Complementary Practitioner, Mr B
Complementary Practice Clinic

A Report by the
Mental Health Commissioner

(Case 18HDC00423)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. Mr A suffered from an anxiety disorder. To help him to manage this disorder, he took venlafaxine, a serotonin and noradrenaline reuptake inhibitor. At the time of these events, Mr A had been taking venlafaxine for 11 years.

2. Mr B provides alternative health services.

3. Mr A attended an initial appointment with Mr B at his clinic on 4 October 2016. Subsequently, Mr A attended 43 further appointments with Mr B, concluding with a final appointment on 13 April 2017. Mr B did not record clinical notes about the services he provided to Mr A at these appointments.

4. At one of the appointments, Mr B advised Mr A to consider ceasing venlafaxine "cold turkey". Mr A began tapering off venlafaxine, and ceased taking it entirely within five weeks. Mr A said that consequently his nervous system became destabilised, and both his mental and physical capabilities were impaired significantly.

5. The manufacturer of Efexor-XR (the brand of venlafaxine that Mr A had been taking) publishes a consumer medicine information sheet. The sheet warns consumers not to taper off venlafaxine too quickly, especially if they have been taking it for a long time, lest they develop a variety of adverse discontinuation symptoms. It also advises consumers to obtain the help of a doctor if they decide to taper off venlafaxine.

Findings

6. It was found that Mr B's advice to Mr A that he consider ceasing venlafaxine "cold turkey" put Mr A at risk of developing discontinuation syndrome and a number of side effects. Therefore, Mr B's provision of the advice breached Right 4(4) of the Code.

7. Adverse comment was made about the clinic for omitting to have a complaints procedure that complies with Right 10(6) of the Code.

8. Adverse comment was made about the clinic for failing to record any clinical notes of Mr A's 44 appointments with Mr B.

Recommendations

9. It was recommended that Mr B reflect on his failure to minimise the potential harm to Mr A, and that Mr B provide a written apology to Mr A.

10. It was recommended that the clinic implement (a) a written policy that staff are not to advise consumers about matters relating to medications; (b) a written documentation policy; and (c) a complaints procedure that reflects consumers' rights and providers' obligations under the Code.

Complaint and investigation

11. The Health and Disability Commissioner (HDC) received a complaint from Mr A about the services provided to him by a clinic and Mr B. The following issues were identified for investigation:

- *Whether the clinic provided Mr A with an appropriate standard of care between October 2016 and April 2017.*
- *Whether Mr B provided Mr A with an appropriate standard of care between October 2016 and April 2017.*

12. This report is the opinion of Kevin Allan, Mental Health Commissioner, and is made in accordance with the power delegated to him by the Commissioner.

13. The parties directly involved in the investigation were:

Mr A	Consumer/complainant
Mr B	Complementary practitioner/provider
Clinic	Complementary practice clinic/provider

14. In-house expert advice was obtained from general practitioner (GP) Dr David Maplesden, and is included as Appendix A.

Information gathered during investigation

Introduction

Mr A

15. At the time of events, Mr A suffered from an anxiety disorder.[1] To help him to manage his symptoms, Mr A was prescribed venlafaxine under the brand name Efexor-XR.[2] He had been taking venlafaxine for 11 years, and was on a dosage of 75mg per day.

Mr B

16. Following a period of working in a different area of health care, Mr B became interested in working with people diagnosed with a variety of mental health issues, including anxiety issues.

17. Mr B told HDC that he believes that mental health and physiological health are strongly interconnected, and that some mental health issues, such as anxiety, can be addressed through both psychological and physiological means.

[1] A mental disorder characterised by intense, excessive, and persistent worry about everyday situations.

[2] An antidepressant and anxiolytic (anti-anxiety) medication. It acts as a serotonin and noradrenaline reuptake inhibitor (an SNRI), i.e., it inhibits the reabsorption of the chemicals serotonin and noradrenaline in the brain.

The clinic

18. Mr B provides services to his clients through the clinic.

Appointments with the clinic

19. Mr A approached the clinic for help with addressing his anxiety disorder. Mr A first met with Mr B on 4 October 2016. Following this initial appointment, the clinic began arranging regular appointments between Mr A and Mr B — usually two or three each week. Between 4 October 2016 and 13 April 2017, the clinic arranged 54 such appointments. Mr A attended 44 appointments and cancelled the other 10. These cancellations occurred for a variety of reasons, including Mr A sometimes having mental-health-related difficulties leaving his house.

Discussion about ceasing venlafaxine

20. Mr A and Mr B discussed the possibility of Mr A ceasing his venlafaxine medication. Mr A recalls that he and Mr B had this discussion some time in February 2017, while Mr B recalls that they had the discussion shortly before Mr A stopped attending his appointments with the clinic on 13 April 2017.

Advice about ceasing venlafaxine

21. Mr A told HDC that Mr B recommended that he cease taking venlafaxine abruptly. Mr A said that he expressed hesitation to do this, so Mr B recommended that he taper off the venlafaxine as quickly as possible. Mr A stated that Mr B did not explain to him the risks of ceasing or tapering off venlafaxine. Mr A further said that Mr B advised him that he would probably feel better within two weeks of ceasing taking venlafaxine, but that if he was not feeling better within two weeks, then he could return to taking venlafaxine. Mr A told HDC that Mr B did not recommend that he consult with anyone either before or during the process of tapering off the venlafaxine.

22. Mr B told HDC that during the consultation he informed Mr A that he had had many clients who had struggled to address their mental health issues while on medication, but who managed to address them successfully after they stopped taking their medication. Mr B stated that he advised Mr A to consider ceasing venlafaxine "cold turkey"[3] because he thought that coming off slowly might be too difficult for him and could put stress on his body for longer than necessary. Mr B said that he emphasised to Mr A that ceasing his venlafaxine would be useful and safe only if Mr A attended regular sessions with the clinic, and if Mr A allowed the clinic to monitor him.

23. Mr B further stated that he and Mr A discussed the risk that Mr A would suffer withdrawal symptoms while tapering off venlafaxine and after ceasing the medication. Mr B said that it was primarily for this reason that he emphasised to Mr A that he would need to allow the clinic to monitor him. Mr B said that he also advised Mr A to discuss ceasing venlafaxine with his prescribing doctor before he began doing so, but Mr A was unwilling to consult his prescribing doctor because of his negative feelings about the medical profession. Mr B commented:

[3] In this case, "cold turkey" means abrupt complete cessation of the use of an addictive drug.

> "I said that 'IF' he was going to do this [stop taking venlafaxine] that it would be my recommendation that he has extra care with me (daily check in even) so I can assess how he is doing and support him, and that if he needed, he would need to be co-managed with GP/psychiatrist and I told him to not even think about it without proper supervision."

24. On 7 February 2018, Mr A complained directly to Mr B about the care he had received, in particular the advice to stop taking his medication. On the same day, Mr B wrote to Mr A responding to his complaint, and stated:

> "My suggestion came from hearing you in your sessions … as you may or may not know SSRI medication is known to increase the risk of suicide …
>
> Often when one of my clients is suicidal and they come off the drugs, after the withdrawal period of a few weeks they are surprised to find their suicidal thoughts go. That was my hope for you."

25. Mr B further commented in the letter:

> "[F]rom watching my clients who have come off with slowly tapering off versus cold turkey — my suggestion for you was to do in one go if you think you could, as I thought prolonging the suffering that you were in would be very dangerous for you …
>
> I also told you that I never suggest for people to come off cold turkey, my normal recommendation is to come off slowly BUT I felt for you this would be a better safer option."

Mr A tapers off venlafaxine

26. Mr A told HDC that after the consultation with Mr B, he began tapering off his venlafaxine, and ceased taking the medication about five weeks after he began tapering it off. On 19 February 2017, Mr A sent Mr B an email in which he mentioned that he had already begun tapering off his venlafaxine.

27. Mr A told HDC that after he ceased taking his venlafaxine medication, his nervous system became destabilised, and his mental health deteriorated. He further stated that his mental and physical capabilities were impaired to the point that he could not drive or walk in a straight line.

Mr A stops attending appointments with Mr B

28. Mr A attended 14 appointments with Mr B at the clinic between 19 February 2017 and his final appointment on 13 April 2017. After this day, the clinic arranged several further appointments between Mr A and Mr B; however, Mr A did not attend any of these. Mr A explained that one of the main reasons why he stopped attending the clinic appointments was the physical impairment he had developed as a result of ceasing venlafaxine.

29. Mr B told HDC that when Mr A stopped coming in for sessions, he did not know whether Mr A was still taking venlafaxine, was tapering it off, or had already ceased it altogether.

Mr B understood from a social media post made by Mr A that he was still satisfied with the care that had been provided by the clinic.

Further information

Mr A

30. Mr A said that eventually he resumed his venlafaxine medication, and gradually began to feel more stable and positive about life. He stated that his recovery process was very slow.

Mr B

31. Mr B told HDC that he does not tell his clients what to do. However, he offers encouragement, and sometime shares stories about what his other clients have done.

32. Mr B explained to HDC:

> "I have worked with many clients who have been on medication for years, even decades. Most of my clients come off the medication themselves while they are having care with me, and then tell me that they have done so. Some do it slowly and some go cold turkey. Very rarely do I myself suggest someone come off medication. However, there are a few exceptions — two in the last twelve years I have been practising. The reasons for these exceptions include when what we are doing is not creating much lasting or cumulative change, and the person is suicidal. Suicidal thoughts are also a well known side effect of anti-depressants such as SSRIs. This is what I believed was happening with [Mr A].
>
> …
>
> In the past when I have helped people come off medication, I have seen some profound changes helping people through this. It is often very hard for a few weeks. As I help support people along the way, they make great changes. IF in the case, someone was not responding, I would refer out to someone else. I would NEVER suggest someone stop taking medication if they have no support. As [Mr A] stopped coming in for care/help, he was taking the suggestion out of context."

33. Mr B told HDC that if Mr A followed the clinic's care plan with his support, he was sure that he could manage Mr A appropriately.

34. Mr B stated that Mr A was the only client to whom he had spoken about ceasing medication abruptly, and that Mr A would be the last. He told HDC:

> "I actually tell all my clients when they start care (for the few that are on meds), that if you decide to come off the medication, do it slowly and see your doctor about it, and do it when you are ready."

The clinic

35. The clinic records in an appointments log the appointments it schedules with its clients, the appointments that clients attend, and the reasons clients give for cancelling their appointments. However, it does not record clinical notes. The clinic told HDC that this is

because the particular nature of the services it provides makes recording clinical notes too "abstract in nature and unhelpful". As a result, there are no notes of the 44 consultations between Mr B and Mr A.

36. The clinic told HDC that although it has a procedures manual for running the practice on a day-to-day basis, it does not have any policies or protocols for dealing with complaints from clients.

37. The clinic stated that after Mr A complained to Mr B, the partners and staff at the clinic discussed how they would deal with a client such as Mr A in the future. The partners and staff resolved that if a future client ceases to follow the clinic's care plan (for example, by cancelling too many appointments), they will explain to the client that they will disengage from them unless they continue to follow the clinic's care plan.

38. The clinic told HDC that if a future client ever expresses an interest in ceasing his or her medication, then "that is up to them personally and they are to consult the person who prescribed [their medication]. The clinic will just be there to support the process but leave it up to the person who prescribed to suggest how to go about this and monitor it."

Manufacturer's Consumer Medicine Information Sheet on Effexor XR[4]

39. In 2017, Pfizer Australia Pty Ltd, a company that manufactures venlafaxine under the brand name Efexor-XR, published a consumer medicine information sheet about Efexor-XR. The sheet advises Efexor-XR consumers:

> "Do not suddenly stop taking Efexor-XR or lower the dose if you have been taking it for some time. If possible, your doctor will gradually reduce the amount you take each day before stopping the medication completely."

40. The sheet warns:

> "[I]f you stop taking [Efexor-XR] suddenly, your condition may worsen or you may have unwanted side effects such as: headache, nausea and vomiting, dizziness, insomnia, nervousness, anxiety, confusion and agitation, diarrhoea, sweating, loss of appetite, tremor, flu-like symptoms, impaired coordination and balance, [and] tingling or numbness of the hands and feet."

41. The sheet further advises Efexor-XR consumers that "[s]lowly reducing the amount of Efexor-XR being taken reduces the possibility of these effects occurring".

Responses to provisional opinion

42. Mr A was provided with an opportunity to respond to the "Information gathered" section of the provisional opinion. He emphasised to HDC that his abrupt cessation of venlafaxine had severely impacted on his health and well-being, and that this had been extremely

[4] This information was accessed from the New Zealand Medicine and Medical Devices Safety Authority website.

unpleasant for him. He also expressed his continued frustration about the way that the clinic had treated him.

43. Mr B and the clinic were provided with opportunities to respond to the relevant parts of the provisional opinion. Their responses have been incorporated into the report as appropriate.

44. The clinic told HDC that it had "taken the recommendations given" in the provisional opinion, and had "begun updating [its] policies, complaint procedure and the running of the practice, a new paperless system for taking notes and a consent form for new clients with clear outlines of what [the practice] provide[s]".

Opinion: Mr B — breach

Introduction

45. I consider Mr B to be a healthcare provider under the Health and Disability Commissioner Act 1994 (the Act),[5] which states that a "healthcare provider" includes "any … person who provides, or holds himself or herself out as providing, health services to the public or a section of the public, whether or not any charge is made for those services". "Health services" are defined as including services to promote and protect health, prevent disease or ill health, and treatment, nursing, rehabilitative, and diagnostic services.[6]

46. Mr B helps his clients to develop strategies for dealing with their mental health issues by increasing their awareness of the connections between the body and the mind. Since this service is aimed at helping clients to improve or rehabilitate their mental and physiological health, I am satisfied that Mr B was acting as a healthcare provider for the purposes of the Act. He is therefore subject to the duties in the Code of Health and Disability Services Consumers' Rights (the Code).

Failure to minimise potential harm — breach

47. At the time of these events, Mr B provided services as a facilitator to clients suffering from mental health issues.

48. When Mr B first met Mr A, he had been taking venlafaxine for 11 years. His prescribed dosage at the time was 75mg per day.

49. Mr A attended 44 appointments with Mr B at the clinic between 4 October 2016 and 13 April 2017. At one of these appointments, Mr B and Mr A discussed whether Mr A should cease taking venlafaxine.

[5] Section 3(k) of the Act.
[6] Section 2(1) definition of "health services".

50. Mr A and Mr B have differing accounts about what Mr B said to Mr A at the appointment where they discussed Mr A ceasing venlafaxine. They disagree about:

a) When the consultation occurred;

b) Whether Mr B advised Mr A about the risks of ceasing venlafaxine (including the risks of ceasing it "cold turkey"); and

c) Whether Mr B advised Mr A to consult his prescribing doctor before ceasing venlafaxine.

51. However, they both agree that Mr B advised Mr A that he should consider ceasing venlafaxine, and that if he did so, he should consider ceasing it "cold turkey". I note that Mr B told HDC that he advised Mr A that ceasing venlafaxine would be safe and useful only if he continued to attend appointments at the clinic.

52. HDC obtained in-house expert advice from GP Dr David Maplesden, about the consequences of ceasing venlafaxine abruptly.

53. Dr Maplesden stated that venlafaxine is associated with a discontinuation syndrome[7] similar to that of other SNRI and SSRI medications.[8] He advised that the syndrome is more common and severe among those who cease venlafaxine than among those who cease many other SNRI and SSRI medications, owing to the pharmacokinetics of venlafaxine.

54. Dr Maplesden advised that when a consumer ceases or tapers off venlafaxine, the risk of suffering discontinuation syndrome is related in part to how long the person has been taking venlafaxine, what dosage he or she has been taking, and how quickly the person withdraws from the medication. Dr Maplesden stated that because Mr A had been taking venlafaxine for an extended period, he may have been at an increased risk of suffering discontinuation syndrome.

55. Dr Maplesden commented that while there are various strategies for reducing the risk of discontinuation syndrome, he could find "no reference to abrupt discontinuation of venlafaxine as being a reasonable therapeutic option".

56. Dr Maplesden stated:

> "If [Mr A] wished to stop his venlafaxine, or expressed concern that it was no longer effective, accepted practice in primary care would have been supervised very gradual withdrawal of the medication after discussion with the prescriber, with consideration given to timely introduction of a new agent if pharmacotherapy[9] remained a consideration. If subsequent management involved treatment other than medication,

[7] A general term for adverse symptoms suffered as result of ceasing addictive medication.
[8] Serotonin and noradrenaline reuptake inhibitors (SNRIs) inhibit the reabsorption of both serotonin and noradrenaline, while selective serotonin reuptake inhibitors (SSRIs) inhibit the reabsorption of serotonin only.
[9] The treatment of illnesses (especially mental illnesses) with medication.

> [Mr A] required close monitoring for symptoms of discontinuation syndrome or recurrence of the symptoms which had required the initial prescribing."

57. I accept Dr Maplesden's advice. I note in particular that Dr Maplesden could find no evidence to support the abrupt cessation of venlafaxine as a reasonable therapeutic option. I also note that the unique pharmacokinetics of venlafaxine, coupled with the length of time Mr A had been taking the medication, meant that he may have been at an increased risk of developing discontinuation syndrome.

58. Further, the Effexor-XR (venlafaxine) Consumer Medicine Information Sheet expressly states:

> "Do not suddenly stop taking Effexor-XR or lower the dose if you have been taking it for some time. If possible, your doctor will gradually reduce the amount you take each day before stopping the medication completely."

59. The information sheet goes on to state that if a consumer stops taking the medication suddenly, "your condition may worsen or you may have unwanted side effects", which include headaches, nausea, vomiting, dizziness, insomnia, nervousness, anxiety, confusion, agitation, diarrhoea, sweating, loss of appetite, tremors, flu-like symptoms, impaired coordination and balance, and tingling or numbness of the hands and feet.

60. I acknowledge that Mr B stated that he told Mr A to see a doctor, and that he should cease taking venlafaxine only if he continued to attend appointments at the clinic. Mr A told HDC that Mr B did not recommend that he consult with anyone either before or during the process of tapering off the venlafaxine. Given the conflicting recollections, and the absence of any contemporaneous documentation, I am unable to make a factual finding regarding whether Mr B advised Mr A to see a doctor.

61. However, whether or not Mr B advised Mr A to see a doctor, I am critical that Mr B suggested to Mr A that he should consider ceasing venlafaxine. Mr B is not a medical doctor, and has no authority to make prescriptions or recognised expertise in providing advice on medications to health consumers. This is evidenced by Dr Maplesden's advice and the Effexor-XR information sheet, both of which identify a medical professional/ prescriber as having the appropriate expertise to provide advice on ceasing the medication. I consider that Mr B created a risk to Mr A in making this suggestion, in particular that Mr A would accept his suggestion that he cease venlafaxine "cold turkey", or taper it off rapidly, and, as a result could develop discontinuation syndrome and a number of side effects.

62. Further, as Mr B was operating outside the scope of his practice as a wellness facilitator by making the suggestion to consider ceasing venlafaxine and providing his opinion on how it should be done, I do not consider that the risks of providing such advice were materially mitigated by his advice that Mr A should continue to attend appointments with the clinic regularly. I remind Mr B that all healthcare providers, including alternative healthcare

providers, are obliged to recognise the limits of their expertise when providing care to consumers.

63. I note that Mr B did not record clinical notes of his 44 appointments with Mr A. I am concerned that he failed to do so. Clinical records allow a provider to verify when and what occurred during a consultation, and also allow care to be provided in an appropriate fashion, in light of past treatment, including if a new provider becomes involved.

64. In summary, I consider that the advice Mr B provided regarding ceasing the venlafaxine put Mr A at risk of developing discontinuation syndrome and a number of side effects. I am also concerned that Mr B failed to document his appointments with Mr A. Accordingly, I find that Mr B did not minimise the potential harm to Mr A, and therefore breached Right 4(4) of the Code.[10]

Opinion: The clinic — adverse comment

Omission to have a complaints policy

65. The clinic told HDC that although it has a procedures manual for running the practice on a day-to-day basis, it does not have any policies or protocols for dealing with complaints from clients.

66. The Code guarantees every consumer "the right to complain about a provider in any form appropriate to the consumer".[11] Right 10(6) of the Code requires:

> "Every provider, unless an employee of a provider, must have a complaints procedure that ensures that —
>
> (a) the complaint is acknowledged in writing within 5 working days of receipt, unless it has been resolved to the satisfaction of the consumer within that period; and
>
> (b) the consumer is informed of any relevant internal and external complaints procedures, including the availability of —
>
> (i) independent advocates provided under the Health and Disability Commissioner Act 1994; and
>
> (ii) the Health and Disability Commissioner; and
>
> (c) the consumer's complaint and the actions of the provider regarding that complaint are documented; and
>
> (d) the consumer receives all information held by the provider that is or may be relevant to the complaint."

[10] 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."
[11] Right 10(1).

67. The right to complain is important, as it helps to safeguard consumers' rights. The obligation in Right 10(6) upholds consumers' right to complain by setting out the minimum standards with which a provider's complaints procedure must comply. Accordingly, I am critical of the clinic for not having a complaints procedure that reflects consumers' rights and providers' obligations under the Code.

Failure to document appointments

68. The clinic stated that it does not record clinical notes, as it has found them to be "abstract in nature and unhelpful". I strongly disagree that accurate documentation of consultations/appointments is unhelpful. On the contrary, clinical records allow a provider to verify when and what occurred during a consultation, and also allow care to be provided in an appropriate fashion, in light of past treatment, particularly if a new provider becomes involved.

69. I appreciate that the clinic provides complementary health services, and that the particular features of the type of care it provides would influence the types of records it could keep. However, it is not acceptable for the clinic to keep no records at all of observations made of consumers, or advice or services given to consumers. I recommend that the clinic revise its practice of not taking notes, and develop a robust documentation policy.

Recommendations

70. I recommend that Mr B:

a) Provide a written apology to Mr A. The apology is to be sent to HDC within three months of the date of this report, for forwarding to Mr A.

b) Reflect on his failure to minimise the potential harm to Mr A, and provide a written report to HDC on his reflections and the changes to his practice he has instigated as a result of this case, within three months of the date of this report.

71. I recommend that the clinic:

a) Implement a written policy that states that staff are not to advise consumers about matters relating to medications, and provide HDC with a copy of that policy within three months of the date of this report.

b) Implement a written documentation policy, and provide HDC with a copy of the policy within three months of the date of this report.

c) Implement a complaints procedure that reflects consumers' rights and providers' obligations under the Code (in particular, under Right 10(6)), and provide HDC with a copy of the procedure within three months of the date of this report.

Follow-up actions

72. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Director of Mental Health, the Ministry of Health, and the New Zealand Medicine and Medical Devices Safety Authority, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: In-house advice to the Commissioner

The following in-house expert advice was obtained from Dr David Maplesden, a general practitioner:

"David Maplesden

2 July 2018

1. Thank you for the request that I provide limited clinical advice in relation to the complaint from [Mr A] about the care provided to him by [Mr 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.

2. I have been asked to provide information on the potential consequences of abrupt cessation of the medication Efexor-XR (venlafaxine) in relation to a complaint from [Mr A]. Venlafaxine is an antidepressant and anxiolytic agent that acts as a serotonin- and noradrenaline-reuptake inhibitor (SNRI). It is used primarily in major depressive disorder, with labelled uses in New Zealand including major depression, generalized anxiety disorder, social anxiety disorder and panic disorder. [Mr A] had been taking the medication for 12 years. I was unable to establish the precise dose of venlafaxine [Mr A] was taking at the time of the events in question. The clinical indication for prescribing appears to have been generalised anxiety disorder or mixed anxiety/depressive disorder, and it is apparent also that [Mr A]'s symptoms were not well controlled at the time he was provided with advice to stop his medication.

3. The manufacturer New Zealand data sheet (Efexor-XR) includes the following comments:

(i) When ARROW — VENLAFAXINE XR at a dose of 75 mg/day or greater has been administered for more than 1 week is stopped, it is recommended whenever possible that the dose be tapered gradually to minimise the risk of discontinuation symptoms. In clinical trials with venlafaxine extended release, tapering was achieved by reducing the daily dose by 75 mg at 1 week intervals. To facilitate tapering below 75 mg of ARROW — VENLAFAXINE XR, physicians may consider prescribing the 37.5 mg tablets once daily. The period required for tapering may depend on the dose, duration of therapy, and the individual patient. Patients should be advised to consult their physician before abruptly discontinuing ARROW — VENLAFAXINE XR.

(ii) Discontinuation effects are well known to occur with antidepressants. Discontinuation symptoms have been assessed both in patients with depression and in those with anxiety. Abrupt discontinuation, dose reduction, or tapering of venlafaxine at various doses has been found to be associated with the appearance of new symptoms, the frequency of which increased with increased dose level and with longer duration of treatment. Symptoms reported included agitation, anorexia, anxiety, confusion, dry mouth, fatigue, paraesthesias, vertigo, hypomania, nausea, vomiting,

dizziness, convulsion, headache, diarrhoea, sleep disturbance, insomnia, somnolence, sweating and nervousness. Where such symptoms occurred, they were usually self-limiting, but in a few patients lasted for several weeks. There is also a report of a withdrawal syndrome, confirmed by two challenges in a 32-year-old woman who had received venlafaxine 300 mg daily for 8 months. It is, therefore, recommended that the dosage of ARROW — VENLAFAXINE XR be tapered gradually and the patient monitored. The period required for discontinuation may depend on the dose, duration of therapy and the individual patient.

4. A 2011 review article and case study included the following comments:

Dual-action antidepressants serotonin-norepinephrine reuptake inhibitors (SRNIs) are widely used to treat depression. Owing to its efficiency and safety, venlafaxine holds a prominent place in this group of depressants. Abrupt venlafaxine discontinuation involves a high risk of withdrawal syndrome. Mechanism of its development is similar to that of selective serotonin reuptake inhibitors (SSRIs), but of higher intensity. Venlafaxine withdrawal symptoms may include several somatic symptoms as well as several psychiatric symptoms. In some cases, symptoms may look like a stroke … Withdrawal syndrome is a real risk for each venlafaxine treated patient. The possibility of its occurrence should be always kept in mind and patients should be timely informed about it. In this way, the risk of venlafaxine withdraw syndrome could be reduced, unnecessary stress to patients prevented and the costs of medical treatment lowered.

5. A regularly updated literature review service includes the following comments:

Abrupt discontinuation of venlafaxine commonly causes discontinuation symptoms due to its relatively short half-life (approximately 5 hours) and that of its active metabolite desvenlafaxine (approximately 11 hours). The discontinuation symptoms of venlafaxine are similar to, but can be more severe, than those produced by discontinuation of SSRIs. As an example, a randomized trial that compared venlafaxine with escitalopram found that after the drugs were abruptly stopped, venlafaxine led to more discontinuation symptoms, including agitation, diaphoresis, dizziness, fatigue, nausea, restlessness, and tremor … We suggest tapering the daily dose by 37.5 to 75 mg each week over four weeks to reduce discontinuation symptoms. Patients who have difficulty tapering off of venlafaxine may benefit from switching to fluoxetine 10 to 20 mg per day; the fluoxetine can then be tapered off, typically without discontinuation effects.

6. Comments

(i) It is recognised that venlafaxine is associated with a discontinuation syndrome similar to other SSRI and SNRI medications but the syndrome is more common and more severe than many other medications in these groups because of the pharmacokinetics of venlafaxine.

(ii) The risk of discontinuation syndrome is related in part to the duration and dosage of the medication, and rate of withdrawal. [Mr A] had been taking the medication for

a very extended period which may have placed him at increased risk of discontinuation syndrome.

(iii) Various strategies for reducing the risk of discontinuation syndrome are described in the literature reviewed. I could find no reference to abrupt discontinuation of venlafaxine being a reasonable therapeutic option.

(iv) If [Mr A] wished to stop his venlafaxine, or expressed concern that it was no longer effective, accepted practice in primary care would have been supervised very gradual withdrawal of the medication after discussion with the prescriber, with consideration given to timely introduction of a new agent if pharmacotherapy remained a consideration. If subsequent management involved treatment other than medication, [Mr A] required close monitoring for symptoms of discontinuation syndrome or recurrence of the symptoms which had required the initial prescribing."