained from the pharmacy for the same client, dated 12 December 2009 was not dispensed until 8 August 2010.

6.34 Another prescription of a different IHRB client was for loniten (100 x 10 mg tablet x 5 repeats) dated 12 December 2009. On the client card there is an entry which states that the client was supplied with one pack of loniten on December 12 2009. This prescription has not been dispensed. A potential 500 loniten tablets are available on this prescription.

6.35 The evidence is that Mr Cohen obtains medication in bulk and on prescription for different clients than those to whom he provides it. He maintains that he only provides medication where a client has a prescription from a medical practitioner.

Issue IV- Mr Cohen deliberately altered two client prescriptions to increase the dosage of items dispensed

6.36 Two prescriptions obtained from the pharmacy and dispensed by the pharmacist for Mr Cohen's clients have been altered. The first prescription was for 15% minoxidil + 0.0025% retin A x 16 bottles and it was written on 19 March 2010. The prescribing doctor was spoken to by commission investigators on 6 October 2010 and the doctor

viewed a faxed copy of the original prescription. The doctor states that the prescription was originally written for 6 bottles of 15% minoxdil + 0.0025% retin A. The prescription has been altered from 6 to 16 after the doctor gave it to his client. An entry on the IHRB client card indicates that Mr Cohen received this prescription on 24 March 2010. His records show that he received a script for 15% minoxidil + retin A for 6 bottles. An order form dated 30 April 2010 signed by Mr Cohen and addressed to the pharmacist shows that Mr Cohen placed an order for 6 bottles of 10% minoxidil solution for this client and then a further 6 bottles of 15% minoxidil. This prescription was dispensed on 12 May 2010. Computer records obtained from the pharmacist confirm that 12 bottles of minoxidil were dispensed on 12 May 2010. The client was spoken to by commission investigators on 18 November 2010 and he states that he did not alter the prescription. He states that he forwarded it to Mr Cohen soon after he received it like he always does and received the minoxidil in the post.

6.37 The second altered IHRB client prescription was for 12x100ml bottles of 5% minoxidil solution mixed with 0.025 retin A and it was written on 21 November 2009. The IHRB client card indicates that the client was sent 11x100ml bottles of 5% minoxidil with 0.025 retin A on December 12 2009. The actual prescription was dispensed by the pharmacist on 9 August 2010. The client card also shows that the client returned these bottles on 10 March 2010 due to suffering from "eruptions" (adverse reaction to scalp). He was sent 5% solution without retin A as a replacement on 12 April 2010.

6.38 The prescribing doctor was spoken to by commission investigators on 7 October 2010. He viewed a faxed copy of the prescription and states that he only authorised 1 bottle. He states that x12 in ink has been added by someone else. It is unknown who received the medication dispensed by the pharmacist for Mr Cohen on 9 August 2010.

6.39 Mr Cohen denies that he altered these prescriptions and also states that he has never altered a client's prescription in any way.

Issue V- Mr Cohen has supplied prescription medications to clients who had not been assessed or provided with a prescription by a medical practitioner.

6.40 The second complainant became a client of IHRB in late 2006. During his first consultation with Mr Cohen he was shown a number of photographs of people who had been successfully treated by Mr Cohen. The complainant states that Mr Cohen said he would supply him with 12 bottles of minoxidil topical solution which contained his "special spices". The complainant states that Mr Cohen said that the spices were a safe herbal solution. It was not until the second consultation that the complainant decided to purchase the program and he paid Mr Cohen $3,000. During his second consultation with Mr Cohen the complainant was supplied with two small bottles of minoxidil solution. No prescription was supplied but the complainant is unsure what concentration the minoxidil was. The complainant states that Mr Cohen said it would be better to start the program straight away. He was also advised that he would need to go to his GP in order to get a prescription for proscar. The complainant was provided with a list of several GPs who had previously prescribed proscar for IHRB clients. The complainant was then told by Mr Cohen to return in a few days to collect some more minoxidil. He states that Mr Cohen did not advise him that there may be side effects of the products and medication he was using.

6.41 Mr Cohen allegedly told the complainant that proscar was just a tablet that will make hair grow faster. The complainant obtained a prescription from his doctor for proscar but went to a pharmacy himself to have it dispensed rather than forwarding it to Mr Cohen. A few days after the second consultation the complainant states that he went to see Mr Cohen at the IHRB office and picked up 2 or 3 bottles of minoxdil.

6.42 After about a month of using these products the complainant started to suffer from an itchy scalp and chest/breast tenderness. Having researched the side effects of proscar he decided to take fewer of the tablets.

6.43 In early 2007 the complainant states that he received a phone call from Mr Cohen to attend IHRB premises for a check up on how the treatment was going. Mr Cohen took several photographs of the complainants scalp. During this consultation the complainant states that he was supplied with 6 bottles of minoxidil. The bottles had someone else's name on them. The complainant states that Mr Cohen told him not to worry since the bottles were the same as the previous ones supplied to him.

6.44 In January 2008 the complainant visited Mr Cohen. He was supplied with some more minoxidil and gave Mr Cohen the bottles in his possession which had expired. The complainant states that he asked Mr Cohen about the side effects of proscar that he had read on the internet. He states that Mr Cohen told him that there was nothing to worry about and that lots of people take it. The complainant states that he was told that it will not affect him if he takes one to two milligrams a day.

In late January 2008 the complainant was supplied with six new bottles of minoxidil solution. Upon applying this new batch of topical solutions he stated that he suffered from an allergic reaction. The reaction was such that the complainant presented at the emergency room of Sydney Hospital for treatment. He advised the doctor that the cause of the rash to his head was a new shampoo he had been using. This was due to the embarrassment the situation was causing him. The following day the complainant states he went back to IHRB and new solutions were ordered. The complainant showed Mr Cohen how bad the rash was on his head was. The subsequent topical solutions had the same adverse effect and the rash on his head was getting worse. The complainant states that Mr Cohen insisted that the rash was nothing to do with the bottles of minoxidil topical solution. He states that Mr Cohen did not advise him to stop the treatment.

6.45 The complainant states that he asked Mr Cohen for a refund but instead of providing a refund, Mr Cohen supplied him with a product called "Capro Natural". The complainant states that Mr Cohen told him that the "Capro Natural" contained only "Indian curries" and no minoxidil. By mid 2008 the complainant states that he had seen no improvement in his hair growth. He attended IHRB and Mr Cohen suggested that he go to his GP and ask for a prescription for Ioniten. The complainant states that Mr Cohen did not advise him that Ioniten is not recommended by the FDA or TGA as a hair regrowth product. At the same time the complainant advised that he had run out of proscar. At this point, the complainant alleges that Mr Cohen supplied him with a packet of proscar which had another client's name on the packaging. The complainant states that he paid around $80 for the proscar.

6.46 The proscar medication was obtained by commission investigators on 9 September 2010. The client details on the proscar match the details of a different IHRB client.

6.47 Mr Cohen states that he may have recommended Ioniten to the complainant and he may not have told him it was not approved by the TGA. He denies ever selling

proscar in mid 2008 to the complainant without a prescription. He suggests that maybe the complainant stole the proscar from his office. Mr Cohen states that he would never supply medication with other people's names on it, particularly with proscar.

6.48 In interview on 12 October 2010 Mr Cohen was reminded by Commission investigators that during the police search warrant a package for one of his client's was located in the reception area of IHRB which contained minoxidil solutions and proscar. The client name on the box of proscar medication was different to the name on the package. Mr Cohen explained that the client "still had a prescription for proscar". Mr Cohen stated that sometimes he will provide a box of proscar to a client if he has prior knowledge that the client had a prescription for proscar at some point. He stated that there had simply been a mix up on this occasion in relation to the wrong clients proscar being placed in the wrong package.

6.49 Mr Cohen stated the second complainant went off his program for over a year and he had not seen him for some time. He then states that the complainant came to see him a few months ago and he did not complain. Mr Cohen said he told the complainant during this visit "if you want to, you better go on – I think it's loniten and proscar, exactly what I tell other people"

6.50 Further details of the complainant's statement were then disclosed to Mr Cohen. This included the details of the complainants visit to IHRB on 2 September 2010. The complainant states that he spoke with Mr Cohen about growing his hair back. He also states that he decided to go back since he was owed six bottles of minoxidil. The complainant then states that he was supplied with a bottle of 15% minoxidil solution without a prescription. He also claims that he was supplied with loniten (100x10mg) tablets and finasteride (30x5mg) tablets without a prescription, together with a pill splitter. These items had no prescribing doctor details, and no client details. The complainant states that he paid for these items via EFTPOS at a cost of $185 and provided the Commission with a copy of the receipt. The complainant states that the minoxidil was a free sample for a trial. Mr Cohen's IHRB price list includes loniten at a cost of $100 and finasteride at $85.

6.51 These items were amongst medications obtained by Commission investigators from the first complainant on 9 September 2010.

6.52 Mr Cohen denies supplying this medication to the complainant. He states that the complainant came to see him on 2 September 2010 and whilst in his office he must have stolen the medication. Mr Cohen did not deny that he would have had possession of the proscar and loniten on his premises. The commission received a letter from Mr Cohen dated 15 October 2010, stating that the complainant purchased 2 bottles of Saw Palmetto Complexes at a cost of $140, 1 bottle of Dermaclean for $25 and 1 bottle of shampoo for $20. He states that the complainant had told him that he had given up treating his hair and just wanted to keep up good hygiene. When Mr Cohen left the room for a short while, he says that the complainant must have stolen the medication.

6.53 The second complainant had been provided, at some time, with prescriptions for all of the medication provided to him by Mr Cohen. Mr Cohen's selling of medications to the second complainant, prescribed for other clients, would be consistent with other examples set out in this decision. Both complainant one and two state that they have received bottles of minoxidil from Mr Cohen without first seeing a doctor. The concentration of this minoxidil is unknown. Entries on client record cards indicate that some clients have been supplied prescription medication during their first

consultation with Mr Cohen. Mr Cohen states that these entries are simply mistakes. Subsequently, the clients were prescribed the same medication by their doctor.

Issue VI-. Whether Mr Cohen was recommending loniten tablets, a prescription medication, to clients as a hair regrowth medication knowing that it is not approved in Australia by the TGA

6.54 Loniten is not approved by the FDA or the TGA as a hair growth medication. Loniten official Food and Drug Administration USA (FDA) information states "Use of Loniten tablets, in any formulation, to promote hair growth is not an approved indication". When interviewed Mr Cohen agreed with this. He states "I'm suggesting if the doctor approves". When asked if he tells his clients that loniten is not approved by the TGA when he recommends it he states "sometime I say it, sometimes I don't". When asked if it is ethical for him to recommend loniten when the prescribing doctor does not realise that it isn't approved by the TGA, Mr Cohen replied "no, if he's a doctor, he should realise. My job is to try and get the utmost out of a customer to regrow his hair. That is my job".

6.55 When Mr Cohen supplies his preformatted letter to doctors, he refers to minoxidil and finasteride as being approved by the FDA and TGA for hair growth. On other occasions he will hand write proscar and loniten on the letter. Mr Cohen does not inform the potential prescribing doctors that loniten is not approved by the TGA. He told the Commission "I'm nobody to mention it".

6.56 17 prescriptions for loniten were located during the search of IHRB premises. A further 3 were located at the pharmacy already dispensed to IHRB clients.

6.57 On his own admission, Mr Cohen recommends loniten tablets to clients knowing that it is not approved for hair growth by the TGA and without advising clients of its status.

Issue VII- Whether Mr Cohen has endangered the health and well being of clients by supplying medications without medicine information sheets and advising them to apply prescribed "topical solution" after they had experienced adverse side effects

6.58 The first complainant visited IHRB on 11 September 2008. He used a false name because he stated that Mr Cohen gave him reason to fear that his confidentiality would not be respected. The complainant states he was told that the topical solutions contained "special Indian curries" which Mr Cohen stated were "herbs" formulated during his 39 years of research and development and world exclusive innovation.

6.59 On the same day the complainant paid Mr Cohen $3,700 and he was provided with 6 bottles of "topical hair regrowth solution" Three of these bottles have been obtained by the Commission and the minoxidil is of 5% concentration which makes it non prescription schedule 2 medication. The complainant states that each of the bottles supplied contained a sticky residue at the bottom of the outside of the bottle which may have originally contained the details of a different client for whom the medication had been compounded. The complainant states that he has since contacted the compounding pharmacist and the pharmacist confirmed that the bottles he had dispensed did originally contain labels on the bottom which had client details.

The complainant states that the medication supplied to him was a combination of schedule 2 minoxidil and schedule 4 minoxidil mixed with retin A. The Commission has not obtained any of the schedule 4 minoxidil provided to the complainant. He states that he never received any client warning information sheets and was not aware of the potential side effects. He was also not aware at the time that Mr Cohen was not authorised to supply/sell these medications.

6.60 On 26 March 2009 Mr Cohen provided the complainant with a letter to forward to his doctor. This letter was a request for the doctor to prescribe the complainant with minoxidil + retin A, proscar and loniten. He was advised by Mr Cohen that the new program required half a tablet of proscar a day (2.5mg). The complainant states that Mr Cohen did not offer any advice as to what the potential side effects of these medications were. The complainant also alleges that Mr Cohen also falsely claimed that loniten had been approved by the FDA and TGA for hair growth. The content of an email dated 29 April 2009 from Mr Cohen to the complainant supports the complainant's allegation. In this email Mr Cohen states "Loniten is actually minoxidil and has been approved by the TGA and FDA to help re-growth". The complainant in an email to Mr Cohen dated 4 June 2009 stated that his dermatologist had told him that Loniten is not designed for hair growth and that he had been warned that the side effects of proscar included sexual dysfunction.

6.61 The complainant was unable to obtain a prescription for these items. The fact that he had given Mr Cohen a false name which was the name on the doctor's letter may have been a reason for this.

6.62 The complainant states that it was the retin A in the solutions supplied that caused a painful rash to his scalp in June 2009. He states that this reaction occurred after he used a new bottle of solution from the six originally supplied and the only difference to the bottle was the words retin A on the label. This painful rash extended to the complainants back and caused bruising to his scalp. He states that two courses of antibiotics were required. The complainant states that he was advised by Mr Cohen that the rash had nothing to do with IHRB products and he was advised to continue with their use after the rash had subsided. The complainant thus continued to apply the topical solution. He claims he was not advised to seek medical advice.

6.63 In interview Mr Cohen stated that the complainant came to see him and supplied a false name. He states that he never supplied him with prescription only medication and the reason why he could not obtain a prescription was the fact he provided a false name. He states that the complainant even had an e mail account in the false name and he believes that the complainant has set out to try and destroy his business.

6.64 On 21 July 2006 the third complainant attended IHRB for a consultation with Mr Cohen. He was provided with a questionnaire and the complainant states that he informed Mr Cohen of his 3 infected hair follicles. The complainant explained that he was taking antibiotics to clear the infection and he states that he was informed by Mr Cohen that this would not interfere with the treatment. The IHRB client card indicates that an appointment was made for the complainant to return to IHRB in two weeks after the infection had cleared. During this initial consultation the complainant states that Mr Cohen had written the name and strength of the topical solution he required. This was the only time the complainant ever saw Mr Cohen. After this initial consultation, everything was conducted over e mail and phone calls.

6.65 The complainant states that Mr Cohen told him that he was going to go bald since he had the common form of "male pattern baldness", but that Mr Cohen stated that his

treatment would grow his hair back. He states that Mr Cohen also told him that his program was exclusive as he would be adding his "own special curries" to the topical solution. The complainant was provided with an information pack which he states only contained a few facts and no mention of any risks involved in the treatments supplied. The complainant states that there was no information as to the possible side effects of applying the topical solutions. He states that Mr Cohen said that his program was safe for him and everyone else without adverse side effects.

6.66 The complainant states that he purchased Mr Cohen's "hair regrowth treatment program" on 9 August 2006. This was through the Sun Herald newspaper who was advertising IHRB services. The complainant then went to see a doctor who he had selected from a list of doctors which Mr Cohen provided him with. The prescription for minoxidil and retin A was obtained by the complainant and sent to Mr Cohen for the compounding of the solutions. The solutions were received by the complainant on 19 October 2006.

6.67 The package received by the complainant included 12 bottles of minoxidil with retin A. According to the complainant there were no health warnings or advisory information sheets included for any of the items. The complainant states that he was completely unaware of what the possible side effects of the minoxidil solutions may have been. According to the complainant these were not explained by Mr Cohen either during their initial consultation or after he purchased the program.

6.68 The complainant states the labels on the bottles described the contents as 5% minoxidil with instructions on how many times to apply the solution. He states that the labels clearly stated that the user should read the leaflet carefully before use. However, the complainant states that there were no such leaflets. He also states that the bottles had the bottom labels missing where his name and the prescribing doctor's details should have been.

6.69 Within a week of using the products the complainant states that he noticed that his feet were itching. After a month his body was itching all over and at times this was unbearable. It was so bad he thought that his home had been infested with fleas.

6.70 At the end of December 2006 the complainant went to see his doctor. His eyes were now also swollen and his head was beginning to leak with a yellow serous fluid. He was having dizzy spells, his eyes were sensitive to light and his heart was beating oddly. The doctor advised the complainant to cease taking everything, including antibiotics, shampoos or foods etc. This reduced the facial swelling, bleeding and leaking of serous fluid. The chronic itching of the skin remained.

6.71 The complainant states that he did not use any more IHRB products until July 2007. On 11 July 2007 he states that he informed Mr Cohen via email of the severe reaction he had to his products the previous year. In the email he asks Mr Cohen if his reactions and side effects were common with other customers and asks for advice as to other treatments should his second attempt at applying the topical solutions not work out.

6.72 In reply via telephone the complainant states that Mr Cohen said that he had never heard of any client having such a reaction to his topical solution. The complainant states that Mr Cohen told him "it was safe for him to continue with his program and that he should do so". Mr Cohen asked for the bottles which were going out of date to be returned to him. The complainant complied with this request; keeping one bottle so he could reapply the solution.

6.73 On 13 July 2007 Mr Cohen via e mail advised the complainant to "please re start by applying only 0.5ml every evening for a week, if no adverse reaction takes place, go to 1.00ml" Mr Cohen did advise the complainant to stop if the minoxidil solution caused excessive itching, burning or irritation. There is no record in the photocopy of the complainant's client card of Mr Cohen advising him to consult with a doctor first before recommencing the treatment.

6.74 Within hours of reapplying the topical solution the complainant states that he experienced an adverse reaction that was even more severe than the first one he experienced in 2006. He states that his face ballooned and his eyes closed over due to the swelling. He also states that Yellow serum ran freely from his head for the next 48 hours. The complainant was examined by his doctor who provided medication to try and reverse the reaction.

6.75 The complainant states that he sent a further email to IHRB with a number of photographs attached. These photographs were of his head and face and depict the adverse reaction that the complainant experienced when he reapplied the topical solutions. The complainant states that Mr Cohen said in a return phone call that he "had never seen such a reaction". The complainant states that Mr Cohen said that the complainant "obviously had a problem". A refund was refused since the complainant had not used any of the alternative IHRB products.

6.76 On 15 August 2007 the complainant emailed IHRB and advised that he had been informed that the cause of his allergic reaction was the topical solution and the symptoms would take quite a while to settle down. Mr Cohen agreed that it would be best at this point not to try any form of alternative treatment. On 21 August 2007 the complainant sent an e mail to IHRB requesting a refund. He also left phone messages but states that he received no response.

6.77 On 20 September 2007 the complainant states that Mr Cohen phoned him and suggested that he had Ioniten tablets to give him which in his case would be better since this would bypass the skin and therefore avoid another allergic reaction. The complainant states that Mr Cohen said that Ioniten was "tablet minoxidil". The complainant states that nothing about the side effects of Ioniten were explained to him and he was not advised to go back to a doctor for a prescription. He declined the offer. A report by a doctor confirms that the complainant is allergic to minoxidil.

6.78 The complainant contacted the pharmacist who compounded the minoxidil solutions. The pharmacist responded to a request from the complainants solicitors and provided different versions of client information leaflets that he would forward to IHRB whilst he was compounding minoxidil with retin A for Mr Cohen from 2005-10. Complainants who gave evidence to the commission say that Mr Cohen never provided them with this information.

6.79 The complainant provided a report from a Trichologist[5] dated 27 October 2009 which draws conclusions about the life threatening consequences which may have resulted when the complainant re - applied the topical solutions. The effect of his opinion is "the consultant compounded the severity of the complainant's reactions by continuing to advise him to re-commence his topical treatment. This potentially might have lead to life threatening consequences for the complainant such as cardiac or respiratory arrest". This opinion is shared by another Trichologist. He states "the biggest mistake IHRB made was in allowing the complainant to recommence the

[5] Trichologists are not medical practitioners. They specialise in the scientific study of problems of the hair and scalp.

treatment". Both of these reports were compiled for a firm of solicitors who were acting on behalf of the complainant in his court case against IHRB.

6.80 Mr Cohen says that when the third complainant came to him he said "sorry, I will not sell you my program until you come back after you get your scalp treated". The photo copy of his IHRB client card confirms that the complainant attended IHRB on 21 July 2006 and was advised to "see his doctor and fix it".

6.81 Mr Cohen said that the complainant then purchased the hair regrowth program remotely which meant there were no personal consultations. Mr Cohen said that the complainant then supplied him with a prescription and he supplied the minoxidil solution to him. Mr Cohen states that when the complainant started to get infected he advised him to stop but the complainant was very insistent. Mr Cohen states that he never saw the complainant's infection, only photographs which he sent him. He states that after he had heard that the infection had cleared he said to the complainant "I would suggest you don't use the retin A". He states that the complainant has gone "beyond my, what you call it, instructions not to do things".

6.82 Mr Cohen confirms that a number of bottles of topical solution containing minoxidil and retin A were returned to him by the complainant. He confirms that he would have probably supplied these bottles of minoxidil to other clients, unless the date had expired, in which case he would have thrown them away.

Response from Mr Cohen under s 40 of the Act.

6.83 As required by the Health Care Complaints Act Mr Cohen was provided with the opportunity to respond to the Commission's proposal to make a prohibition order, issue a public statement and publish its decision.

Issue I - supply of medication contrary to the PTG Act 1966

6.84 In his response to the Commission of 14 February 2011 Mr Cohen accepted that he had a practice of supplying medications when such medications ought to have been supplied only by a pharmacist. He accepted that this was inappropriate but stated that he did not knowingly break the law.

Issue II - supplying prescription only medication to clients using medication obtained under the prescriptions for other clients

6.85 Mr Cohen accepted that at least on occasion he dispensed medications to clients using medications that he obtained from other client's prescriptions. He re-iterated that he only ever supplied the identical medication to a client that had already been prescribed by a doctor and that the evidence was that this only occurred occasionally. He accepted the provision of medications obtained from another patient's script was inappropriate.

Issue III - maintaining bulk supplies of medications for dispensing to clients

6.86 Mr Cohen states that the delay between the date of the scripts being written and then dispensed is not evidence that he retained prescriptions for the purpose of bulk dispensing and that there is no evidence that this occurred.

Issue IV - altering of prescriptions

6.87 Mr Cohen did not make any submissions in relation to this issue since the Commission made no findings.

6.88 **Issue V- Mr Cohen has supplied prescription medications to clients who had not been assessed or provided with a prescription by a medical practitioner.**

Mr Cohen submitted that the evidence clearly shows that as a matter of general practice he would not supply medications unless a script was obtained. He also submitted that the evidence that he did supply medications without a script having been issued is very limited and that even if the alleged instances referred to by the Commission were accurate, they are isolated occasions.

6.89 **Issue VI - recommending Ioniten tablets as a hair regrowth medication knowing that it has not been approved for that purpose in Australia by the TGA**

Mr Cohen acknowledges that is inappropriate to recommend Ioniten in the knowledge that it is not approved by the TGA for the promotion of hair growth. He accepts that it is appropriate that the condition be placed on him that he informs his clients that Ioniten is not approved by the TGA in Australia to promote hair growth. Mr Cohen maintains that this was his practice.

6.90 **Issue VII - Whether Mr Cohen has endangered the health and safety of clients in providing them medication**

Mr Cohen denies that he supplied the first complainant with prescription only medication without a prescription. He also states that he did not make the representations claimed by the third complainant. Mr Cohen maintained that he gave information sheets setting out the risks of the medication supplied and that he explained the side effects verbally.

6.91 Mr Cohen further stated that the prohibition orders proposed by the HCCC were adequate to protect the public and that there was nothing to be gained by making a public statement.

7. Decision.

7.1 Mr Cohen provides a service that:

- Offers clients advice about the causes of hair loss and how to reverse its effects.
- Recommends and supplies to clients treatments using "Topical Solutions" which are a combination of prescription medication (minoxidil + retin A) and non prescription medications designed to stimulate hair growth.
- Recommends and supplies to clients prescribed oral medication such as finasteride (proscar) and Ioniten to stimulate hair growth
- Recommends and supplies to clients a number hygiene and herbal products as an aid for blocking DHT, the primary contributing factor in male pattern baldness (MPB)

I am satisfied the Mr Cohen is a health practitioner providing a health service for the purposes of the *Health Care Complaints Act 1993* and that the Code of Conduct for unregistered health practitioners as prescribed by regulation under section 10AM of

the *Public Health Act 1991* applies to him so far as his hair regrowth business is concerned.

Issue I – supply of medication contrary to the PTG Act 1966

7.2 On his own admission, Mr Cohen has been unlawfully supplying his clients with minoxidil, proscar and loniten, medications listed under schedule 2 and 4 of the PTGA 1966. Mr Cohen is not authorised to supply these medications to his clients. Mr Cohen's explanation is that he was unaware of the PTGA legislation and believed that he was acting as an authorised agent for his clients.

The PTGA contains specific requirements for record keeping and the writing and filling of prescriptions to ensure that they are not inappropriately obtained, and that the client is appropriately instructed in the use of the drug.

Mr Cohen admitted that on occasion he was not sure if the proscar and loniten he supplied to clients contained the relevant advisory information sheets. Mr Cohen has also stated that he supplied packets of proscar to his clients if he was aware that a prescription had been previously prescribed. I am satisfied that IHRB clients are not being appropriately advised as to the potential side effects of taking proscar and loniten or receiving the standard warnings which are normally enclosed in the packaging of prescription medication.

Issue II – supplying prescription only medication to clients using medication obtained under the prescriptions for other clients

7.3 The Commission obtained substantial evidence that Mr Cohen dispensed medication to clients for whom it was not prescribed, using medication obtained from prescriptions of other clients. Mr Cohen's evidence as to the extent of this practice was self-serving and unreliable. His initial evidence was that this occurred rarely, and, in response to the numerous examples produced to him he conceded that he had engaged in the practice to the extent of those examples but denied that it was his common practice. The Commission is in possession of evidence which suggests that this was the common practice of Mr Cohen.

I am satisfied that it was Mr Cohen's common practice to supply prescription-only medication to clients from medication he had obtained under the prescriptions for other clients. It should be noted that there is not enough firm enough evidence to reach a conclusion that Mr Cohen, in supplying to one patient with another patient's medication, supplied anything other than the medication prescribed for the patient receiving it.

Issue III – maintaining bulk supplies of medications for dispensing to clients

7.4 I am satisfied that Mr Cohen had an arrangement with a pharmacist whereby orders were placed by him for medication without production of relevant prescriptions and that, when this medication was not provided in the quantities prescribed by medical practitioners, he maintained bulk supplies of such medication to provide to other clients.

Issue IV – altering of prescriptions

7.5 Evidence obtained by the Commission is that two IHRB client prescriptions were altered from the amounts prescribed by medical practitioners enabling the prescriptions to be dispensed in a greater amount to that originally prescribed. Although it would be consistent with Mr Cohen's generally cavalier approach to the use of prescription medication I am unable to be satisfied that he altered these prescriptions.

Issue V – supply of prescription-only medications to clients who had not been provided with a prescription for that medication by a medical practitioner

7.6 The evidence of the second complainant is that he was sold loniten, proscar and 15% concentration minoxidil by Mr Cohen at IHRB premises on 2 September 2010 without a prescription. Mr Cohen denies selling the medication to the complainant saying that the complainant must have stolen it.

While Mr Cohen was not a reliable witness, it is also clear that the complainants in this matter have significant grievances against Mr Cohen due to his past treatment of them. Mr Cohen's general approach to the use of prescription medication, based on an examination of the documentary evidence, is that he does document the receipt of a prescription before providing it to a client.

Further investigation would be required to reach a determination on whether prescription-only medication had been provided on this one occasion without Mr Cohen first sighting a prescription. This does not appear to be necessary for the Commission's purposes of determining whether or not Mr Cohen breached the code of conduct for unregistered practitioners and the making of the necessary orders for the protection of the public health and safety.

Issue VI – recommending loniten tablets as a hair regrowth medication knowing that it has not been approved for that purpose in Australia by the TGA

7.7 Loniten is not an approved medication for hair regrowth in Australia. Loniten is a treatment for high blood pressure. Mr Cohen is aware of this and admitted as much. Mr Cohen's position is that if a medical practitioner prescribes loniten, it is that practitioner's responsibility to advise the patient of the effects of the medication. Mr Cohen takes no responsibility for advising his clients of status of the medication. Mr Cohen does not advise the potential prescribing doctors, of which he provides a list to clients, that the use of loniten tablets, in any formulation to promote hair growth, is not an approved indication. Mr Cohen states "my job is to try and get the utmost out of a customer to regrow his hair. That is my job".

I am satisfied that Mr Cohen not only failed to advise clients that loniten was not approved by the TGA and FDA(USA) for hair regrowth but also advised at least one client, probably more, that it was so approved.

Issue VII – Whether Mr Cohen's conduct was a risk public health and safety.

7.8 Mr Cohen has worked in the hair loss industry for many years. Over that time it has become his practice to treat prescription medication as one of the tools of his trade and to use it in the most expedient and profitable way. He maintains control over his clients' use of such medication by marketing it in conjunction with his own hair loss remedies. While the process may be convenient to clients, it allows Mr Cohen to provide the medication as his own treatment.

In conducting his business, Mr Cohen has become casual about the way in which this medication is provided to his clients. This has resulted in him providing prescription-only medication to clients without their prescriptions being filled and without adequate explanation of the side effects. This is both in breach of the law designed to ensure that medications with harmful effects are handled by properly qualified people and a risk to the health and safety of Mr Cohen's clients.

7.9 In terms of the Commission's jurisdiction, I find that Mr Cohen has breached Clause 3(1) of the Code of Conduct for unregistered health practitioners in that he has failed to provide health services in a safe and ethical manner.

8.0 Having determined that Mr Cohen has breached the Code of Conduct and that his conduct poses a risk to the health and safety of the public, the Commission makes the following prohibition order under section 41A(2)(a)(ii) of the *Health Care Complaints Act* placing conditions on Mr Cohen's practice:

1. Mr Cohen must not be in possession of any client prescriptions.

2. Mr Cohen must not obtain, supply or sell any medications requiring a prescription by a medical practitioner or required to be sold only by a pharmacist.

3. Mr Cohen must inform his clients that Ioniten is not approved in Australia by the Therapeutic Goods Administration when advising clients about hair regrowth prescription medication.

The conditions in the prohibition order will be permanent.

8.3 The Commission also issues the following public statement under section 41A(2)(b) of the *Health Care Complaints Act*:

"The Health Care Complaints Commission (the Commission) conducted an investigation into Mr Samuel Cohen and the Institute of Hair Regrowth and Beauty (IHRB).

The investigation found that Mr Cohen has been supplying and selling prescription and non prescription pharmacy-only medication directly to his clients and has been supplying clients with medication obtained from other clients' prescriptions. He has also been selling medication to clients without their prescriptions having been dispensed.

The medication provided by Mr Cohen had not been dispensed appropriately labelled with client and prescribing doctor's details and has not provided clients with important medicine warning information sheets as to the side effects of the medication. Mr Cohen has recommended the drug Ioniten to his clients as an approved medication in Australia for hair regrowth. Loniten is not approved by the Therapeutic Goods Administration (TGA) and the use of Ioniten tablets, in any formulation to promote hair growth, is not an approved indication.

Mr Cohen recommends to his clients topical solutions for application to the scalp which are a combination of minoxidil and topical retinoids such as retin A. Such a combination is not recommended by the TGA due to the possibility of enhanced minoxidil absorption and consequently increased potential for adverse reactions.

Mr Cohen has breached the code of conduct for unregistered health practitioners in that he has failed to provide health services in a safe and ethical manner and his provision of health services is a risk to public health and safety.

The Commission made a prohibition order under section 41A(2)(a)(ii) placing the following conditions on Mr Cohen's practice:

- Mr Cohen must not be in possession of any client prescriptions.
- Mr Cohen must not obtain, supply or sell any medications requiring a prescription by a medical practitioner or required to be sold only by a pharmacist
- Mr Cohen must inform his clients that Ioniten is not approved in Australia by the Therapeutic Goods Administration when advising clients about hair regrowth prescription medication.

The conditions in the prohibition order will be permanent.

Mr Cohen claims that the practice of directly supplying medication to clients is common throughout the hair regrowth industry. It is also evident that a number of General Practitioners have been prescribing Ioniten and minoxidil mixed with topical retinoids without being aware of relevant guidelines.

Given the complexity of the matter and the apparent public interest in the full circumstances being disclosed, the Commissions Statement of Decision will also be made public".

Kieran Pehm
Commissioner.

22 FEB 2011