Medical Centre
General Practitioner, Dr B

A Report by the
Health and Disability Commissioner

(Case 19HDC01558)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. This report concerns the inappropriate prescribing of medication to a woman in the course of managing her psoriasis — primarily, the prescribing of Neotigason in 2013, and the prescribing of steroids from 2012 to 2018. Mostly, her general practitioner (GP) prescribed the drugs in question, although other GPs at the medical centre were involved in the woman's care over this time.

2. In 2013, the GP prescribed the woman with Neotigason, a medication with a high frequency of causing severe and life-threatening birth defects to fetuses. However, at the time of prescribing, the GP failed to exclude pregnancy in the woman adequately or provide her with information about the harmful long-term effects of the medication. The woman underwent two terminations as a result of taking the medication.

3. Between 2012 and 2018, multiple GPs at the medical centre (including her GP) prescribed the woman with large amounts of Dermol cream, alongside other oral steroids, despite an alert on her file advising them to "[b]e cautious with scripting Dermol" as the woman was overusing it, and against the advice of two letters sent to the GP from the woman's dermatologist. The GPs also failed to advise the woman that overuse of Dermol could result in adverse side effects. In November 2018, the woman was diagnosed with drug-induced Cushing's syndrome caused by long-standing heavy use of topical and oral steroids.

Findings

General practitioner

4. The Commissioner found that the GP's prescribing failures were serious and numerous, and that he did not take appropriate care when prescribing the woman with both Neotigason and steroid medication. Accordingly, the Commissioner found the GP in breach of Right 4(1) of the Code. The Commissioner considered that the services provided by the GP did not minimise the potential harm to the woman or optimise the quality of her life, and, accordingly, that he breached Right 4(4) of the Code.

5. The Commissioner also considered that the GP did not provide the woman with adequate information about the medications he was prescribing, most notably that she should avoid pregnancy for at least two years after she stopped taking Neotigason, and that overuse of Dermol could result in adverse side effects. Accordingly, the Commissioner found the GP in breach of Rights 6(2) and 7(1) of the Code.

Medical centre

6. The Commissioner considered that the medical centre failed to deliver services to the woman with reasonable care and skill in that it had the information it needed to cease prescribing Dermol to the woman, yet its system failed to ensure that the information reached the prescribing clinicians; in addition, multiple GPs across a number of years did not follow MCNZ's guidelines, and did not take note of the information on the woman's file that strongly suggested that Dermol prescribing was inappropriate and unsafe.

Accordingly, the Commissioner found that the medical centre breached Right 4(1) of the Code.

7. The Commissioner considered that the deficiencies in coordination of the woman's care and overall clinical oversight were reflective of poor systems of care at the medical centre, and, accordingly, the Commissioner found the medical centre in breach of Right 4(5) of the Code.

Recommendations

8. The Commissioner recommended that the GP undertake an audit of patients for whom he has prescribed teratogenic medications in the past 12 months, to ensure that all prescribing requirements have been met, and attend the Medical Protection Society's workshop "Achieving safer and reliable practice"; undertake further training on informed consent; and provide a written apology to the woman.

9. The Commissioner recommended that the medical centre meet with all staff involved in the management of the woman to discuss the findings of this report; undertake an audit of all patients at the practice being prescribed steroids and teratogenic medication to ensure that the prescribing practice aligns with the relevant standards; provide HDC with an update on the effectiveness of the changes it has made since these events; undertake a review of a sample of patient long-term medication lists in the PMS, to ensure that they are current and accurate; remind all GPs at the practice of the importance of adding alerts to a patient's file for important external advice; consider introducing a policy regarding the prescribing of teratogenic medication to women of childbearing potential, requiring that such consumers are to receive written information about the medication, as well as provide their written consent to taking the medication before it is prescribed; and provide a written apology to the woman for its breach of the Code.

10. The Commissioner also recommended that the Medical Council of New Zealand undertake a competency review of the GP.

11. The GP and the medical centre were both referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act.

Complaint and investigation

12. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided by the medical centre and Dr B. The following issues were identified for investigation:

- *Whether the medical centre provided Ms A with an appropriate standard of care between 2012 and 2020.*

- *Whether Dr B provided Ms A with an appropriate standard of care between 2012 and 2020.*

13. The parties directly involved in the investigation were:

Ms A	Consumer
Medical centre/provider	
Dr B	General practitioner (GP)/provider

Also mentioned in this report:

Dr C	GP
Dr D	Dermatologist

14. In-house clinical advice was obtained from vocationally registered GP Dr David Maplesden (Appendix A).

Information gathered during investigation

Background

15. Ms A (aged in her thirties during the period of these events) had been a registered patient at the medical centre since 1986, and was registered with GP Dr B.[1] Ms A's medical history included the development of severe guttate psoriasis[2] in 2008, and her long-term medications included the topical steroids Daivobet[3] and Dermol.[4]

16. This report relates to the inappropriate prescribing of medication to Ms A in the course of managing her psoriasis, and concerns two main issues — the prescribing of Neotigason in 2013, and the prescribing of steroids from 2012 to 2018. Mostly, the prescribing in question was performed by Dr B, although many other GPs at the medical centre were involved in Ms A's care over this time.

Prescribing of Neotigason

17. This section of the report discusses the prescribing of Neotigason to Ms A by Dr B in 2013.

[1] Dr B is a vocationally registered GP with an annual practising certificate from the Medical Council of New Zealand. He is one of the partners who operate the medical centre.
[2] Psoriasis is a chronic autoimmune condition that causes the rapid build-up of skin cells, scaling on the skin's surface, inflammation, and redness. Guttate psoriasis is a type of psoriasis characterised by multiple small scaly plaques.
[3] A topical steroid ointment used only on skin affected by plaque-type psoriasis.
[4] A topical steroid cream used to help reduce inflammation, redness, and itchiness in areas affected by a skin disease.

Neotigason

18. Neotigason (generic name acitretin) is an oral retinoid[5] used in the treatment of severe psoriasis when the psoriasis is resistant to other forms of therapy. Neotigason is a powerful human teratogen[6] that has a high frequency of causing severe and life-threatening birth defects to fetuses. This risk can persist until the product has been completely eliminated from the patient's system, which can take at least two to three years following the end of treatment.

19. For this reason, Neotigason is strictly contraindicated in pregnant women and women of childbearing potential unless all of the conditions of the "Pregnancy Prevention Programme" are met (discussed in more detail in the "relevant standards" section below).

20. These conditions include ensuring that the patient understands the teratogenic risk of the medication, the need to undergo regular pregnancy testing before treatment, during treatment, and periodically for a period of three years after stopping treatment, as well as the need for effective contraception for one month before starting treatment, throughout the entire duration of treatment.

Prescribing and informed consent

21. On 9 October 2013, Ms A presented to Dr B at the medical centre for a check-up of her skin.

22. Dr B told HDC that at this appointment, Ms A did not appear to be responding well to the topical steroid therapies that she was using, and he had seen good responses from patients who had been treated with Neotigason. He said that he was mindful of the long-term risks of prolonged steroid use, and considered that trialling Ms A on Neotigason would mean that her psoriasis could be managed without so much steroid use.

23. Dr B told HDC:

> "While my memory of this consultation is not entirely clear, I can recall informing [Ms A] that Neotigason was teratogenic, and I explained that this meant it was very likely to be harmful to foetuses. I asked [Ms A] if there was a possibility that she might be pregnant, to which she responded there was not and that she was taking oral contraception."

24. Ms A told HDC that at this appointment, she can remember Dr B telling her that she had to use two forms of birth control while on Neotigason, but he did not tell her why. Ms A cannot remember whether she was on oral contraception at this time.

25. Dr B did not inform Ms A that the risks of Neotigason can persist for up to three years following the end of the treatment. In a letter to ACC, Dr B stated that he did not inform Ms A of how long the teratogenic effects of Neotigason could last because he himself was

[5] Retinoids are a class of chemical compounds that are derived from vitamin A or are chemically related to it.
[6] An agent or factor that causes malformation of an embryo.

not aware that they were so prolonged. He also noted that he did not supply Ms A with a copy of the information sheet regarding the drug, which does mention the long-term risks.

26. Dr B documented the appointment in Ms A's clinical notes as follows:

> "Here re[garding] skin. Lots of very small lesion[s]. Has some control with Dermol but the problem of long term skin safety. Discussed options. Will try Neotigason as long as bloods satisfactory … Contraception re-started."

27. Ms A was prescribed a 30-day supply of Neotigason that same day, along with a three-month supply of the oral contraceptive pill. Dr B did not perform a pregnancy test at this consultation. He told HDC that he was reassured that Ms A was taking oral contraception before he prescribed the Neotigason, but he accepts that he should have performed a pregnancy test at this consultation, and regrets omitting to do so.

28. Dr B subsequently completed a Pharmac Special Authority form for Neotigason, confirming that pregnancy had been excluded in Ms A prior to prescribing, and that Ms A had been informed not to become pregnant for at least two years following cessation of the medication.

29. Dr B did not complete a documented plan with respect to regular pregnancy testing, and there is no evidence of any subsequent steps taken to ensure that Ms A had reliable contraception for at least two years following cessation of the treatment.

First termination of pregnancy

30. On 8 November 2013, Ms A presented to the medical centre as she had taken three at-home pregnancy tests over the last 24 hours that all showed a positive result. She was seen by a GP, who documented in Ms A's clinical notes:

> "Not planning pregnancy.
> TAKING NEOTIGASON, stopped taking this today as aware of defects.
> Very concerned/anxious.
> Not sure what wanting to do with pregnancy.
> …
> [Impression]: pregnancy with teratogenic drug."

31. Ms A ceased taking Neotigason on this day, and did not resume taking it at any time after this.

32. A radiology maternity ultrasound was performed on 12 November 2013 and confirmed that Ms A was pregnant. The gestational age of the embryo was estimated at around six and a half weeks. A referral to the Early Pregnancy Clinic at the public hospital was sent from the medical centre, and stated:

> "Thank you for seeing [Ms A] urgently for advice/counselling regarding teratogenicity of [Neotigason]. She is currently 7 weeks' gestation in her second pregnancy … This pregnancy was not planned. She has been taking NEOTIGASON for her psoriasis since

> the 9th October … [Ms A] is understandably under a lot of emotional stress at the moment with regards to possibility of birth defects and thinking about continuation of pregnancy vs termination."

33. The decision was made to terminate the pregnancy, and the surgery was performed on 13 December 2013. Ms A had a complicated recovery and developed a postoperative infection from retained products following the surgery.

Second termination of pregnancy

34. Dr B next saw Ms A on 30 May 2014 and 4 September 2014 for further input into her skin issues. He did not prescribe her with any further contraception at these appointments. Dr B told HDC that he was aware that Ms A was seeing a gynaecologist around this time, and wrongly presumed that her contraception was being managed by her specialist. He stated: "In hindsight, I accept it would have been appropriate to inquire as to what method of contraception she was using."

35. On 24 March 2015, Ms A presented to the medical centre as she had had unprotected sex earlier that month and four at-home pregnancy tests had returned a positive result.

36. A referral was sent to the Day Surgery Unit of the public hospital on 1 April 2015, and stated:

> "[Ms A] finds herself pregnant again with a date of conception of the 1st March … There is an increased risk of foetal abnormality for 2–3 years after use of Neotigason. [Ms A] does not feel that she can continue with this pregnancy unsupported with the potential for foetal abnormality."

37. Ms A underwent a second termination of pregnancy on 10 April 2015. She told HDC that she was not informed about the dangerous effects of Neotigason. She is concerned that proper protocol and due diligence was not followed, and that this cost her the lives of two unborn babies.

38. Dr B told HDC that these events were a significant experience for him, and that he was devastated for Ms A. He stated that he met with her to apologise for what had happened, referred her for specialist treatment and counselling, and credited her account as a gesture of good faith. He told HDC that he has since ceased prescribing Neotigason to his patients.[7]

Prescribing of steroids

39. This section of the report discusses the prescribing of steroids to Ms A from 2012–2018, by multiple GPs at the medical centre, including Dr B.

[7] With the exception of one male patient who has taken Neotigason on a long-term basis under the supervision of a dermatologist. Dr B told HDC that he now prescribes isotretinoin (a retinoid used for the treatment of acne, and also a teratogen) instead of Neotigason.

40. Ms A was first prescribed Dermol cream by a dermatologist in October 2008 as treatment for her psoriasis. Dermol was listed as a long-term medication in Ms A's clinical file at the medical centre, and she was prescribed the cream regularly by Dr B and other GPs at the practice. The prescription was documented in her notes as:

> "0.05% oint[ment] 30g. [Quantity]: 2.
>
> Apply [twice daily] to affected areas once weekly [as needed.]"

41. Dr B told HDC that most of Ms A's prescriptions for Dermol were provided by telephone or as an aside at the end of a consultation regarding other health-related issues.

42. Throughout 2012 to 2018, Ms A also had some input into her care from the Dermatology team at the public hospital.

Prescribing of steroids between 2012 and 2018

43. On 29 August 2012, Dr C (a doctor at the medical centre at the time) sent Ms A a letter regarding her Dermol use, as he was concerned that she may have been overusing it. The letter stated:

> "After seeing you earlier in the week I took some time to review your notes regarding your psoriasis. I note that you have been prescribed quite a lot of Dermol by various doctors at our practice over the past 15 months and I am concerned that you may be overusing it. This is a concern because it suggests the psoriasis is not as well controlled as it could be and the overuse of this VERY strong steroid may be harming your skin and potentially the rest of your body."

44. In response to my provisional opinion, Ms A told HDC that she does not recall being sent this letter.

45. Dr C also placed an alert on Ms A's file in the medical centre's practice management system (PMS), which stated: "Be cautious with scripting Dermol, overusing." However, the alert was not observed, and between 29 August 2012 and 1 February 2014, Ms A was prescribed Dermol cream 15 times by six different doctors. Dr B was the prescriber for eight of these prescriptions.

46. The medical centre told HDC that at that stage the alert was one of many on Ms A's file, and, in this instance, important clinical alerts such as the alert that Dr C had placed on Ms A's file were buried under unnecessary administrative alerts. As a result, the important clinical alerts were being undermined by the non-clinical alerts.

47. On 1 February 2014, Ms A was reviewed by dermatologist Dr D at Dr B's request. On examination, Dr D noted that Ms A had obvious areas of skin atrophy[8] and striae[9] owing to the abuse of Dermol, and he was concerned that she had been using the cream at a rate of approximately one tube per day for a number of years.

[8] The wasting (thinning) or loss of body tissue or an organ.
[9] A form of scarring on the skin with an off-colour hue.

48. Dr D sent a letter to Dr B stating: "It is essential that [Ms A] never uses Dermol again." Dr D prescribed Ms A with Daivobet, a weaker steroid cream, to use daily instead of Dermol, and a plan was made for her to be reviewed by him again in four months' time.

49. Dr D's letter was received and scanned into the medical centre's PMS on 12 February 2014, and showed in Ms A's clinical notes as: "[Inbox] Scanned document — DERMATOLOGY."

50. Dr B acknowledged that he saw the letter, but stated that he did not see the sentence that advised against Ms A's use of Dermol. He told HDC:

> "I have no recollection of this advice from [Dr D]. I am also at a complete loss as to how or why this happened, but I omitted to note this advice in [Ms A's] notes, which meant the prescribing of the Dermol continued by the practice and other dermatologists involved in her care."

51. On 3 May 2014, Ms A was reviewed again by Dr D. Dr D noted in a letter to Dr B:

> "[Ms A's] psoriasis has flared since stopping the Dermol and she says that Daivobet is not controlling it. She has had a lot of stress recently which will not help [the] matter … I have advised that psoriasis can be quite unstable after coming off Dermol but she should certainly not restart this."

52. Dr D's second letter was received and scanned into the medical centre's PMS on 16 May 2014, and showed in Ms A's clinical notes as: "[Inbox] Scanned document — DERMATOLOGY." However, the advice stipulated in the letter was not noted in Ms A's clinical record. Dr B acknowledged that he saw this letter, and stated: "Again, I did not take on board that statement."

53. Between 12 February 2014 and 12 November 2015, Ms A was prescribed Dermol 19 times by three different doctors and, of these, Dr B was the prescriber 17 times.

54. On 12 November 2015, while Dr B was on leave, a locum GP prescribed Ms A with an increased dose of Dermol — six tubes a month instead of her usual two tubes a month — and inadvertently set this increased prescription as a routine long-term medication with repeats. The reason for this increase was not documented in Ms A's clinical notes. The medical centre told HDC that owing to the passage of time that has passed, and the locum GP not having worked at the practice for over four years, it is unable to explain why the Dermol was prescribed in this way.

55. The incorrect prescription dose was not detected by the other GPs at the practice. Between 12 November 2015 and 16 November 2018, Ms A was prescribed six 30g tubes of Dermol a further 11 times, by two doctors. Dr B was the prescriber for eight of these prescriptions.

56. The medical centre told HDC that at the time of these events, the repeat prescribing system at the practice allowed for a script to be pre-printed and signed by the GP, without the GP having the patient's file open. The medical centre stated:

> "Because the prescription moving forward showed in [Ms A's] notes as a long-term medication with repeats, any prescription requests from [Ms A] moving forward from that date were signed off by several of the GPs at the practice, so several of the GPs at the practice were at fault."

57. The medical centre told HDC that at all times, practitioners had access to all patients' medical notes as they required, including when signing repeat prescriptions. The medical centre stated that it is a practitioner's personal responsibility to decide whether a review of a patient's medical notes is necessary before signing a prescription.

58. Between 2016 and 2018, Ms A was also prescribed both short and prolonged courses of prednisone[10] approximately 17 times alongside the Dermol cream. The prescribing was performed by various doctors including Dr B, who initiated the prednisone prescribing for Ms A's "moderately severe perioral dermatitis[11]" on 25 January 2016. The rationale for prescribing the oral steroids over this period was documented by the doctors as treatment for various skin conditions, recorded as folliculitis,[12] psoriasis, polymorphic light eruption,[13] and perioral dermatitis. However, on multiple occasions, prednisone was prescribed by Dr B with no documentation of his rationale for prescribing.

Development of Cushing's syndrome[14]

59. On 16 November 2018, Ms A presented to the medical centre to query whether she had Cushing's syndrome, after a friend had noticed her stretch marks and wondered whether this was the cause. Ms A was seen by a GP, who noted that Ms A had been using an "excessive" amount of Dermol — around 2.5 kilograms per year over the last few years.

60. The GP diagnosed Ms A with likely drug-induced iatrogenic[15] Cushing's syndrome caused by a long-standing heavy use of topical and oral steroids. An urgent dermatology referral was sent to the public hospital for further management. Subsequently, endocrine testing and investigations were performed, and Ms A's diagnosis of Cushing's syndrome, along with adrenal insufficiency,[16] was confirmed on 28 February 2019.

61. Dr B told HDC that it is clear that there were several occasions when the scripting of Dermol could have, and should have, been queried. He stated: "I accept that I missed the written warnings regarding the scripting of Dermol, which I deeply regret."

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[10] An oral steroid that prevents the release of substances in the body that cause inflammation.
[11] An inflammatory rash involving the skin around the mouth.
[12] A common skin condition in which hair follicles become inflamed.
[13] A rash caused by sun exposure in people who have developed sensitivity to sunlight.
[14] A condition that occurs from exposure to high cortisol levels for a long time. The most common cause is the use of steroid drugs. Signs are a fatty hump between the shoulders, a rounded face, and pink or purple stretch marks.
[15] Relating to illness caused by medical examination or treatment.
[16] A condition in which the adrenal glands do not produce adequate amounts of steroid hormones.

62. The medical centre acknowledged that prescribing errors had been made by a range of GPs at the practice. It stated:

> "The practice can only sincerely apologise again to [Ms A] for the outcome of the Dermol prescribing by the practice and ensure her that we continue to be very proactive to ensure that prescribing from the practitioners working at the practice is safe."

63. Ms A did not wish to continue seeing Dr B, as she had felt let down by him for a second time, and switched registration to another GP at the practice.

Information provided to Ms A about Dermol

64. Dr B told HDC that given the length of time that has passed since these events, he cannot recall the details of his conversation with Ms A regarding the risks and side effects of using Dermol. He believes that in those circumstances, he would have advised her to apply it in a manner consistent with her prescription, and would have told her that it is a potent product that can have long-term side effects, in particular the thinning of the skin.

65. Dr B told HDC that up until this case, he was not aware that topical steroids could cause Cushing's syndrome.

66. Ms A stated that she was told that the cream would eventually thin her skin, but was not told that this would cause stretchmarks, or that her veins and blood vessels would be able to be seen. She also said that she was never told that the overuse of Dermol could lead to Cushing's syndrome. She told HDC:

> "I also presumed my doctors would check and keep an eye on my skin, which they did many times over the years so I never worried about it. If I had been told what would truly happen there is no way I would ever have used that cream, it has ruined my life."

Further information

Medical centre

67. The medical centre told HDC that throughout this complaint, it has identified shortcomings in its systems and policies. It stated:

> "We have undertaken to remedy these shortcoming[s] and continue to improve using Cornerstone[17] as our benchmark standard for the practice and in our patient care."

68. Since these events, the practice has moved to e-prescribing as a further safeguard to correct any prescribing errors, as any repeat requested by a patient must now be reviewed directly on the computer record by the signing GP before the prescription can be sent to the pharmacy. The new system also alerts GPs if the prescription is not in range of the prescribing recommendations.

[17] Cornerstone is a programme that assesses practices using the "Aiming for Excellence standard". The programme is coordinated by the practice assessment team at the Royal New Zealand College of General Practitioners. The medical centre told HDC that the practice received Cornerstone accreditation in 2015.

69. In addition, the practice has been actively clearing up all patient alerts to ensure that administration alerts do not obstruct clinical or critical alerts intended for GPs. All staff have been involved to clear any alerts that are no longer valid, and a dedicated nurse is working through the thousands of alerts on patients' files for correction. The practice stated that this process is ongoing.

70. The medical centre told HDC that it has also provided more training to its locums, and has enlisted a dermatologist to provide specialist training to its GPs on the appropriate use of steroids, the management of psoriasis, and ensuring the safety of female patients when prescribing isotretinoin.[18]

Dr B

71. Dr B told HDC that he is extremely sorry for what has happened to Ms A, and for the impact this has had, and continues to have on her. He said that he has spent a significant amount of time reflecting on the deficiencies in his care and the systemic issues at the practice, which played a part in what happened. He stated:

> "I have reflected on my role in [Ms A's] care at length and I deeply regret that I did not provide [Ms A] with the highest level of care. It is for this reason that I have taken steps to improve my practice and to support [Ms A] in any way that I can."

72. Dr B told HDC that since these events, he has lengthened his consultation times with his patients and takes more time to read and review incoming correspondence. He stated that he now also has a lower threshold for seeking specialist input into care for patients who present with dermatology issues.

Response to provisional opinion

73. Ms A was provided with the opportunity to comment on the "information gathered" section of the provisional opinion, and her comments have been incorporated into this report where relevant. In addition, Ms A highlighted the significant and ongoing impact from the management of the Neotigason and steroids. She stated:

> "I should have been protected, I should have been safe. Instead I had to bury 2 of my children, live with years of pain and will forever have extreme skin issues that will cause me delayed wound healing, infections, skin tears, not to mention what will happen to me when I am older."

74. The medical centre was provided with the opportunity to comment on the provisional opinion, and accepted that deficiencies in its systems likely contributed to the shortcomings in the care Ms A received at the medical centre. However, the medical centre does not accept that responsibility for clinical decision-making, including the prescribing of Ms A's medication, lay with the medical centre, and submitted that ultimately this responsibility rests with the individual practitioner exercising their professional judgement.

[18] A retinoid medication used for the treatment of acne. Isotretinoin can cause birth defects.

75. Dr B was provided with the opportunity to comment on the relevant sections of the provisional opinion. He stated that it is an understatement to say that HDC's investigation and knowledge of the adverse effects these events have had on Ms A have been a salutary lesson, and that in his 38 years of practice, he has always prided himself on providing the highest standards of care to his patients, and is disappointed that he did not do so in this case.

Relevant standards

76. The New Zealand Medsafe data sheet for acitretin (Neotigason) stipulates that it is highly teratogenic and is contraindicated in women of childbearing potential unless all of the following conditions of the Pregnancy Prevention Programme are met:

> "• [The patient] has severe forms of psoriasis …
> …
> • She understands the teratogenic risk.
> • She understands the need for rigorous follow-up on a monthly basis.
> • She understands and accepts the need for effective contraception, without interruption, 1 month before starting treatment, throughout the entire duration of treatment and for 3 years after the end of treatment …
> …
> • She is informed and understands the potential consequences of pregnancy and the need to rapidly consult if there is a risk of pregnancy or if she might be pregnant.
> • She understands the need and accepts to undergo regular pregnancy testing before, ideally monthly during treatment and periodically with 1–3 monthly intervals for a period of 3 years after stopping treatment …
> • She has acknowledged that she has understood the hazards and necessary precautions associated with the use of acitretin.
> …"

77. The data sheet also stipulates that the prescriber of acitretin must ensure:

> "• The patient complies with the conditions for pregnancy prevention as listed above, including confirmation that she has an adequate level of understanding.
> • The patient has acknowledged the aforementioned conditions.
> • The patient understands that she must consistently and correctly use one highly effective method of contraception (i.e. a user-independent form) or two complementary user-dependent forms of contraception, for at least 1 month prior to starting treatment and is continuing to use effective contraception throughout the treatment period and for at least 3 years after cessation of treatment.
> • Negative pregnancy test results have been obtained before, during and periodically with 1–3 monthly intervals for a period of 3 years after stopping treatment. The dates and results of pregnancy tests should be documented.

…

If pregnancy occurs after stopping treatment there remains a risk of severe and serious malformation of the foetus. This risk persists until the product has been completely eliminated, which is within 3 years following the end of treatment."

78. The New Zealand Medsafe data sheet for Dermol (dated June 2018) states:

"**Use in psoriasis**

Topical corticosteroids should be used with caution in psoriasis as rebound relapses, development of tolerances, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin have been reported in some cases. If used in psoriasis careful patient supervision is important."

79. In April 2010, the Medical Council of New Zealand published standards for "Good prescribing practice". These were updated in November 2016. The standards published in April 2010 state:

"You should only prescribe medicines or treatment when you have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's needs and are therefore satisfied that the medicines or treatment are in the patient's best interests. Doctors should be familiar with the indications, side effects, contraindications, major drug interactions, appropriate dosages, effectiveness and cost-effectiveness of the medicines that you prescribe."

80. The Medical Council of New Zealand's updated publication on "Good prescribing practice" (November 2016) states:

"[I]t is important that any system for issuing a repeat of an earlier prescription issued to a patient takes full account of the obligations to prescribe responsibly and safely and that the doctor who signs the prescription takes responsibility for it."

81. It also states that before signing a repeat prescription, the prescriber must be satisfied that secure procedures are in place to ensure that:

"
- The patient is issued with the correct prescription.
- Each prescription is regularly reviewed so that it is not issued for a medicine that is no longer required.
- The correct dose is prescribed for medicines where the dose varies during the course of the treatment.
- You have appropriate information available (which may include access to the patient's clinical records) so that you can review the appropriateness of the repeat prescription.
- Any subsidy conditions that have changed since the last prescription (such as a change to subsidised medicines or a change to the patient's Dispensing Frequency requirements) are amended by you on the prescription.

- You review all relevant information before completing the prescription, and ensure that the patient record is maintained and updated.
- Repeat prescriptions should include details about the number of the repeats allowed within a given time frame and, for the patient's benefit, clear instructions relating to the dosage including quantity, frequency and route."

Opinion: Medical centre — breach

82. Ms A has been a registered patient of the medical centre since 1986 and has a history of severe psoriasis. During the period of 2012 to 2018, Ms A was regularly prescribed a topical steroid, Dermol, alongside oral steroids for the treatment of her psoriasis. During this time and as early as 2012, the medical centre had information and alerts in its system that Ms A was overusing Dermol. Additional letters were received by the practice from specialist dermatologists advising that Ms A should never use or restart Dermol again. Despite this, multiple GPs at the medical centre continued to prescribe high quantities of Dermol to Ms A. Between 2012 and 2018, Ms A was prescribed Dermol approximately 44 times at a rate of about 2.5 kilograms per year. As a result of the overuse of steroids, on 28 February 2018, Ms A was diagnosed with drug-induced Cushing's syndrome and adrenal insufficiency.

83. As Ms A's registered medical practice, the medical centre was responsible for having adequate systems in place to ensure that Ms A's long-term medications were being prescribed appropriately. In my opinion, there were deficiencies in the standard of care provided to Ms A by the medical centre in three respects.

84. First, the medical centre's administrative system was cluttered with alerts. The medical centre told HDC that at the time of these events, the Dermol alert was one of many on Ms A's file. The practice stated that in this instance, important clinical alerts such as the alert that Dr C had placed on Ms A's file were being buried under unnecessary administrative alerts. As a result, the clinical alert about Ms A's overuse of Dermol was missed, and she continued to be prescribed large amounts of the medication by multiple GPs at the practice for six years after the alert was placed on her file.

85. Second, at the time of these events, the repeat prescribing system at the medical centre allowed for a script to be pre-printed and signed by the GP, without the GP having the patient's file open. The medical centre told HDC that its practitioners had access to all patients' medical notes as they required, including when signing repeat prescriptions, and stated that it is a practitioner's personal responsibility to decide whether a review of a patient's medical notes is necessary before signing a prescription.

86. My in-house advisor, GP Dr David Maplesden, noted that the repeat prescribing practice at the medical centre at the time of events "meant the GP did not have to access the patient notes to complete the prescription and possibly contributed to the patient 'alert' discussed being missed by the GP". Medical centres need robust systems in place to ensure the

facilitation of communication and cooperation between each doctor, and this is even more vital when a patient is seeing multiple providers. I acknowledge the medical centre's submission that the practitioners had a personal responsibility in deciding whether or not to access and review patients' clinical notes before prescribing. However, the prescribing system in place at the time meant that GPs did not have to look at the patient's file, even though they could have. This enhanced the potential for alerts to be missed.

87. I note that the medical centre has since moved to e-prescribing, and that any repeat prescription requested by a patient must now be reviewed directly on the computer record by the signing GP before the prescription can be sent to the pharmacy.

88. Third, there was a pattern of poor care at the medical centre, whereby multiple GPs, across a number of years, did not take note of information on Ms A's file that clearly stated that Dermol prescribing was inappropriate and unsafe. On 29 August 2012, a doctor at the medical centre became concerned about the amount of Dermol that Ms A was using. He placed an alert on her file that stated: "Be cautious with scripting Dermol, overusing." The alert was not observed by the GPs at the medical centre, and between 29 August 2012 and 1 February 2014, Ms A was prescribed Dermol cream 15 times by six different doctors.

89. The medical centre received two letters from Ms A's specialist dermatologist, on 12 February and 16 May 2014, advising against Ms A's use of Dermol. The letters were scanned into Ms A's file, but were not observed by the GPs at the medical centre. Between 12 February 2014 and 12 November 2015, Ms A was prescribed Dermol 19 times by three different doctors.

90. On 12 November 2015, a locum GP prescribed Ms A with an increased dose of Dermol, and set this as a routine long-term medication with repeats. There was no documented clinical rationale for the increase. Again, the GPs at the medical centre failed to observe or correct this error, and between 12 November 2015 and 16 November 2018, Ms A was prescribed the increased dose of Dermol 11 times, by two different doctors.

91. In response to my provisional opinion, the medical centre submitted that the failures that occurred were a result of individual clinical decision-making, and that the practice was not responsible for the clinical decision-making of its doctors. I disagree. While there is certainly individual accountability and clear standards that place obligations on individual providers for safe and adequate prescribing, in my view the multiple failures by numerous staff over several years demonstrate a pattern of poor care, reflecting the inadequacies of the practice management system for prescribing, for which the medical centre had responsibility.

92. Had the prescribing practice involved the GP having direct access to the patient's clinical notes at the time of prescribing, and had important clinical alerts not been cluttered with administrative alerts on patient files and overlooked by multiple staff, these factors would have supported GPs at the medical centre to ensure that their prescribing was appropriate and safe. I am critical that the medical centre had the information it needed to monitor Ms

A's use of Dermol, and that it could have facilitated the limitation or cessation of prescribing Dermol to Ms A, yet its system failed to ensure that the information reached the prescribing clinicians. As a result, Ms A unintentionally overused steroids and was diagnosed with drug-induced Cushing's syndrome and adrenal insufficiency.

93. For failing to facilitate the appropriate prescribing of steroids to Ms A, I find that the medical centre breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[19]

94. Furthermore, the poor practice management systems led to ineffective communication and cooperation between the various GPs who saw Ms A, as well as between the GPs and the various external dermatologists. This Office has stated previously[20] that care must be seen as a continuum, and individual and system behaviour must reflect that continuum. Care must be integrated and collaborative — particularly for patients who see multiple GPs. Doctors and their systems must be connected with each other intentionally. Patients will receive better care as a result. The deficiencies in coordination of Ms A's care and overall clinical oversight are reflective of poor systems of care at the medical centre, in breach of Right 4(5)[21] of the Code.

Opinion: Dr B — breach

Introduction

95. Dr B had been Ms A's registered GP at the medical centre since 1986, and was the main clinician involved in the management of Ms A's severe psoriasis. In 2013, Dr B commenced Ms A on Neotigason for treatment of her psoriasis, and over the period of 2012–2018 he was Ms A's main prescriber of Dermol and oral steroids.

96. As a healthcare provider, Dr B had an obligation to comply with the Code, and relevant standards such as the Medical Council's statement on "Good prescribing practice" when providing Ms A with care. It is evident that on multiple occasions Dr B failed to observe his obligations, and let down Ms A as a result.

Care provided to Ms A

Prescribing of Neotigason

97. On 9 October 2013, Ms A presented to Dr B at the medical centre for assistance with her psoriasis. At this appointment, Dr B prescribed Ms A with a 30-day supply of Neotigason. This is an oral retinoid used in the treatment of severe psoriasis when the psoriasis is resistant to other forms of therapy. It is a powerful human teratogen with a high frequency of causing severe and life-threatening birth defects to fetuses.

[19] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."
[20] HDC case 19HDC00536, available at https://www.hdc.org.nz.
[21] Right 4(5) states: "Every consumer has the right to co-operation among providers to ensure quality and continuity of services."

98. The New Zealand Medsafe data sheet for Neotigason stipulates that it is strictly contraindicated in pregnant women and women of childbearing potential unless all of the conditions of the "Pregnancy Prevention Programme" are met, and that the prescriber must ensure that:

- The patient is on effective contraception, without interruption, for one month before starting treatment, throughout the entire duration of the treatment, and for three years after the end of treatment.
- A negative pregnancy test result has been obtained before, during, and periodically within 1–3 monthly intervals for a period of three years after stopping treatment. The dates and results of pregnancy testing should be documented.

99. The data sheet also states that if pregnancy occurs after stopping treatment, there remains a risk of severe and serious malformation of the fetus within three years following the end of treatment.

100. At the 9 October consultation, Dr B documented: "Will try Neotigason as long as bloods satisfactory … Contraception restarted." Dr B did not carry out a pregnancy test for Ms A. He wrote a prescription for a three-month supply of the oral contraceptive pill. Dr B told HDC that his memory of the consultation is "not entirely clear", but he recalls asking Ms A whether there was a possibility that she might be pregnant, to which she responded that she was not and was taking oral contraception. This is not documented. Ms A told HDC that she cannot remember whether she was on oral contraception at this time.

101. Subsequently, Dr B completed a Pharmac Special Authority form for Neotigason, confirming that pregnancy had been excluded in Ms A prior to prescribing, and that Ms A had been informed not to become pregnant for at least two years following cessation of the medication. However, Dr B has accepted that he had in fact done neither of those things. In addition, there is no documented evidence that Dr B continued to prescribe contraception or carry out periodic pregnancy tests as recommended for a period of three years after stopping treatment. Dr B told HDC that he "wrongly presumed" that Ms A's gynaecologist was managing her contraception. He accepts that it would have been appropriate to enquire as to what method of contraception Ms A was using.

102. Dr B advised that at the time of prescribing Neotigason to Ms A, he was not aware that the teratogenic risks of the medication were so prolonged.

103. On 8 November 2013 (one month after commencing Neotigason), Ms A presented to the medical centre because she was pregnant. Subsequently, Ms A underwent a termination. On 24 March 2015 (around 16 months after the initiation of Neotigason), Ms A again presented to the medical centre because she was pregnant, and underwent a further termination at this time.

104. My in-house clinical advisor, GP Dr David Maplesden, stated:

> "I believe [Dr B] failed to follow recommended and accepted practice with respect to prescribing of [Neotigason] for a female patient of child-bearing potential, and he failed to follow the general prescribing principles."

105. Dr Maplesden concluded that Dr B's management of Ms A would be met with severe disapproval by his peers.

106. I accept Dr Maplesden's advice. In my view, Dr B did not satisfy himself sufficiently that Ms A had been taking oral contraception for at least one month prior to the initiation of Neotigason. Dr B's clinical note stating that contraception had been "restarted" suggests that Ms A was not on oral contraception without interruption for one month prior to commencing treatment. With hindsight, it is clear that Ms A was, in fact, not on adequate contraception given her positive pregnancy test soon after commencing Neotigason.

107. I am also very concerned about the complete lack of pregnancy testing prior to, during, and after treatment, and this is compounded by a lack of evidence indicating that there was a concerted effort to ensure that Ms A remained on contraception during and after treatment.

108. I am critical of Dr B's deficit in knowledge around the long-term teratogenic effects of Neotigason. I would have expected a GP of Dr B's experience to have made himself aware of current guidance about, and risks of, treatment prior to prescribing it to patients.

109. Lastly, I am critical that Dr B provided false information on the Pharmac Special Authority form. This was an opportunity for him to realise his errors, and he failed to do so, and instead provided false information on the form.

110. In my view, Dr B's prescribing of Neotigason was both incompetent and unsafe.

Prescribing of steroids

111. Whilst Dr B was not the initial prescriber of Ms A's Dermol cream, he was Ms A's usual and registered GP, and the main prescriber of the medication from 2012 to 2018. In this time, Ms A was prescribed Dermol 44 times, and Dr B was the prescriber for 33 of those 44 times. During this period, he also concurrently prescribed Ms A with oral steroids for her various skin concerns. On 28 February 2018, Ms A was diagnosed with drug-induced Cushing's syndrome and adrenal insufficiency. Dr B told HDC that up until this case, he was not aware that topical steroids could cause Cushing's syndrome.

112. In addition to the clinical alert on Ms A's file, which read, "Be cautious with scripting Dermol, overusing," Dr B was sent two separate letters from dermatologist Dr D warning against any future use of Dermol for Ms A, owing to concerns around her safety. Dr B acknowledged that he read the letters, but he failed to action and adhere to the advice in the letters. In Ms A's clinical notes, there is a brief reference to the dermatology letters with the words "[Inbox] Scanned document — DERMATOLOGY", but there is no explicit reference to the important advice and warnings within the letters, and no further alert was placed on Ms A's file. The failure to document the advice from the letters in Ms A's

clinical record further enabled the medication to be prescribed by both Dr B and other GPs at the practice for a number of years.

113. Dr B acknowledged that it is clear that there were several occasions when the scripting of Dermol could have, and should have, been queried, and stated: "I accept that I missed the written warnings regarding the scripting of Dermol, which I deeply regret."

114. Dr Maplesden advised that his peers would be concerned at the following aspects of Ms A's management:

> "a. The failure by [Dr B] to adequately monitor and appropriately limit [Ms A's] use of Dermol ointment, particularly after concerns were raised by a colleague in August 2012 and an alert placed on the file.
>
> b. The failure by [Dr B] to note and follow the specialist advice provided to him by [Dr D] in February and May 2014 regarding the signs of steroid misuse [Ms A] was already exhibiting and the need to stop any further prescribing of Dermol. The failure to place any further alert on the file or reference to the specialist letters means subsequent providers were not aware of the explicit advice provided by [Dr D]."

115. Furthermore, Dr Maplesden advised that he was concerned about Dr B's prescribing of oral steroids for treatment of a rash diagnosed as perioral dermatitis in January 2016, and stated that "such therapy is not indicated for treatment of that condition and can worsen the condition".

116. Dr Maplesden concluded that Dr B's management of Ms A's steroid use as discussed above departed from accepted practice to at least a moderate degree.

117. I accept Dr Maplesden's advice. Dr B had a responsibility to prescribe Dermol appropriately. He was provided with three separate warnings against prescribing Ms A with Dermol, and failed to note and adhere to the warnings. This is of significant concern. I am also concerned at his apparent lack of knowledge of the side effects of prolonged high volume usage of Dermol. Dr B's excessive and inappropriate prescribing of both topical and oral steroids to Ms A shows a lack of care and skill, as well as a disregard for Ms A's safety.

Conclusion — standard of care

118. Dr B's prescribing failures in this case were serious and numerous. Ms A trusted Dr B to know what he was doing, and on multiple occasions he let her down. I am concerned about the following aspects of the care Dr B provided:

<u>Neotigason</u>

- The failure to satisfy himself sufficiently that Ms A had been taking oral contraception for at least one month prior to commencing treatment;

- The lack of any pregnancy testing prior to, during, and after treatment, compounded by a lack of evidence indicating that there was a concerted effort to ensure that Ms A remained on contraception during treatment and for three years after treatment;
- Dr B's deficit knowledge around the long-term teratogenic effects of Neotigason; and
- The completion of a Pharmac Special Authority form for Neotigason with false information.

Steroids

- The inappropriate prescribing of Dermol and the failure to recognise, monitor, and limit Ms A's excessive use of Dermol, despite the letter from his colleague and the alert placed on her file in 2012;
- The failure to follow specialist dermatology advice on two occasions, and to place a further alert on Ms A's file and/or document the advice in her clinical record;
- The prescription of prolonged courses of oral steroids for unspecified skin conditions, including in 2016 for perioral dermatitis, when oral steroids are not indicated for this condition and can make it worse.

119. Dr B did not take appropriate care when prescribing Ms A with both Neotigason and steroid medication. Accordingly, I find Dr B in breach of Right 4(1) of the Code.

120. As a result of Dr B's failure to take the necessary steps before and after prescribing Neotigason, Ms A became pregnant while she was experiencing the effects of a teratogenic medication, and underwent the trauma of two terminations. Furthermore, as a result of the failure to monitor, limit, and adhere to numerous warnings about the risks of Dermol, Ms A's continued long-term high volume use led to a diagnosis of Cushing's disease. In these circumstances, Dr B did not provide services in a manner that minimised the potential harm to, and optimised the quality of life of, Ms A. Accordingly, I find that Dr B also breached Right 4(4)[22] of the Code.

Information provided to Ms A

121. Informed consent is at the heart of the Code. Under Right 6(2), "Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstance, needs to make an informed choice or give informed consent." Under Right 7(1), "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent."

Neotigason

122. Dr B told HDC that whilst his memory of the consultation in which he prescribed Ms A with Neotigason is not entirely clear, he can recall informing her that the medication is teratogenic, and explaining that this means that it is very likely to be harmful to fetuses. Ms A told HDC that she can remember Dr B telling her at this appointment that she had to

[22] Right 4(4) states: "Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer."

use two forms of birth control while on Neotigason, but he did not tell her why. Dr B stated that he did not inform Ms A of how long the teratogenic effects of Neotigason could last because he himself was not aware that they were so prolonged.

123. Ms A appears to have been aware that Neotigason could cause birth defects, as the notes of her presentation to the medical centre on 8 November 2013 state: "TAKING NEOTIGASON, stopped taking this today as aware of defects." However, it is clear that Dr B did not inform Ms A that the teratogenic effects of Neotigason can last up to three years after cessation of treatment.

124. As mentioned above, Ms A went on to have two pregnancy terminations in 2013 and 2014 whilst using and after stopping Neotigason respectively.

125. The Pharmac Special Authority form that is to be completed when prescribing Neotigason requires the prescriber to confirm that they have informed the patient not to become pregnant for at least two years following cessation of the medication.

126. The New Zealand data sheet for Neotigason states that it is contraindicated in women of childbearing potential unless the strict conditions of the Pregnancy Prevention Programme are met. This includes ensuring that the woman has acknowledged and understands the need to prevent pregnancy while taking the medication, and for three years after the end of treatment.

127. Dr Maplesden advised:

> "It is apparent [Dr B] did not advise [Ms A] of the risks of [Neotigason] teratogenicity extending for at least two years following cessation of the drug, and of the need for reliable contraception over this period. … [T]he primary responsibility lay with [Dr B]."

128. I agree. In my view, the risk of teratogenicity extending for at least two years after ceasing treatment with Neotigason is information that Ms A, as a woman in her thirties of childbearing potential, could reasonably have expected to receive, prior to deciding whether to commence treatment. I am critical that Dr B failed to inform Ms A accordingly. This could have gone some way in preventing the second termination of pregnancy in 2014.

Dermol

129. Regarding the information that would be expected to be given to a patient using Dermol, Dr Maplesden advised:

> "[I]t would be expected that a patient is given fairly explicit instructions and warnings when a potent or ultra-potent steroid cream is prescribed including where to use it and where not to use (eg not on face or flexures), how much to use and how long it can be used for (usually in association with 'step-down' therapy to less potent steroids after a fixed period) and the risks of not following instructions including permanent skin damage."

130. As outlined above, Ms A had a long history of severe psoriasis, and her regular medication included large quantities of Dermol. It is well established that overuse of steroids can lead to the development of adverse side effects, including Cushing's syndrome.[23] Accordingly, I consider that it was reasonable for a consumer in Ms A's circumstances to expect to be given clear instructions for using Dermol, and be warned of the risks of overusing it.

131. During the course of Dr B's prescribing of Dermol to Ms A, he did not warn her against overusing it, and advise her of the risks of doing so. As mentioned above, she went on to develop significant side effects such as skin atrophy, striae, and eventually drug-induced Cushing's syndrome.

132. The Medical Council of New Zealand's published standards for "Good prescribing practice" also stipulate that doctors should be familiar with the side effects of the medicines that they prescribe.

133. I endorse the MCNZ's published standards. In the context of long-term and high-volume prescribing of Dermol to Ms A, I am critical that Dr B failed to inform her that overuse of the cream could increase her chance of developing harmful side effects. In my view, the onset of Cushing's disease was preventable, and adequate information around the risks of Dermol could have assisted this.

Conclusion

134. In summary, Dr B failed to provide the following information about the medications he was prescribing to Ms A:

- That she should avoid pregnancy for at least two years after she stopped taking Neotigason. This is information that a woman in her thirties of childbearing potential ought to have been informed of prior to deciding whether she should commence the treatment.
- That overuse of Dermol could result in adverse side effects.

135. This failure contributed to the adverse consequences for Ms A by depriving her of the opportunity to be reasonably informed of the risks, give informed consent to treatment with Dermol and Neotigason, and participate in her own care. Accordingly, I find that Dr B breached Rights 6(2) and 7(1) of the Code.

Recommendations

136. I recommend that Dr B:

a) Undertake an audit of any patients for whom he has prescribed teratogenic medications in the past 12 months to ensure that all prescribing requirements have

[23] https://dermnetnz.org/topics/topical-steroid/

been met. The outcome of the audit is to be sent to HDC within six months of the date of this report.

b) Attend the Medical Protection Society's workshop "Achieving safer and reliable practice". Dr B is to report back to HDC within six months of the date of this report, with details of the content of the training and evidence of having attended.

c) Undertake further training on informed consent, and provide HDC with evidence that the training has been completed, within six months of the date of this report.

d) Provide a written apology to Ms A for his breaches of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Ms A.

137. I recommend that the medical centre:

a) Meet with all staff involved in the management of Ms A to discuss the findings of this report, including the importance of monitoring steroid use, informed consent, following the Medical Council of New Zealand's "Good prescribing practice" guidelines, and the current medical guidance on the management of psoriasis. The medical centre is to provide HDC with minutes of this meeting within four months of the date of this report.

b) Undertake an audit of all patients at the practice being prescribed steroids and teratogenic medication to ensure that the prescribing practice aligns with the relevant standards. If the audit does not indicate 100% compliance, the medical centre should consider what further improvements could be made to its system. The results of the audit are to be sent to this Office within six months of the date of this report.

c) Provide HDC with an update on the effectiveness of the changes it has made since these events. The update is to be sent to HDC within six months of the date of this report.

d) Undertake a review of a sample of patient long-term medication lists in the PMS, to ensure that they are current and accurate. Evidence that this has been done is to be sent to HDC within six months of the date of this report.

e) Remind all GPs at the practice of the importance of adding alerts to a patient's file for important external advice.

f) Consider introducing a policy regarding the prescribing of teratogenic medication to women of childbearing potential, requiring that such consumers are to receive written information about the medication, as well as provide their written consent to taking the medication before it is prescribed. The outcome of this consideration is to be sent to HDC within four months of the date of this report.

g) Provide a written apology to Ms A for its breaches of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Ms A.

138. I recommend that the Medical Council of New Zealand undertake a competency review of Dr B.

Follow-up actions

139. Dr B will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken.

140. The medical centre will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken.

141. A copy of this report with details identifying the parties removed, except the name of the expert who advised on this case, will be sent to the Medical Council of New Zealand and the Royal New Zealand College of General Practitioners, and they will be advised of Dr B's name.

142. A copy of this report with details identifying the parties removed, except the name of the expert who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Addendum

143. The Director of Proceedings decided to issue proceedings in the Health Practitioners Disciplinary Tribunal.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from Dr David Maplesden:

"1. Thank you for the request that I provide clinical advice in relation to the complaint from [Ms A] about the care provided to her by [Dr B]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors. I have reviewed the information on file: complaint from [Ms A]; response from [the medical centre]; response from [Dr B]; GP notes [the medical centre].

2. There are two aspects to [Ms A's] complaint:

(i) [Dr B] prescribed her the teratogenic drug acitretin (Neotigason) in 2013 without confirming she was not pregnant. [Ms A] was actually pregnant at the time and required a termination of pregnancy.

(ii) [Ms A] was diagnosed with Cushing Syndrome in November 2018 as a consequence of over-prescribing of clobetasol propionate (Dermol) ointment (a very potent topical steroid formulation) over seven years despite there being an alert in her notes since 2012 regarding such prescribing. There was also a letter on file from [Ms A's] dermatologist (2014) stating she was not to be prescribed further Dermol. Despite these precautions, [Dr B] and other GPs at [the medical centre] continued to prescribe excessive amounts of Dermol on a regular basis.

Prescribing of acitretin

3. In his response to HDC, [Dr B] notes he initiated acitretin therapy for [Ms A] in October 2013 as management of guttate psoriasis and in an attempt to reduce her reliance on steroid creams. He had seen good responses to the therapy in other patients. [Dr B] states: *I was aware of its teratogenic effects and asked if there was a possibility that she might be pregnant and ensured she had contraception. Regrettably I omitted to perform a pregnancy test prior to [Ms A] commencing the medication. My prescribing led to two subsequent pregnancies being terminated*. [Dr B] no longer initiates acitretin therapy.

4. In a letter to ACC dated 7 May 2019, [Dr B] gives further detail regarding [Ms A's] second termination (April 2015) required because of the long-term teratogenic effect of acitretin following cessation of the drug (see below). [Dr B] stated: *At the initial consultation we discussed the potential for harm to a developing foetus and the need to have adequate contraception. She was however not informed by me of how long the teratogenic effect could last (I was not aware it was so prolonged). I had not supplied her with a copy of the information sheet regarding the drug which does mention this.*

5. Clinical notes dated 9 October 2013 ([Dr B]) include*: Here re skin. Lots of very small lesions* [consistent with guttate psoriasis]. *Has some control with dermol but the problem of long term safety. Discussed options. Will try neotigason as long as bloods satisfactory. Bloods ordered. Contraception restarted*. A special authority for

prescribing of acitretin was applied for and received electronically (see below) and prescriptions provided for acitretin 25mg once daily x 30 and the oral contraceptive Ava-30 ED. Blood results (lipid profile, CBC, liver and renal function) were unremarkable and [Ms A] was notified of the results on 14 October 2013. There is no reference to pregnancy test being performed and no detail regarding discussion about the safety of the medication and precautions required.

6. On 8 November 2013 [Ms A] presented to [a provider at the medical centre] having had a positive home pregnancy test. She was approximately two weeks overdue for her period (implying a LMP around the start of October 2013, consistent with early pregnancy scan on 12 November 2013 dating pregnancy as 6+3 weeks). In view of the high risk of teratogenicity associated with acitretin use, termination of pregnancy was advised although [Ms A] was initially ambivalent. However she eventually proceeded to termination on 13 December 2013 complicated by retained products of conception requiring further surgery a week later. At follow-up on 27 February 2014 (provider …) [Ms A] remained amenorrheic and was using condoms for contraception. Notes include: *wanting more kids although aware is not the best time to get preg re risk to fetus from recent meds*. The precise nature of this discussion is not clear from the notes. There is no record of subsequent prescribing of acitretin. There is no record of further prescriptions for oral contraception before [Ms A] fell pregnant again in March 2015.

7. [Ms A] had persistent amenorrhoea following her termination and was referred to the DHB gynaecology service (seen 21 March 2014). At the clinic visit it was noted [Ms A] was not using any contraception but there is no record of contraceptive advice being provided to her. Her amenorrhoea was felt to be secondary to weight loss and ultrasound scan arranged (performed 4 April 2014 — showed blood in uterus). [Ms A] presented to [the public hospital] ED on 4 April 2014 with vaginal bleeding thought to be a normal period. There is no reference to contraception in the ED note. Through the remainder of 2014 [Ms A] had consultations with the DHB dermatology and infectious diseases services in relation to her skin condition. On 24 March 2015 [Ms A] presented to [the medical centre] (provider …) having had a positive home pregnancy test. The pregnancy was unintended (failure of emergency contraception) although [Ms A] had not been using the oral contraceptive pill. [Ms A] was referred for termination of pregnancy which was performed later in April 2015. Referral note included: *There is an increased risk of foetal abnormality for 2–3 years after use of Neotigason. [Ms A] does not feel that she can continue with this pregnancy unsupported with the potential for foetal abnormality.*

8. An issue of the Medsafe Prescriber Update in June 2010[1] noted the following information regarding acitretin prescribing:

[1] Medsafe. Acitretin (Neotigason) — points to remember. Prescriber Update. June 2010; 31(2): 16 https://www.medsafe.govt.nz/profs/PUArticles/AcitretinJune2010.htm

- *Acitretin should only be prescribed by physicians who are experienced in the use of systemic retinoids and understand the risks associated with treatment. A number of important precautions must be considered when prescribing this medicine.*
- *Acitretin is highly teratogenic and is contraindicated in pregnant women and nursing mothers. It should not be used in women of childbearing potential unless a number of prescribing conditions are met (see Neotigason data sheet).*
- *If acitretin is used in a woman of childbearing potential, pregnancy must be avoided for two years following discontinuation of therapy. Strict contraception must be used for one month prior to, during, and for 24 months after treatment. In addition alcohol must be avoided during and for two months after treatment due to an interaction that increases the concentration of etretinate. Etretinate is also highly teratogenic and has a longer half-life than acitretin. The mechanism for this interaction is not yet understood.*
- *Acitretin is also contraindicated in patients with severely impaired hepatic or renal function and in patients with chronic abnormally elevated blood lipids. Hepatic function, serum cholesterol and serum triglycerides should be assessed prior to starting acitretin treatment and regularly during therapy.*

9. A current Medsafe data sheet for acitretin (Novatretin) notes the drug is strictly contraindicated in: pregnant women; women of childbearing potential unless all of the other conditions of the Pregnancy Prevention Program are met. The Pregnancy Prevention Program is a comprehensive set of requirements of prescribing of the drug, some of which are listed below:

- *The potential for pregnancy must be assessed for all female patients.*
- *She understands the teratogenic risk.*
- *She understands the need for rigorous follow-up on a monthly basis.*
- *She understands and accepts the need for effective contraception, without interruption,* ***1 month before starting treatment, throughout the entire duration of treatment and for 3 years after the end of treatment****. At least one highly effective method of contraception (i.e. a user-independent form) or two complementary user-dependent forms of contraception should be used.*
- *Even if she has amenorrhea she must follow all the advice on effective contraception.*
- *She is informed and understands the potential consequences of pregnancy and the need to rapidly consult if there is a risk of pregnancy or if she might be pregnant.*
- *She understands the need* ***and accepts to undergo regular pregnancy testing before, ideally monthly during treatment and periodically with 1–3 monthly intervals for a period of 3 years after stopping treatment****.*

- *She has acknowledged that she has understood the hazards and necessary precautions associated with the use of acitretin.*

Requirements for pregnancy testing are listed as:

According to local practice, medically supervised pregnancy tests with a minimum sensitivity of 25mUI/mL are recommended to be performed, as follows

- ***Prior to starting therapy***
- ***At least one month after the patient has started using contraception, and shortly (preferably a few days) prior to the first prescription, the patient should undergo a medically supervised pregnancy test. This test should ensure the patient is not pregnant when she starts treatment with acitretin.***
- *Follow-up visits should be arranged at regular intervals, ideally monthly. The need for repeated medically supervised pregnancy tests every month should be determined according to local practice including consideration of the patient's sexual activity, recent menstrual history (abnormal menses, missed periods or amenorrhea) and method of contraception. Where indicated, follow-up pregnancy tests should be performed on the day of the prescribing visit or in the 3 days prior to the visit to the prescriber.*
- *Women should undergo pregnancy test periodically with 1–3 monthly intervals for a period of 3 years after stopping treatment.*

10. The current Pharmac Special Authority form for acitretin[2] includes the following requirements which the prescriber must confirm have been completed before the medication can be prescribed (I am not aware there has been any significant change in the content of the form since 2013):

- *Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice*

and

- *Applicant has an up to date knowledge of the safety issues around acitretin and is competent to prescribe acitretin*

and

- *Patient is female and has been counselled and understands the risk of teratogenicity if acitretin is used during pregnancy and the applicant has ensured that the possibility of pregnancy has been excluded prior to the commencement of the treatment and that the patient is informed that she must not become pregnant during treatment and for a period of two years after the completion of the treatment*

[2] https://www.pharmac.govt.nz/2020/02/01/SA1476.pdf Accessed 4 February 2020

11. Comments

(i) It is apparent [Dr B] did not take the required and recommended steps to exclude current pregnancy in [Ms A] before he advised her to commence taking acitretin in October 2013.

(ii) It is apparent [Dr B] did not advise [Ms A] of the risks of acitretin teratogenicity extending for at least two years following cessation of the drug, and of the need for reliable contraception over this period. There were probably missed opportunities for other providers to have reinforced this information to [Ms A] between 2013 and 2015 (DHB gynaecology providers in particular) but the primary responsibility lay with [Dr B].

(iii) [Dr B] has not documented any plan with respect to monitoring of [Ms A's] pregnancy tests as advised in the drug information discussed above and there is no evidence such monitoring ever took place. There is nothing to suggest [Dr B] took steps to ensure [Ms A] had reliable contraception for at least two years following cessation of acitretin.

(iv) In my experience, acitretin is rarely initiated by primary care clinicians, particularly in women of childbearing age, although [Dr B] was entitled to initiate the drug (vocationally registered GP). The Medical Council of NZ statement on good prescribing practice[3] (post-dating the events in question but with prescribing principles described consistent with those in earlier versions of the statement) includes:

- *Be familiar with the indications, adverse effects, contraindications, major drug interactions, appropriate dosages, monitoring requirements, effectiveness and cost-effectiveness of the medicines that you prescribe*
- *Ensure that the patient (or other lawful authority) is fully informed and consents to the proposed treatment and that he or she receives appropriate information, in a way they can understand, about the options available; including an assessment of the expected risks, adverse effects, benefits and costs of each option*
- *Satisfy yourself that the patient understands how to take or use any medicine prescribed and is able to take it or use it*
- *Keep a clear, accurate and timely patient record containing all relevant clinical findings; decisions made; adverse drug reactions (date, name of medicine and description of reaction); information given to the patient about the medicines and any other treatment prescribed*

(iv) I believe [Dr B] failed to follow recommended and accepted practice with respect to prescribing of acitretin for a female patient of child-bearing potential, and he failed to follow the general prescribing principles stated above. He completed a Pharmac

[3] https://www.mcnz.org.nz/our-standards/current-standards/medical-care-and-prescribing/good-prescribing-practice/ Accessed 5 February 2020

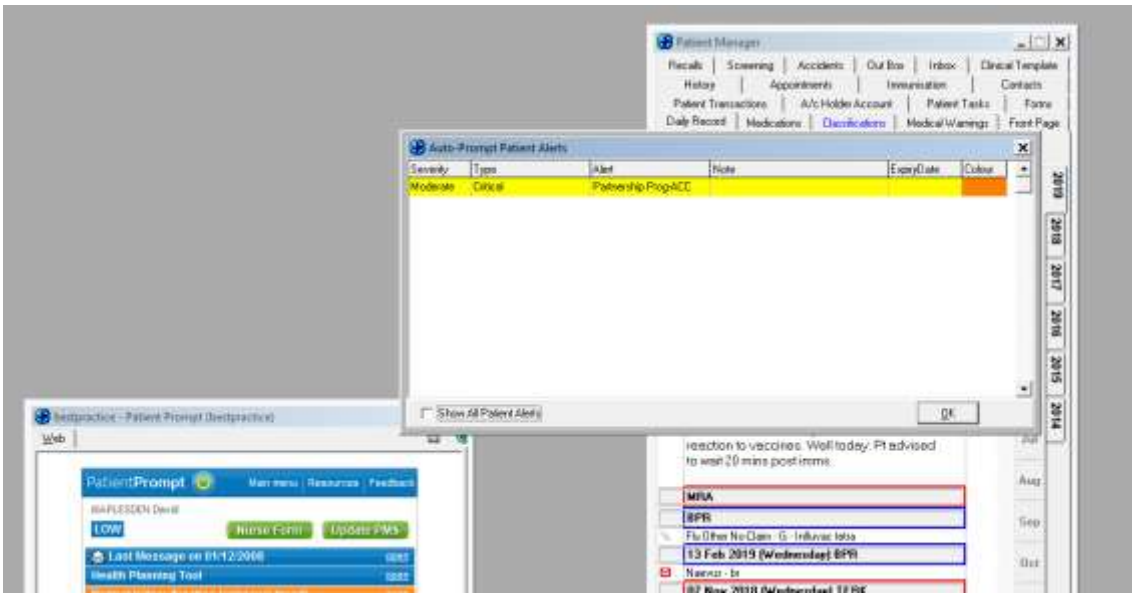
Special Authority form confirming pregnancy had been excluded in the patient and the patient had been informed not to become pregnant for two years following cessation of acitretin when current pregnancy had not been adequately excluded and appropriate information had not been provided. [Ms A] suffered the trauma of two pregnancy terminations. I believe [Dr B's] management of [Ms A], for the reasons described above, would be met with severe disapproval by my peers. I note [Dr B] no longer prescribes acitretin and has undertaken further education on safe prescribing of isotretinoin (an acne treatment with significant teratogenic potential). I recommend [Dr B] undertake an audit of any patients for whom he has prescribed isotretinoin in the past 12 months to ensure all prescribing requirements have been met.

Prescribing of clobetasol dipropionate (Dermol) ointment

12. The responses from [Dr B] and [the medical centre] include the following points (consistent with the clinical notes) regarding prescribing of Dermol cream for [Ms A]. [Ms A] developed severe guttate psoriasis in 2008 with Dermol ointment prescribed initially by a dermatologist in May 2011 to good effect (no dermatologist letter on file for this date). Clinical notes are available from January 2012 by which stage [Ms A] was receiving 3x30g tubes of Dermol per prescription[4] with instructions: *apply twice daily to area for 5 days t …* [remainder obscured]. Locoid lipocream was being prescribed concurrently at that time and I have assumed there were instructions to change to a weaker steroid (Locoid) after the five days. [Dr B] states [Ms A's] requirement for Dermol slowly increased.

13. On 27 August 2012 [Ms A] saw [Dr C] at [the medical centre] requesting a trial of Daivobet for scalp psoriasis. This was prescribed together with a repeat of Dermol (3 x 30g tube as noted above). However, on 29 August 2012 [Dr C] wrote to [Ms A] stating he had reviewed her notes and was concerned at the amount of Dermol she had been prescribed *by various doctors at* [the] *practice over the past 15 months … This is a concern because it suggests the psoriasis is not as well controlled as it could be and the overuse of this VERY strong steroid may be harming your skin and the rest of your body.* [Dr C] advised [Ms A] to stop using Dermol and come in for full review of her psoriasis with the option of another dermatologist referral. [Dr C] placed an alert on the PMS stating: ***Be cautious with scripting Dermol, overusing***. The [medical centre's] response notes [Ms A] had four alerts on her file (including administration alerts) and the prescribing alert was easy to overlook. Alerts generally appear as a priority when the patient file opens as per the example below (one alert), and can be graded by type and severity. It is not clear what severity was assigned to the alert in question.

[4] I cannot determine if any repeats were provided on the prescription but there is later reference to three repeats per prescription (30 January 2013). Dr B refers in his response to the amount prescribed being intended for one month's use, implying there was sufficient for three months' use per script (original plus two repeats).



14. On 3 October 2012 provider … noted: Using a lot of Dermol — [Dr C] wrote to pt concerned about this, says stopped it but needs something for scalp … A steroid scalp application was prescribed and referral made to the DHB dermatology service (expected wait six months). On 13 November 2012 provider … wrote: *using Dermol — only cream that works. Has extensive psoriasis on back and face. Plan: hydrocortisone to face and dermol*. It appears a further dermatology referral was made at this time and Dermol script repeated as per previous description. The Dermol prescription was repeated on 7 January 2013 ([provider's initials] — per consult) and on 30 January 2013 [provider's initials] (with [Dr B]) reviewed [Ms A] regarding a persistent hand rash. Notes include: *Prescribed 3 dermol + 3 repeats by* [provider] *3 weeks ago, requesting more, declined as have been concerns about dermol overuse*. Dermatologist review was still awaited with the DHB dermatology department having very restricted availability.

14. Following the consultation on 30 January 2013, the Dermol scripts recorded were for 1 x 30g tube although it is unclear if there were repeats. Dermol prescriptions were provided on ten occasions over the next 12 months (until the dermatologist review noted below) with the majority signed by [Dr B] on telephone request. On 14 June 2013 [Dr B] also prescribed [Ms A] a course of oral steroids for flare of her psoriasis, and acitretin trial was commenced in October 2013 as previously discussed. A further referral to the DHB dermatology service was made on 22 July 2013.

15. [Ms A] was reviewed by dermatologist [Dr D] on 1 February 2014. His clinic letter to [Dr B] includes: *Of concern is that for a number of years she has been using Dermol cream at a rate of about one tube per da*y [presumably 30g tube and I am unable to confirm this usage based on the available notes]. *Fortunately at present she has managed to reduce the consumption of Dermol to about one tube every two weeks* [consistent with notes at that time*] … she has obvious areas of skin atrophy and striae due to abuse of Dermol. It is essential that she never uses Dermol again. We are going*

to have to wean her on to weaker steroids gradually … Daivobet and Eumovate preparations were prescribed with plan for review in four months and consideration of phototherapy trial. At review on 3 May 2014, [Dr D] noted [Ms A's] psoriasis had flared after coming off the Dermol *but she should certainly not restart this*. Phototherapy was arranged although was not particularly successful and a trial of antibiotics was undertaken in late 2014 under the auspices of the DHB infectious diseases service. [Dr B] states in his response that he viewed and filed the dermatologist letters but does not recall seeing or acknowledging the warnings regarding avoidance of Dermol, and there was no additional alert or advice placed on the clinical record in this regard. The letters were filed on 12 February and 16 May 2014.

16. Following the advice provided by [Dr D] in February 2014, [Ms A] was provided with a further seven prescriptions for Dermol 30g x 1 tube (unclear re repeats) over the next five months. The majority were prescribed by [Dr B] on telephone request. One prescription was provided by [provider] on 22 July 2014 with the note *only 1 tube dermol concerns how much dermol …* On 4 September 2014 [Dr B] reviewed [Ms A] as *psoriasis flaring on shoulders and some mildly on face. Plan: Dermol a few days to establish control then beta mixture. Advantan a few days on non-oral areas of face …* A prescription was provided for 3 x 30g tubes Dermol (again unclear if any repeats). A further script for 2 x 30g tubes of Dermol was provided by [Dr B] on 8 September 2014 (per phone) with that script repeated on 22 September and 24 November 2014 but no further Dermol prescribed in 2014.

17. [Ms A] received a further script for Dermol 30g x 2 on 15 January 2015 ([Dr B]) but no further scripts until 24 August 2015. During the remainder of 2015 the script was repeated on four occasions ([Dr B], usually telephone request). On 12 November 2015, in addition to [Dr B] being recorded as providing a script for 2 x 30g Dermol (may have been generated but not provided as [Dr B] was apparently on leave at the time), [a] provider (a locum) provided a script for 6 x 30g tubes Dermol (telephone request). [Dr B] notes: [The locum GP] *prescribed an increased dose of Dermol (from two tubes a month to six tubes a month) … and inadvertently set this as routine long-term medication with repeats. The reason for the increase was not recorded in the notes. The next prescription for Dermol was 11 months later and unfortunately, because the incorrect prescription dose showed in [Ms A's] notes as a long-term medication with repeats, the repeat prescriptions provided by myself and other GPs included the incorrect increased dose, which led to large amount of Dermol being supplied to [Ms A].* I note [Ms A] did not attend scheduled dermatology appointments on 25 May, 30 November and 16 December 2015 and was subsequently discharged from the dermatology service.

18. On 25 January 2016 [Dr B] prescribed [Ms A] a short course of oral steroids (10 x 20mg tabs prednisone total) for a flare of perioral dermatitis. Referral was made back to the dermatology service (appointment made for May 2016 but [Ms A] failed to attend and no further appointment was offered). The rash flared on withdrawal of oral steroids and a further longer reducing course was prescribed on 3 February 2016

by [Dr B] (starting at 40 mg then reducing by 5mg every four days — 24 x 20mg tabs/50 x 5mg tabs supplied). On 27 October 2016 [a provider] prescribed [Ms A] a further course of oral steroids (starting at 40mg with reduction similar to above, 93 x 5mg tabs provided) for a generalized follicular rash (no specific diagnosis recorded). On 8 November 2016 [Ms A] was seen again by the infectious diseases service having self-referred and possible fungal rash was diagnosed and treated. The report notes [Ms A] had recently begun using Dermol ointment again (prescription for 6 x 30g tubes provided 3 October 2016 by …). Further prescriptions for Dermol (6 x 30g) were provided on three occasions between October 2016 and January 2017.

19. On 6 March 2017 [a provider] noted: *flare of psoriasis. Not being helped by dermol (which she is using in large doses*). In past has required course of oral steroids. A prescription was provided for short course of oral steroids. On 13 March 2017 [Dr B] recorded: *short course steroids has not been enough to settle her folliculitis. For course same as one she had in October last year.* A script was provided for 93 x 5mg prednisone tablets, starting dose 40mg for three days with subsequent gradual reduction. A further course of prednisone was prescribed by [Dr B] on 5 April 2017 (total 15 x 20mg tabs) with blood tests ordered and skin biopsy performed (10 April 2017) by him. Further oral steroids were prescribed by [Dr B] on 10 April 2017 (40mg for 5 days, 20mg for 5 days) and again on 20 April 2017 (slow reduction from 20mg daily, 50 x 5mg tabs provided). On 8 May 2017 [Dr B] prescribed further Dermol ointment (6 x 30g with repeats as previously) and dermatology referral was made. On 9 June 2017 dermatologist [Dr E] corresponded with [Dr B] noting [Ms A's] history, investigation results and photographs of the rash was most consistent with a polymorphic light eruption and [Ms A] could contact the clinic directly to make an urgent appointment next time the rash flared.

20. Steroid prescriptions provided by [Dr B] during the remainder of 2017 included: 26 June: 6 x 30g Dermol (telephone request); 27 September: 6 x 30g Dermol (telephone request); 1 November: 10 x prednisone 20mg and 100 x prednisone 5mg (no consult notes); 27 November: 14 x 20mg and 28 x 5mg prednisone (no consult notes); 8 December: 14 x 20mg and 100 x 5mg prednisone (consult notes include: *has had clearing of face rash with oral steroid, is still on 30mg, to wean now in one week steps of 5mg and see me in one month*).

21. The oral steroids were continued into 2018 with provisional diagnosis recorded as polymorphic light eruption and perioral dermatitis (doxycycline being prescribed intermittently). On 17 January 2018 [Dr B] recorded [Ms A] as taking 5mg prednisone with plan to withdraw in 1 mg increments (200 x 1mg tabs provided). Further Dermol was also provided (6 x 30g). On 13 February 2018 [a provider] reviewed [Ms A] with flare of her perioral rash noting she had been using Advantan cream on the rash which had made it worse. Plan was for six week course of doxycycline with sun exposure precautions, and short course prednisone starting at 20mg (unclear if she had completely withdrawn from the previous course at this stage). [Ms A] was reminded she could attend the dermatology service at short notice and did this on 2 March 2018 when [Dr E] recorded: *The rash on her face was perioral dermatitis an[d] this is now*

settling with the doxycycline prescribed. I note she was also given Advantan but this should not be used in this condition as it will potentiate it as will prednisone. I note [Ms A] is slowly reducing her prednisone and this is a good thing as being on prednisone makes her psoriasis quite unstable as well.

22. [Dr B] continued to provide [Ms A] with repeat prescriptions for Dermol cream (6 x 30g tubes on four occasions between January and September 2018). On 16 November 2018 [Ms A] was reviewed by [a provider] as she had become suspicious she might have symptoms of Cushing syndrome. [The provider] noted: *Was on steroid until about 5/12 ago and is over-using dermol — has had 2250 grams this year and similar last year 2.8kg!). Uses it for treatment on psoriasis which is over whole body — guttate psoriasis. Iatrogenic Cushing. Stopped dermol several weeks ago and only using it prn now so prob little use trying to wean her off it.* Subsequent blood tests confirmed likely Cushing syndrome and [Ms A] was referred to the DHB endocrinology and dermatology services. In a letter dated 17 December 2018, [Dr E] (dermatologist) noted: *I am surprised she has continued to use large quantities [o]f Dermol as I see [Dr D] … warned against this a couple of years ago …* [Ms A] was subsequently started on methotrexate for her psoriasis with interim steroid replacement therapy and very slow withdrawal from both oral and topical steroids (as Synacthen tests had shown ongoing HPA suppression). It is expected she will make a slow recovery from the distressing symptoms of her iatrogenic Cushing's syndrome.

23. Comments:

(i) I believe my peers would be concerned at the following aspects of [Ms A's] management which are evident from the preceding discussion:

a. The failure by [Dr B] to adequately monitor and appropriately limit [Ms A's] use of Dermol ointment, particularly after concerns were raised by a colleague in August 2012 and an alert placed on the file.

b. The failure by [Dr B] to note and follow the specialist advice provided to him by [Dr D] in February and May 2014 regarding the signs of steroid misuse [Ms A] was already exhibiting and the need to stop any further prescribing of Dermol. The failure to place any further alert on the file or reference to the specialist letters means subsequent providers were not aware of the explicit advice provided by [Dr D].

c. The prescribing of oral steroids by [Dr B] for treatment of a rash diagnosed as perioral dermatitis in January 2016 when such therapy is not indicated for treatment of that condition and can worsen the condition[5].

d. The prescribing of prolonged courses of oral steroids by various [providers at the medical centre] including [Dr B] in 2016 and 2017 for unspecified skin condition/s (variously recorded as folliculitis, psoriasis, polymorphic light eruption and perioral dermatitis) in a patient who was using large amounts of very potent topical steroids

[5] https://dermnetnz.org/topics/periorificial-dermatitis/ Accessed 4 February 2020

concurrently, without specialist confirmation that the benefits of such treatment outweighed the potential risks and without proactive review for possible adverse effects of such a regime. In particular, [Dr B] prescribed oral steroids on 27 September and 1 and 27 November 2017 without recording consultation details (presumably telephone consult) including indications for the prescribing. Mitigating factors include: a dermatologist referral was made in May 2017 and initial advice (based on referral details) received a month later with [Ms A] invited to attend acutely for review when the rash flared (but oral steroids continued to be prescribed for rash flares without such review having taken place); the role of oral steroids in management of psoriasis is unclear with common use at odds with many guideline recommendations[6]; oral steroids can be used in the management of polymorphic light eruption[7]; once [Ms A] had received sufficient doses of steroids to cause potential HPA axis suppression, gradual withdrawal was an appropriate management strategy.

e. In summary, I believe [Dr B's] management of [Ms A] as discussed above departed from accepted practice to at least a moderate degree with some mitigating factors discussed above. Additional mitigating factors include difficulty accessing timely dermatology specialist input over the period in question, and [Ms A's] non-attendance at a number of dermatology appointments in 2015.

(ii) I note [the medical centre's] repeat prescribing practice at the time of the events in question evidently involved practice nurses generating a prescription and providing it to the GP to sign. This meant the GP did not have to access the patient notes to complete the prescription and possibly contributed to the patient 'alert' discussed being missed by the GP. Nevertheless, this method of repeat prescribing is common in my experience with there being an expectation that the practice has a robust repeat prescribing policy which includes review of patient alerts, drug allergies and any drug monitoring requirements (including period since the patient was last reviewed) by the clinician (nurse or GP) generating the prescription. Nevertheless, it remains the responsibility of the clinician signing the prescription to take whatever steps are necessary to satisfy the clinician that the medications being prescribed are appropriate for that patient. I recommend the [medical centre's] policy on repeat prescribing at the time of the events in question be obtained for review, together with relevant revised policies.

(iii) The responses from the practice and [Dr B] outline various remedial actions taken since [Ms A's] complaint and these include practice audits (very potent steroid prescribing), education, changes in management of repeat prescribing and use of the alert module of the PMS, involvement of a clinical pharmacist in the primary care team and improved collegial interaction if there are any concerns regarding management of a patient. [Dr B] has facilitated ACC claims for treatment injury and removed financial barriers for the immediate investigation and management of [Ms

[6] Mrowietz U et Domm S. Systemic steroids in the treatment of psoriasis: what is fact, what is fiction? J Eur Acad Dermatol Venereol. 2013 Aug;27(8):1022–5

[7] https://www.dermnetnz.org/topics/polymorphic-light-eruption/ Accessed 4 February 2020

A's] iatrogenic Cushing Syndrome. The practice and [Dr B] have apologised to [Ms A] for the distress caused to her in regard to both the steroid and acitretin prescribing. I think these actions are appropriate and I have no further recommendations in this regard."

The following further advice was received from Dr Maplesden:

"1. [Ms A] expresses concern that she was prescribed Betnovate scalp application and Daivobet scalp application by [a GP] on 7 April 2020 when she had requested Betnovate and Daivonex. [The GP] explained to [Ms A] that the error related to his failure, on 12 December 2019, to change [Ms A's] current prescription of Daivobet from the current (at that time) 'long-term medication' classification (appears in blue coloured font at the top of the list of medications prescribed) and the failure to identify the new prescription of Daivonex as long-term (therefore this medication remained in black coloured font further down the list of medications prescribed in relation to date prescribed). When [Ms A] requested repeats of her medications, Daivobet was selected in preference to Daivonex because it was listed as a long-term medication. The prescribing error was detected by the pharmacist who queried it with [Ms A] and [the GP] prior to dispensing and the error was remedied. Daivobet has since been inactivated as a long-term medication.

Comment: Betnovate scalp application contains the moderately potent steroid betamethasone valerate. Daivonex scalp application contains the non-steroid medication calcipotriol. Daivobet contains calcipotriol and betamethasone as the dipropionate, somewhat more potent than the valerate but less potent than Dermol (clobetasol propionate). The medications were for application to a relatively small body area (scalp). There is limited clinical rationale for prescribing two steroid containing scalp applications if they were to be used concurrently but some patients might alternate use of the preparations so the actual prescribing of the two medications together would not necessarily be a departure from accepted practice. What is evident is that the prescribing error was a consequence of [the GP] failing to adequately maintain [Ms A's] prescriptions so that Daivobet continued to be classified as a long-term medication when this classification should have been removed. It is a relatively simple (tick box) process to reclassify prescriptions as long-term or not long-term. Nevertheless, based on my past experiences as a locum GP for a variety of practices I believe the failure to adequately maintain the patient's medication list is not uncommon although it is potentially unsafe. Under the circumstances I am mildly critical of [the GP's] prescribing error on this occasion. Incorporating review of the patient's long-term medication list at the time of any prescribing might improve management in this regard, and encouraging use of the patient portal for repeat prescribing (where patients can view their long-term medication list and select those medications requiring renewal) is an additional safeguard. It is not clear if [the medical centre] uses a patient portal.

2. I have reviewed the prescribing policies provided by [the medical centre] and developed as part of the Cornerstone accreditation process. The 2013 policy appears

incomplete (page missing) but it might be assumed that if the practice achieved Cornerstone accreditation that year, the policy was deemed adequate by the external assessor. The 2019 policy appears similar to those I have read from other practices and is adequate.

3. The [medical centre's] response dated 25 May 2020 includes the following points:

(i) The original alert placed on [Ms A's] file by provider [Dr C] on 2 June 2014 was classified as moderate severity clinical auto-prompt. I believe this was a reasonable action at the time. The prompt has since been re-classified as high severity, critical clinical auto-prompt which I believe is an appropriate action given [Ms A's] current clinical issues.

(ii) There are ongoing quality improvement activities being undertaken at the practice including: a move to e-prescribing in 2019; increased communication with all local pharmacies to ensure pharmacists have free access to GPs as needed to clarify any prescribing; review of all old alerts in the PMS; nurse assigned to specific GP to assist with results, recalls and management of high needs patients. If practice nurses remain involved in the repeat prescribing process, I recommend part of this process includes review of the long-term medication list to ensure it is current and accurate.

4. [Dr B's] response dated 28 May 2020 is appropriately reflective and outlines measures he has taken since the events in question to reduce the risk of a repeat of the management issues outlined in my original advice. Such measures in addition to those adopted at a practice level (see above) include longer consultation times, closer review of specialist letters and double review process of scanned documentation (hard copy and e-copy), further dermatology training in relation to use of topical steroids and lower threshold for seeking specialist advice. I think these are reasonable and appropriate remedial actions. However, there is no additional clinical information provided which alters the comments made in my original advice regarding overall departures from accepted practice.

5. There is a statement from [a GP] in relation to his prescribing of oral steroids to [Ms A] on 27 October 2016 (see section 18 in my original advice). [The GP] does not recall the consultation in question but states: *I believe my rationale for prescribing prednisone would have been chest infection based on my notes at the time.*

Comment: The clinical notes do not specify whether the prednisone was prescribed for [Ms A's] cough/URTI symptom or for her concurrent rash. The rash had been previously noted (25 October 2016) to resemble folliculitis but had become more inflamed since then (described in [the GP's] statement as a '*scarletina type rash'.* Antibiotics (doxycycline) were prescribed concurrently. Oral steroids had last been prescribed six months' previously. I note physicians commonly prescribe short courses of oral corticosteroids, with one study finding the most common indication to be

acute respiratory tract infection[1]. I am therefore unable to determine that [the GP's] management of [Ms A] on this occasion departed from accepted practice although current evidence suggests such practice is not without risk[2].

6. There is a statement from [a GP] who prescribed [Ms A] a course of oral steroids on 6 March 2017 (see section 19 in my original advice). She notes [Ms A] had a rash on her chest which was recurrent, was not responding to Dermol and which had been treated with oral steroids previously with the last course being 27 October 2016 (one course in the past 13 months). [The GP] felt it was reasonable to trial another course of steroids under the circumstances. [The GP] recognised [Ms A] was using large doses of Dermol at this time and notes in her statement: *In hindsight, I should have placed more emphasis on the amount of topical steroid she was concurrently using.*

Comment: I am mildly critical that [Ms A] was prescribed a course of oral steroids for a presumed flare of psoriasis when she had been using large doses of ultrapotent topical steroid without relief, and the ongoing use of large amounts of ultra-potent steroid was apparently not addressed. Mitigating factors include: this was a 'one-off' intervention by [the GP] with [Ms A] having previously responded to such treatment; as discussed in my previous advice, the role of oral steroids in management of psoriasis is unclear with common use at odds with many guideline recommendations; [Ms A] had had only one course of oral steroids in the previous 13 months, and this was six months previously. I recommend [the GP] review current guidance on management of psoriasis[3].

7. With reference to the specific responses you have requested:

For the care provided by [Dr B], can you please advise:

- *If any of the new information provided changes any aspects of your initial advice* — No
- *If you have any further comments to make on the care provided* – Nil in addition to the discussion in s4

For the care provided by [the medical centre], can you please advise:

- *The adequacy of the relevant policies and procedures* — see s2
- *The appropriateness of the care provided to [Ms A] on 7 April 2020, when the wrong medication was prescribed* — see s1
- *The overall adequacy of the care provided to [Ms A] by [the medical centre] and [medical centre] staff in relation to the steroid prescribing from 2012 to 2019* — the care was inadequate for the reasons discussed in my original advice. [Dr

[1] Waljee A et al. Short term use of oral corticosteroids and related harms among adults in the United States: population based cohort study. BMJ. 2017;357:j1415.
[2] Ebell M. Short Courses of Oral Corticosteroids: Lack of Benefit and Potential Harms for Common Acute Conditions. Am Fam Physician. 2018;98(1):12–13
[3] https://dermnetnz.org/topics/guidelines-for-the-treatment-of-psoriasis/

B] was primarily responsible for the inappropriate prescribing rather than it being due primarily to any deficiency in [the medical centre's] processes given that final responsibility for signing any prescription lies with the GP who is required to ensure the prescription he/she is signing is appropriate for that patient. It is also accepted practice that the GP will review any clinical correspondence addressed to him/her and take adequate steps to ensure any important information contained in that correspondence (in this case the specialist recommendation [Ms A] must avoid using Dermol) is visible in the clinical notes whether that is by disease coding, clinical alerts or some other entry in the notes.

- *If you have any further comments to make on the care provided* — nil in addition to the discussion in this report.
- *If there are any further recommendations that can be made in regards to [the medical centre], considering that despite all the changes made and outlined in [the medical centre's] initial response to this Office, the prescribing error on 7 April still occurred* — see discussion in this report."

The following further advice was obtained from Dr Maplesden regarding the information expected to be given to [Ms A] about the use of Dermol:

> "[I]t would be expected that a patient is given fairly explicit instructions and warnings when a potent or ultra-potent steroid cream is prescribed including where to use it and where not to use (eg not on face or flexures), how much to use and how long it can be used for (usually in association with 'step-down' therapy to less potent steroids after a fixed period) and the risks of not following instructions including permanent skin damage."