

In the High Court of New Zealand | I Te Kōti Matua o Aotearoa
Auckland Registry | Tāmaki Makaurau Rohe
CIV 2025-404-354

Under the Fair Trading Act 1986 and the Consumer Guarantees Act 1993 and in
the matter of a representative proceeding

Between **Theresa Gielen**
First plaintiff

And **Patrick Wyatt**
Second plaintiff

And **Johnson & Johnson (New Zealand) Limited**
First defendant

And **JNTL Consumer Health (New Zealand) Limited**
Second defendant

And **Johnson & Johnson Pacific Pty Limited**
Third defendant

Amended statement of defence

8 August 2025

Bell Gully

Stephen Hunter KC / S V A East / J Q Wilson
Counsel for the first to third defendants
smhunter@shortlandchambers.co.nz / sophie.east@bellgully.com /
jesse.wilson@bellgully.com

1 Queen Street
PO Box 4199
Auckland 1140
+64 9 916 8800

May it please the Court

The defendants by their solicitors say in response to the plaintiffs' amended statement of claim dated 27 June 2025:

Plaintiffs

1. They admit paragraph 1.
2. They admit paragraph 2.
3. They admit the plaintiffs have applied to the High Court for directions under rule 4.24 of the High Court Rules 2016 that they be permitted to bring this proceeding as a representative proceeding on behalf of the persons described in subparagraph (a) and excluding the persons described in subparagraph (b). The defendants oppose the application.

Except as expressly admitted, they deny paragraph 3.

Defendants

4. In relation to paragraph 4, they:
 - (a) admit that the first defendant is Johnson & Johnson (New Zealand) Limited (**J&J (NZ)**), a duly incorporated company having its registered office at 507 Mt Wellington Highway, Mt Wellington, Auckland, 1060, New Zealand; and
 - (b) deny that J&J (NZ) carries on business as a healthcare company, and say further that J&J (NZ) carries on business as a distributor of medical technology.

Except as expressly admitted, they deny paragraph 4.

5. In relation to paragraph 5, they say that J&J (NZ) is ultimately wholly owned by Johnson & Johnson, a company carrying on business in New Jersey, USA.

Except as expressly admitted, they deny paragraph 5.

6. In response to paragraph 6:
 - (a) they admit that the second defendant is JNTL Consumer Health (New Zealand) Limited (**JNTL**), a duly incorporated company having its registered office at Level 9, 4 Williamson Avenue, Ponsonby, Auckland, 1021, New Zealand; and
 - (b) say further that JNTL carries on business as a wholesale distributor of consumer healthcare products in New Zealand.

Except as expressly admitted, they deny paragraph 6.

7. They admit paragraph 7 and say further that JNTL's sole shareholder is JNTL Holdings 2, Inc.
8. They admit paragraph 8.
9. They admit paragraph 9.
10. In response to paragraph 10 they admit, insofar as is the current position:
 - (a) that JNTL distributes healthcare products in New Zealand, and say further that Johnson & Johnson Pacific Australia New Zealand is the trading name of JNTL in New Zealand;
 - (b) that the packaging for the Products states the trading or business name "Johnson & Johnson Pacific Australia New Zealand" and address details as "AUSTRALIA" and "Auckland, NEW ZEALAND";
 - (c) that the packaging for the Products includes contact details in New Zealand and Australia, including the line "New Zealand: 0800 446 147", and that in respect of the Sudafed Products, Codral Products, and Benadryl Chesty Cough & Nasal Congestion, this telephone number is set out under a heading "Consumer Care Centre"; and
 - (d) that the packaging for the Sudafed Products and Benadryl Products refers to the website address as "our website". In New Zealand, the "our" refers to JNTL.

Except as expressly admitted, they deny paragraph 10.

11. They are not required to plead to paragraph 11.

The defendants' activities in relation to the Products

12. In response to paragraph 12, they:

- (a) say that prior to 20 December 2006, Pfizer Inc. was responsible for the Products in New Zealand, and none of the defendants have knowledge of, or involvement with, the Products prior to that date. They therefore deny any matters referred to in the amended statement of claim occurring before 20 December 2006;
- (b) say that between 21 December 2006 and 3 October 2022, J&J (NZ) was the distributor of the Products in New Zealand;
- (c) say that on 3 October 2022, JNTL became the distributor of the products in New Zealand, and that J&J (NZ) has no knowledge of (and therefore denies) any matters referred to in the amended statement of claim occurring after 3 October 2022;
- (d) admit that JNTL currently holds the Marketing Authorisation for the:
 - (i) Codral Products;
 - (ii) Sudafed Products; and
 - (iii) Benadryl Products.
- (e) admit that JNTL is the current publisher of the websites for:
 - (i) the Sudafed Products (homepage: www.kenvuebrands.com/nz/sudafed), which states in part:

This site is published by JNTL Consumer Health (New Zealand) Ltd which is solely responsible for its contents.
 - (ii) the Codral Products (homepage: www.codral.co.nz), which states in part:

This site is published by JNTL Consumer Health (New Zealand) Ltd which is solely responsible for its contents.

- (iii) the Benadryl Products (homepage: www.kenvuebrands.com/nz/benadryl), which states in part:

This site is published by JNTL Consumer Health (New Zealand) Ltd which is solely responsible for its contents.

- (f) admit that J&J (NZ) held the Marketing Authorisation for the Historic Products (as defined in Schedule 1 to the amended statement of claim (**Schedule**)); and
- (g) deny that Johnson & Johnson Pacific Pty Limited (**J&J Pacific**) has attached its brand or mark (in the form of its name) to the Products, and say further that “Johnson & Johnson Pacific Australia New Zealand” is the trading name of JNTL in New Zealand.

Except as expressly admitted, they deny paragraph 12.

13. They admit paragraph 13.
14. They admit paragraph 14.
15. They admit that the New Zealand Medicines and Medical Devices Safety Authority (**Medsafe**) has classified the Products as medicines that are for general sale or pharmacy-only medicines.

Except as expressly admitted, they deny paragraph 15.

16. They admit that each of the Products are medicines to be taken in accordance with a prescribed dosage and each suggest a dosage amount that should not be exceeded in a 24-hour period.

Except as expressly admitted, they deny paragraph 16.

17. They admit that the Products (other than the Historic Products) are available for purchase in New Zealand, and that the Products may be sold in stores, pharmacies, and supermarkets.

Except as expressly admitted, they deny paragraph 17.

18. In response to paragraph 18, they:

- (a) admit that there are other OTC orally administered, PE-containing products that were previously sold in New Zealand;
- (b) deny that the product listed as item 15 of the Schedule was ever sold in New Zealand; and
- (c) otherwise have insufficient knowledge and therefore deny paragraph 18.

19. In response to paragraph 19, they:

- (a) admit that the labelling on some (not all) of the Products refers to the temporary relief of blocked or runny noses; and
- (b) admit that a blocked or runny nose may be one of the symptoms of a cold, flu and/or allergies.

Except as expressly admitted, they deny paragraph 19.

20. They are not required to plead to paragraph 20.

21. They admit paragraph 21.

22. They admit paragraph 22.

23. They admit paragraph 23, and say further that:

- (a) evidence of efficacy is not required for active ingredients that are low risk, and for which efficacy has been well-established; and
- (b) Medsafe reviews the information provided by a person seeking Marketing Authorisation and makes a recommendation to the Minister of Health as to whether the medicine is approvable.

24. They admit paragraph 24, and say further that:

- (a) the Products have the Marketing Authorisation dates set out in the Schedule;
- (b) in granting the Marketing Authorisations, Medsafe considered all of the information relating to the Products that was submitted in accordance with s 21 of the Medicines Act 1981 (including relating to quality, efficacy, and safety) and weighed the likely therapeutic value of the medicine against the risk (if any) of the use of the medicine injuriously affecting the health of any person, as required by s 22 of the Medicines Act 1981; and
- (c) Medsafe's assessment included consideration of efficacy for the purposes of relieving nasal congestion.

25. In response to paragraph 25, they:

- (a) deny that the product listed as item 15 of the Schedule was ever sold in New Zealand; and
- (b) otherwise admit paragraph 25.

PE

26. They admit paragraph 26, and say further that:

- (a) the packaging for each Product includes an identification of each of the active ingredients in that Product;
- (b) the Products have the active ingredients set out in the Schedule, except that:
 - (i) the Products listed as items 11, 14 and 17 of the Schedule contain 20mg/mL of guaiphenesin and 1mg/mL of phenylephrine hydrochloride: and
 - (ii) The Product listed as item 16 of the Schedule contains:

Day Formula: Dextromethorphan hydrobromide monohydrate (10mg), paracetamol (500mg) and phenylephrine hydrochloride (5mg).

Night Formula: Dextromethorphan hydrobromide monohydrate (10mg), paracetamol (500mg) and chlorphenamine maleate (2mg).

27. They deny paragraph 27.

28. They deny paragraph 28.

29. They deny paragraph 29.

Purchases

30. In response to paragraph 30, they say that:

- (a) this paragraph is insufficiently particularised; and
- (b) in any event, they have insufficient knowledge of and therefore deny paragraph 30.

31. In response to paragraph 31, they say that:

- (a) this paragraph is insufficiently particularised; and
- (b) in any event, they have insufficient knowledge of and therefore deny paragraph 31.

32. They are not required to plead to paragraph 32.

33. They deny paragraph 33, and say that further that paragraph 33 is insufficiently particularised.

FIRST CAUSE OF ACTION – BREACH OF SECTION 9 OF THE FAIR TRADING ACT 1986

The defendants repeat paragraphs 1 – 33 above and say by way of response to the plaintiffs' first cause of action:

34. In response to paragraph 34, they:

- (a) admit that J&J (NZ) and J&J Pacific were in trade from at least 31 March 2005; and

- (b) otherwise deny paragraph 34, and say further that JNTL was incorporated on 21 March 2022, and commenced trading on 3 October 2022.

35. In response to paragraph 35, they:

- (a) rely on paragraph 12 above;
- (b) admit that J&J Pacific reviews and approves the Product packaging for JNTL in New Zealand, and that the current or most recent version of the Product labelling contains the wording set out in the Schedule, except that there are some typographical errors in:
 - (A) item 2, which should refer to “nose” rather than “noses”;
 - (B) items 2, 3, and 4, which should refer to “Wherever you see the PE logo...” rather than “Whenever you see the PE logo...”; and
 - (C) item 10, which should state “allow rest” rather than “allows rest”.
- (c) say further that various, not all, of the Product packaging contains statements to the effect that:
 - (i) the relevant Product is for the temporary relief of a range of symptoms that are listed on the packaging;
 - (ii) if symptoms persist or worsen, or new symptoms appear, the consumer should discontinue use and see their doctor;
 - (iii) the consumer should ask their doctor before using the Product if they have any medical conditions; and
 - (iv) the consumer should stop using the Product after a specified period of time;
- (d) say that the packaging of each of the Products is different and has changed from time to time;

- (e) admit that the current version of the websites for the Products, as described in paragraph 12(e), contain information about the use of the Products for the relief of blocked and runny noses;
- (f) admit that the current versions of the websites for the Products, as described in paragraph 12(e), variously contain information to the effect of that set out in paragraph 35(c) above; and
- (g) say further that paragraph 35 is insufficiently particularised.

Except as expressly admitted, they deny paragraph 35.

36. In response to paragraph 36, they:

- (a) admit that statements were made on product packaging in connection with the supply of particular Products, but deny making the Representations as defined in paragraph 35;
- (b) admit that statements that were made on product packaging were made to the public at large, but deny making the Representations as defined in paragraph 35;
- (c) say further that paragraph 36 is insufficiently particularised; and
- (d) otherwise have insufficient knowledge and therefore deny paragraph 36.

37. They deny paragraph 37.

38. They deny paragraph 38.

39. In respect of paragraph 39, they:

- (a) deny making the Representations as defined in paragraph 35;
- (b) say further that the product packaging for various, not all, of the Products and the websites for the Products, as described in paragraph 12(e), contain qualifying statements to the effect that:

- (i) the relevant Product is for the temporary relief of a range of symptoms that are listed on the packaging;
 - (ii) if symptoms persist or worsen, or new symptoms appear, the consumer should discontinue use and see their doctor;
 - (iii) the consumer should ask their doctor before using the Product if they have any medical conditions;
 - (iv) the consumer should stop using the Product after a specified period of time; and
- (c) otherwise deny paragraph 39.

40. They deny paragraph 40, and say further that paragraph 40 is insufficiently particularised.

SECOND CAUSE OF ACTION – BREACH OF SECTION 10 OF THE FTA

The defendants repeat paragraphs 1 – 33 above and say by way of response to the plaintiffs' second cause of action:

41. In response to paragraph 41, they:

- (a) admit that J&J (NZ) and J&J Pacific were in trade from at least 31 March 2005; and
- (b) otherwise deny paragraph 41, and say further that JNTL was incorporated on 21 March 2022 and commenced trading on 3 October 2022.

42. In response to paragraph 42, they:

- (a) rely on paragraph 35 above;
- (b) say further that paragraph 42 is insufficiently particularised; and
- (c) otherwise deny paragraph 42.

43. They deny paragraph 43.

44. In response to paragraph 44, they:
- (a) admit that statements were made on various of the product packaging in connection with the supply of those particular Products, but deny making the Representations as defined in paragraph 35;
 - (b) admit that statements that were made on various of the product packaging were made to the public at large, but deny making the Representations as defined in paragraph 35;
 - (c) say further that paragraph 44 is insufficiently particularised; and
 - (d) otherwise have insufficient knowledge and therefore deny paragraph 44.
45. They deny paragraph 45.
46. They deny paragraph 46.
47. In respect of paragraph 47, they:
- (a) admit that they have not corrected the Representations as defined in paragraph 35, as they deny making representations in those terms;
 - (b) say that at all times they have made qualifications around the use of the Products including that:
 - (i) the relevant Product is for the temporary relief of a range of symptoms that are listed on the packaging;
 - (ii) if symptoms persist or worsen, or new symptoms appear, the consumer should discontinue use and see their doctor;
 - (iii) the consumer should ask their doctor before using the Product if they have any medical conditions;
 - (iv) the consumer should stop using the Product after a specified period of time; and

- (c) say that the packaging of each of the Products has changed from time to time.

Except as expressly admitted, they deny paragraph 47.

- 48. They deny paragraph 48, and say further that paragraph 48 is insufficiently particularised.

THIRD CAUSE OF ACTION – BREACH OF SECTIONS 13(A) AND 13(E) OF THE FTA

The defendants repeat paragraphs 1 – 33 above and say by way of response to the plaintiffs' third cause of action:

- 49. In response to paragraph 49, they:
 - (a) admit that J&J (NZ) and J&J Pacific were in trade from at least 31 March 2005; and
 - (b) otherwise deny paragraph 49, and say further that JNTL was incorporated on 21 March 2022 and commenced trading on 3 October 2022.
- 50. In relation to paragraph 50, they:
 - (a) rely on paragraph 35 above;
 - (b) say that paragraph 50 is insufficiently particularised; and
 - (c) otherwise deny paragraph 50.
- 51. They deny paragraph 51.
- 52. They deny paragraph 52.
- 53. In respect of paragraph 53, they:
 - (a) admit that they have not corrected the Representations as defined in paragraph 35, as they deny making representations in those terms;

- (b) say that the product packaging for various, not all, of the Products contain qualifying statements to the effect that:
 - (i) the relevant Product is for the temporary relief of a range of symptoms that are listed on the packaging;
 - (ii) if symptoms persist or worsen, or new symptoms appear, the consumer should discontinue use and see their doctor;
 - (iii) the consumer should ask their doctor before using the Product if they have any medical conditions;
 - (iv) the consumer should stop using the Product after a specified period of time; and
- (c) say that the packaging of each of the Products has changed from time to time.

Except as expressly admitted, they deny paragraph 53.

54. They deny paragraph 54.

55. In response to paragraph 55, they:

- (a) admit that statements were made on product packaging in connection with the supply of those particular Products, but deny making the Representations as defined in paragraph 35, and say further that various, not all, of the product packaging contains statements to the effect that:
 - (i) the relevant Product is for the temporary relief of a range of symptoms that are listed on the packaging;
 - (ii) if symptoms persist or worsen, or new symptoms appear, the consumer should discontinue use and see their doctor;
 - (iii) the consumer should ask their doctor before using the Product if they have any medical conditions;

- (iv) the consumer should stop using the Product after a specified period of time;
 - (b) admit that the statements that were made on product packaging were made to the public at large, but deny making the Representations as defined in paragraph 35;
 - (c) say further that paragraph 55 is insufficiently particularised; and
 - (d) otherwise have insufficient knowledge and therefore deny paragraph 55.
56. In relation to paragraph 56, they:
- (a) say that paragraph 56 is insufficiently particularised; and
 - (b) otherwise have no knowledge of and therefore deny paragraph 56.
57. They deny paragraph 57, and say further than paragraph 57 is insufficiently particularised.

FOURTH CAUSE OF ACTION – BREACH OF SECTION 6 OF THE CONSUMER GUARANTEES ACT 1993 (CGA)

The defendants repeat paragraphs 1 – 33 above and say by way of response to the plaintiffs' fourth cause of action:

58. In response to paragraph 58, they:
- (a) admit that J&J (NZ) distributed products in New Zealand between 21 December 2006 and 3 October 2022;
 - (b) admit that JNTL distributed products in New Zealand after 3 October 2022;
 - (c) say further that:
 - (i) the Products are not manufactured by any of the defendants;
 - (ii) the brands and marks that are applied to the Products are not owned by any of the defendants; and

- (d) deny that J&J Pacific held itself out to the public as the manufacturer of the Products by attaching, causing or permitting its brand to be attached to the goods and say further that “Johnson & Johnson Pacific Australia New Zealand” is the trading name of JNTL in New Zealand.

Except as expressly admitted, they deny paragraph 58.

59. In response to paragraph 59, they:

- (a) deny that the product listed as item 15 of the Schedule was ever sold in New Zealand;
- (b) admit that the other Products were previously purchased by customers in New Zealand;
- (c) say further that paragraph 59 is insufficiently particularised; and
- (d) otherwise have insufficient knowledge and therefore deny paragraph 59.

60. They deny paragraph 60 and say further that:

- (a) the formula and indications for each of the Products were approved by Medsafe; and
- (b) the Products were of an acceptable quality and fit for purpose.

61. They deny paragraph 61, and say further that paragraph 61 is insufficiently particularised.

FIFTH CAUSE OF ACTION – BREACH OF SECTION 9 OF THE CGA

The defendants repeat paragraphs 1 – 33 above and say by way of response to the plaintiffs’ fifth cause of action:

62. In response to paragraph 62, they admit that the current or most recent version of the labels for each Product contained the statements set out in the Schedule, as modified by paragraph 35 above.

Except as expressly admitted, they deny paragraph 62.

63. In response to paragraph 63, they admit that the defendants were aware of the statements on the current or most recent version of the Product labels, as set out in the Schedule.

Except as expressly admitted, they deny paragraph 63.

64. They deny paragraph 64.

65. They deny paragraph 65, and say further that paragraph 65 is insufficiently particularised.

FIRST AFFIRMATIVE DEFENCE – LIMITATION

66. In respect of the fourth and fifth causes of action:

- (a) For any claim based on an alleged act or omission which occurred prior to 1 January 2011, section 4 of the Limitation Act 1950 provides that actions to recover a sum under an enactment shall not be brought after the expiry of six years from the date on which the cause of action accrued.
- (b) For any claim based on an alleged act or omission which occurred on or after 1 January 2011, section 11(1) of the Limitation Act 2010 provides that it is a defence if the defendant proves that the date on which the claim is filed is at least 6 years after the date of the act or omission on which the claim is based.
- (c) To the extent that any of the acts or omissions alleged to have been committed by the defendants (denied) occurred prior to 1 January 2011 and gave rise to causes of action (denied) which accrued before 13 February 2019 (being six years before the date on which the plaintiffs' claim was commenced), the plaintiffs' claims arising out of those alleged acts and/or omissions are time-barred, pursuant to Section 4 of the Limitation Act 1950.
- (d) To the extent that any of the acts or omissions alleged to have been committed by the defendants (denied) occurred on or after 1 January 2011 and before 13 February 2019 (being six years before the date on which the plaintiffs' claim was commenced), the plaintiffs' claims

arising out of those alleged acts and/or omissions are time-barred, pursuant to Section 11(1) of the Limitation Act 2010.

67. In respect of the first, second and third causes of action:

- (a) Section 43A of the Fair Trading Act 1986 provides that the applicable limitation period is three years after the date on which the loss or damage, or likelihood of loss or damage was discovered or ought reasonably to have been discovered.
- (b) The plaintiffs claim to have purchased Products for the purpose of relieving nasal and/or sinus congestion over a period of 19 years. If the Products were ineffective in providing relief from nasal and/or sinus congestion (which is denied), this ought reasonably to have been discovered shortly after the plaintiffs first started using the Products in 2006 and the limitation period began to run from that time.
- (c) The limitation period for the first to third causes of action started running more than three years before the proceedings were commenced, and the claims are therefore time barred.

68. In respect of each of the causes of action:

- (a) For any claim based on an alleged act or omission which occurred prior to 1 January 2011, section 23B of the Limitation Act 1950 provides that no action may be brought after the last to end of (i) 5 years ending on the close of 31 December 2015 and (ii) 15 years after the date of the act or omission on which the action is based.
- (b) For any claim based on an alleged act or omission which occurred on or after 1 January 2011, section 11(3) of the Limitation Act 2010 provides that it is a defence if the defendant proves that the date on which the claim is filed is at least 15 years after the date of the act or omission on which the claim is based.
- (c) To the extent that any of the acts or omissions alleged to have been committed by the defendants (denied) occurred prior to 13 February 2010, the plaintiffs' claims arising out of those alleged acts and/or omissions are time-barred, pursuant to:

- (i) Section 11(3) of the Limitation Act 2010; or
- (ii) Section 23B of the Limitation Act 1950, for any action based on an alleged act or omission which occurred prior to 1 January 2011.

69. To the maximum extent applicable, and in relation to any plaintiff and Class Member, the defendants rely on the limitation defences in sections 4 and 23B of the Limitation Act 1950, and section 11 of the Limitation Act 2010.

SECOND AFFIRMATIVE DEFENCE – FAILURE TO MITIGATE

70. In respect of each of the causes of action, in the event that the Court finds that any of the defendants have breached the Fair Trading Act 1986 or Consumer Guarantees Act 1993, as applicable (which is denied), and that the plaintiffs have suffered the Loss (which is denied), the plaintiffs have failed to mitigate those losses by:

- (a) Continuing to use the Products that they claim were ineffective in providing relief from nasal and/or sinus congestion over a period of 19 years; and
- (b) Failing to follow the advisory statements set out on the labels for the Products.

Particulars

- (a) The Products contain advisory statements including:
 - (i) If symptoms persist or worsen, or if new symptoms appear, stop use and see your doctor;
 - (ii) Do not use for more than a few days at a time unless a doctor has told you to; and
 - (iii) Ask your doctor before use if you have any medical conditions.
- (b) Further particulars will be provided following discovery.

71. Any damages awarded to the plaintiffs should be reduced to the extent that the Court considers just and equitable having regard to its share in the responsibility for the alleged Loss.

Dated: 8 August 2025

A handwritten signature in black ink, appearing to read 'S M Hunter', written in a cursive style.

S M Hunter KC / S V A East / J Q Wilson
Counsel for the defendants