

**Notice
under s66 of the
Commerce Act 1986**

**Application by Johnson &
Johnson to acquire the stock,
assets and business of the
Consumer Healthcare division
of Pfizer Inc.**

COMMERCE ACT 1986: BUSINESS ACQUISITION

SECTION 66: NOTICE SEEKING CLEARANCE

28 September 2006

The Registrar
Business Acquisitions and Authorisations
Commerce Commission
PO Box 2351
Wellington

Pursuant to s66(1) of the Commerce Act 1986 notice is hereby given seeking **clearance** of a proposed business acquisition.

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11. Australia New Zealand Therapeutic Products Authority report "About the trans Tasman therapeutic products agency project" (available online at <http://www.anztpa.org/about.htm>)

EXECUTIVE SUMMARY

Proposal

- 1 Clearance is sought for the acquisition by Johnson & Johnson (*J&J*) or a company in the J&J group to acquire the stock and/or assets/business of Pfizer Inc. and its New Zealand affiliates to the extent they relate to the New Zealand operations of Pfizer Consumer Healthcare (*PCH*).

The parties

- 2 J&J, which is listed on the New York Stock Exchange, is the ultimate parent company of a global group of companies. J&J's activities are divided into three business segments: consumer; pharmaceutical; and medical devices and diagnostics. In New Zealand, the consumer and medical devices businesses are operated out of one local J&J company, Johnson & Johnson (New Zealand) Limited, and the pharmaceutical division is operated out of Janssen-Cilag Pty Limited, an Australian company. (In this Notice "J&J New Zealand" refers to all activities of the J&J Group in New Zealand, including Janssen-Cilag).
- 3 Pfizer Inc. is listed on the New York, London, Euronext and Swiss stock exchanges. Pfizer Inc. is a global pharmaceutical company that develops, manufactures and sells drugs for human and animal consumption as well as other consumer healthcare products. In New Zealand, Pfizer Inc. operates through Pfizer New Zealand Limited.
- 4 PCH is involved in the business of consumer healthcare and 'over-the-counter' (*OTC*) pharmaceutical products (such as oral care, upper respiratory health, tobacco dependence, gastrointestinal health, skin care, eye care and hair growth products).

Markets affected

- 5 Each of J&J and PCH supply a broad range of pharmaceutical and personal care products into New Zealand. However, the product ranges of the two businesses are largely complementary, and the proposed acquisition will not result in a significant amount of product overlap. In New Zealand, the transaction will give rise to horizontal aggregation in three markets:
 - 5.1 non prescription allergy medication;
 - 5.2 non prescription products for the treatment of worms; and
 - 5.3 non prescription thrush treatments.

No Substantial Lessening of Competition

- 6 J&J submits that no substantial lessening of competition will result from the proposed acquisition in any of the affected markets.

7 In a recent decision in relation to pharmaceutical markets the Commerce Commission said that:¹

7.1 pharmaceutical markets are characterised by strong existing competition; and

7.2 the barriers to expansion from existing competitors ... are relatively low.

8 This is the case in the present circumstances. In each of the three markets where there will be some horizontal aggregation, there is a number of existing competitors and/or near competitors that could readily enter the market by adjusting their product mix. In addition, large multinational suppliers in offshore markets represent a potential source of entry and would impose a strong constraint on the combined J&J / PCH entity. These existing, near and potential suppliers are well placed to expand into the affected markets should the opportunity arise to do so.

Market concentration/large number of competitors

9 In the allergy medication market the combined J&J / PCH entity would have a market share of approximately []% [CONFIDENTIAL], which is within the Commission's safe harbours. There are a significant number of existing competitors, including large multinational suppliers such as GlaxoSmithKline and Procter & Gamble.

10 In the worm treatment market, while the combined entity would have a market share of approximately []% [CONFIDENTIAL] which is outside the Commission's safe harbours, there is another product, DEWORM (manufactured by Cipla Limited and distributed through Multichem), with a [] [CONFIDENTIAL] market share than PCH's COMBANTRIN product. In addition, there are a significant number of products with similar active ingredients available in Australia, which would not be difficult to introduce into New Zealand.

11 In the thrush treatment market, the combined entity would have a market share of approximately []% [CONFIDENTIAL], which is outside the Commission's safe harbours. However, there are at least three existing competitors, including Bayer Healthcare and Pacific Pharmaceuticals.

Barriers to entry and expansion are not significant

12 In each of these three markets, barriers to entry and expansion are unlikely to be significant, particularly for the many large multinational pharmaceutical suppliers, most of which have already have a presence in New Zealand.

13 Suppliers including GlaxoSmithKline, Procter & Gamble, Reckitt Benckiser and Douglas Pharmaceuticals are all established in New Zealand in a range of markets. These large multinationals are familiar with the requirements relating to product registration, and have established distribution systems, local sales offices and

¹ Reckitt Benckiser / Boots Group, Decision 576, November 2005

relationships with pharmacies they would be able to utilise should they wish to introduce a new product into New Zealand.

Countervailing power of customers

- 14 The products in the markets where the proposed transaction gives rise to horizontal aggregation are pharmacy only products (i.e. they do not require a doctor's prescription but they are not available from supermarkets or other retail outlets). Many pharmacies are members of large buying groups, which are collectively able to negotiate favourable terms of supply and price with suppliers. These buying groups will act as a constraint on a combined J&J / PCH.

Conclusion

- 15 Strong existing competition, limited barriers to entry and expansion, and the countervailing power of pharmacies would significantly constrain a combined J&J / PCH entity. Therefore, J&J considers that no lessening of competition will result from the proposed acquisition.

PART I: TRANSACTION DETAILS

1	What is the business acquisition for which clearance is sought?
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- 1 Clearance is sought for Johnson & Johnson (*J&J*) or a company in the J&J group (the *Acquirer*) to acquire the stock and/or assets/business of Pfizer Inc. and its New Zealand affiliates to the extent they relate to the New Zealand operations of Pfizer Consumer Healthcare (*PCH*).
- 2 PCH is involved in the business of consumer healthcare and over-the-counter pharmaceutical products (such as oral care, upper respiratory health, tobacco dependence, gastrointestinal health, skin care, eye care and hair growth products).
- 3 The acquisition for which clearance is sought is pursuant to a Stock Asset Sale and Purchase Agreement dated 25 June 2006 between J&J and Pfizer Inc. under which J&J will acquire the worldwide business of PCH (with the exception of certain products in some countries).
- 4 Certain products in the New Zealand portfolio of PCH are excluded from the transaction, namely the products branded CYKLOKAPRON, FELDENE and PONSTAN.
- 5 In New Zealand, J&J operates through Johnson & Johnson (New Zealand) Limited and Janssen-Cilag, a branch of the Australian Company, Janssen-Cilag Pty Limited. Pfizer Inc. operates as Pfizer New Zealand Limited.

2 Who is the person giving this notice?

2.1 This notice is given by:

Steven Rosenberg
Corporate Secretary
Johnson & Johnson
1 Johnson & Johnson Plaza
New Brunswick
New Jersey 08933
USA

Phone: +01 73 2524 2452

Facsimile: +01 73 2524 5045

2.2 All correspondence and notices in respect of this Notice should be directed in the first instance to:

Chapman Tripp Sheffield Young
Level 35
ANZ Tower
23-29 Albert Street
Auckland

Phone: (09) 357 9020

Facsimile: (09) 357 9099

Attention: Lindsey Jones
(09) 357 9020

Jane Baker
(09) 357 9018

3 Confidentiality

3.1 Do you wish to request a confidentiality order for the fact of the proposed acquisition?

No. Confidentiality is not required for the fact of the proposed acquisition.

3.2 Do you wish to request a confidentiality order for specific information contained in or attached to the notice? If so, for how long? Why?

- (a) Yes. Confidentiality is sought in respect of the information contained in or attached to this Notice, which is set out in square brackets and marked "CONFIDENTIAL". Confidential information has been deleted from the Public Copy of this notice.
- (b) Confidentiality is sought under section 100 of the Commerce Act 1986 and under section 9(2)(b) of the Official Information Act 1982 on the grounds that:
 - (i) the information is commercially sensitive and contains valuable information which is confidential to J&J and PCH; and
 - (ii) disclosure of it is likely to give an unfair advantage to J&J and PCH's competitors and unreasonably prejudice their commercial positions.
- (c) J&J also requests that it is notified of any request made to the Commission under the Official Information Act for the confidential information, and that the Commission seeks J&J's views as to whether the information remains confidential and commercially sensitive at the time those requests are being considered.

4.1 The Applicant**Johnson & Johnson**

Johnson & Johnson
1 Johnson & Johnson Plaza
New Brunswick
New Jersey 08933
USA

Phone: 001 73 2524 2452

Facsimile: 001 73 2524 5045

Attention: Steven Rosenberg

4.2 The Target**Pfizer Consumer Healthcare****c/o– Pfizer New Zealand Limited**

Level 3 Pfizer House
14 Normanby Road
Mt Eden
Auckland

Phone: (09) 638 0000

Facsimile: (09) 638 0021

Attention: John Biddle

All correspondence and enquiries in relation to Pfizer should be directed in the first instance to:

Russell McVeagh
PO Box 8
Auckland

Telephone: (09) 367 8315

Facsimile: (09) 367 8596

Attention: Graeme Quigley
(09) 367 8271

Johnson & Johnson

- 5.1 J&J is the ultimate parent company of a global group of companies. Its shares are quoted on the New York Stock Exchange.
- 5.2 J&J's activities are divided into three business segments:
- Consumer;
 - Pharmaceutical; and
 - Medical Devices and Diagnostics.
- 5.3 In New Zealand, the consumer and medical devices and diagnostics businesses are operated out of one local J&J company, Johnson & Johnson (New Zealand) Limited. The pharmaceutical business is operated out of Janssen-Cilag Pty Limited, an Australian company.
- 5.4 In 2005, J&J achieved a worldwide turnover of approximately US \$50 billion (€41 billion).

Pfizer

- 5.5 Pfizer Inc. is a publicly held corporation listed on the New York, London, Euronext and Swiss stock exchanges. Its headquarters are in New York City. Pfizer Inc. has a presence in 89 countries and its products are available in more than 150 countries.
- 5.6 Pfizer Inc. is a global pharmaceutical company that develops, manufactures and sells drugs for human and animal consumption as well as other consumer healthcare products.
- 5.7 PCH is Pfizer Inc.'s worldwide business division active in consumer and over-the-counter human pharmaceutical products, including self medications for oral care, upper respiratory health, tobacco dependence, gastrointestinal health, skin care, eye care and hair growth.
- 5.8 In New Zealand, Pfizer Inc. operates as Pfizer New Zealand Limited. In 2005, PCH achieved a worldwide turnover of approximately US \$3.9 billion (€3 billion).

6 Does any participant, or any interconnected body corporate thereof, already have a beneficial interest in, or is it beneficially entitled to, any shares or other pecuniary interest in another participant?

- 6.1 Neither J&J nor any of its interconnected bodies corporate has any beneficial interest in shares or any other pecuniary interest in Pfizer Inc. or any of its interconnected bodies corporate.
- 6.2 As far as J&J is aware, neither Pfizer Inc. nor any of its interconnected bodies corporate has any beneficial interest in shares or any other pecuniary interest in neither J&J nor any of its interconnected bodies corporate.

7 Identify any links, formal or informal, between any participant/s including interconnected bodies corporate and other persons identified at paragraph 5 and its/their existing competitors in each market.

7.1 Except for those items listed in paragraph 7.2 below:

- (a) J&J New Zealand does not have any links, formal or informal, with PCH or any other competitor in New Zealand in any of the markets affected by the proposed acquisition; and
- (b) neither J&J, nor any of the other companies in the J&J group has any links, formal or informal, with PCH or any other competitor in any of the markets affected by the proposed acquisition.

7.2 Arrangements between J&J and Pfizer and their competitors are as follows:

- (a) Each of J&J and Pfizer has some products manufactured and packaged by third parties who are competitors in some markets.
- (b) Each of J&J and Pfizer have arrangements with competitors in some offshore markets whereby product is distributed in some countries by those competitors under brands owned by J&J or Pfizer.
- (c) J&J and PCH are members of the following associations:
 - the Food and Grocery Council (formerly the Grocery Manufacturers' Association); and
 - the Association of New Zealand Advertisers.
- (d) J&J is a member of:
 - the Pharmaceutical Association of New Zealand.
- (e) J&J understands that PCH is also a member of the following organisations:
 - the New Zealand Dental Association; and
 - the New Zealand Self Medication Industry.

7.3 Except for those items listed in paragraph 7.2 above, J&J is not aware of whether:

- (a) Pfizer New Zealand has any links, formal or informal, with any other competitor in New Zealand in any of the markets affected by the proposed acquisition; or
- (b) Pfizer Inc. or any of its other trading subsidiaries has any links, formal or informal, with any other competitor in any of the markets affected by the proposed acquisition.

The Commission is requested to make inquiries directly of PCH in this regard.

8 Do any directors of the 'acquirer' also hold directorships in any other companies which are involved in the markets in which the target company operates?

- 8.1 No directors of J&J New Zealand hold directorships in any other companies (other than companies in the J&J group) that operate in the markets in New Zealand in which PCH operates. Inquiries have not been made of the directors of J&J companies outside of New Zealand.

J&J

- 9.1 As noted earlier, J&J's activities are divided into three business segments:
- Consumer;
 - Pharmaceutical; and
 - Medical Devices and Diagnostics.
- 9.2 The Consumer segment's principal products include those for the care of babies and children, skin care, oral and wound care, women's healthcare, as well as nutritional and over-the-counter pharmaceutical products. These products are marketed principally to the general public.
- 9.3 The Pharmaceutical segment's principal worldwide businesses are in the antifungal, anti-infective, cardiovascular, contraceptive, dermatology, gastrointestinal, haematology, immunology, neurology, oncology, pain management, psychotropic (central nervous system) and urology fields. These products are distributed directly to pharmacies, wholesalers and healthcare professionals for prescription use by the general public.
- 9.4 The Medical Devices and Diagnostics segment includes a broad range of products used by or under the direction of healthcare professionals. These products include products for wound care, minimally invasive surgery, circulatory disease management, blood glucose monitoring, professional diagnostics, orthopaedic joint reconstruction, spinal products and disposable contact lenses. These products are used principally by physicians, nurses and therapists in hospitals, diagnostic laboratories and clinics.
- 9.5 For further details about J&J see <http://www.jnj.com/>.

Pfizer

- 9.6 Pfizer Inc.'s activities are divided into three business segments:
- Consumer Healthcare;
 - Pharmaceutical; and
 - Animal Health.
- 9.7 The Consumer Healthcare segment's principal products include over-the-counter products for allergies, coughs / colds, sinus conditions, tobacco dependence, hair growth, eye care, skin care, gastrointestinal care, haemorrhoidal care, diarrhoea, constipation, women's health, oral care and hand sanitisation.
- 9.8 The Pharmaceutical segment's principal products include prescription medications for pain management, tobacco dependence, diabetes, psychiatric disorders, high

cholesterol, oncology, erectile dysfunction and ophthalmology. These products are distributed to wholesalers and pharmacies, and marketed to healthcare professionals for prescription use by the general public.

9.9 The Animal segment's principal products include antibiotics, vaccines and treatments for livestock, domestic animals, horses and swine. These products are distributed to wholesalers, producers and veterinarians.

9.10 For further details about Pfizer see <http://www.pfizer.co.nz>.

Proposed acquisition

9.11 The proposed acquisition of PCH principally concerns personal care and non prescription pharmaceutical or 'over the counter' (*OTC*) products.

10 What are the reasons for the proposal and the intentions in respect of the acquired or merged business?

- 10.1 The rationale for the transaction is to allow J&J to diversify its consumer healthcare portfolio through the addition of new segments, and to add geographic diversity. In addition, J&J anticipates substantial cost savings by eliminating duplicative expenses.
- 10.2 Each of J&J and PCH supply a broad range of pharmaceutical and personal care products into New Zealand. However, as is shown in the table at the end of section 11, the proposed acquisition will not result in a significant amount of product overlap. By combining two product ranges, which are at present highly complementary, the combined J&J / PCH entity will be able to offer consumers a broader range of products while at the same time realising efficiencies in its own business.
- 10.3 For Pfizer, the transaction offers the opportunity to realise premium value on a business that it no longer perceives as strategic. Pfizer seeks to aggressively grow its prescription pharmaceutical business, where it has primary strength. Pfizer will invest the money from the transaction in growing this prescription pharmaceutical business.

PART II: IDENTIFICATION OF MARKETS AFFECTED

Horizontal Aggregation

11 **Are there any markets in which there would be an aggregation of business activities as a result of the proposed acquisition?**

BACKGROUND

11.1 The portfolio of products to be acquired from PCH by J&J in New Zealand includes a range of pharmaceutical products in addition to a range of personal care products. All the products relevant to the New Zealand transaction are OTC products. The products include products for the treatment of:

- gastrointestinal conditions;
- pain;
- upper respiratory disorders; and
- fungal conditions.

11.2 This section outlines some of the key concepts relating to market definition in relation to the broad product categories and explains why products that may fall within those broad categories are not necessarily within the same 'market' for the purposes of the competition analysis.

General principles of market definition in pharmaceutical markets

11.3 In the European Union, drugs are classified into therapeutic classes by reference to the "Anatomical Classification Guidelines" (also known as the "ATC" classification), maintained by the European Pharmaceutical Marketing Research Association (*EphMRA*) and used by Intercontinental Medical Statistics (*IMS*).

11.4 In Decision 398,² the Commission commented on the application of the ATC as follows:

The ATC is hierarchical and has 16 categories (A, B, C, D etc) each with up to four levels. The first level (ATC 1) is the most general and the fourth level (ATC 4) the most detailed. The third level (ATC 3) allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use, and can therefore be used as an operational market definition. These groups of products generally have the same therapeutic indication and cannot be substituted by products belonging to other ATC 3 classes.

However, the EC Commission also notes that the third level of the ATC is not in all cases an appropriate basis for the definition of product markets and that it may be appropriate in certain cases to carry out analyses at other levels of the ATC classification. For example, it may be necessary to combine certain groups of pharmaceutical specialities. This would be the case

² SmithKline Beecham / Glaxo Wellcome, Decision 398, September 2000

where certain products from different ATC classes are substitutes for the treatment of a specific illness or disease.

On the other hand, the EC Commission notes that it may also be appropriate to apply a narrower market definition where the pharmaceutical specialities forming part of a certain ATC 3 class have clearly differing indications. In certain cases, pharmaceuticals may be further subdivided into various segments on the basis of a variety of criteria, and in particular demand-side criteria.

The Commission, through its enquiries, has found that the ATC classification affords an appropriate initial approach to defining product markets. The Commission also notes, however, that there may be instances where broader or narrower classifications are necessary, dependent upon the particular circumstances of the pharmaceuticals and the condition requiring treatment.

11.5 As the Commission noted in Decision 567:³

Medicines are generally divided into two categories, prescription and over-the-counter (OTC) medicines. As the name suggests, prescription medicines are only available from a pharmacy with a prescription from a doctor. OTC medicines can be sold directly to consumers without the need for a prescription by retail pharmacies, supermarkets and some consumer good stores.

11.6 The proposed transaction does not involve the acquisition of any prescription medicines. However, in a few instances there is a PCH OTC product and a J&J prescription product available for the same ailment. While these have been noted, the Applicant does not consider that OTC and prescription products fall within the same market, for the following reasons:

- (a) Prescription medicines are generally used to treat more severe illnesses or ailments than OTC medicines.
- (b) Even where the active ingredients are the same there are differences in terms of the regulatory restrictions applicable to each and with regard to pricing. The pricing of most prescription pharmaceuticals is constrained by regulation, while this is not generally the case for OTC pharmaceuticals.⁴
- (c) Most prescription medicines can be claimed on medical insurance or Community Services Card whereas most non prescription products cannot.

11.7 It is recognised, though, that unlike many other countries, advertising of prescription medicines is not prohibited in New Zealand.

11.8 In relation to OTC products, the Commission noted in Decision 567:

OTC products fall into two categories. Pharmacy-only medicines (also known as restricted medicines) are medicines that can be sold under the direction of a pharmacist without a doctor's prescription but they are not available for self-selection from the pharmacy shelves. Further, the sale must be made by a pharmacist. When selling these medicines, the pharmacist must fulfil

³ Reckitt Benckiser / Boots Group, Decision 576, November 2005

⁴ Zuellig Pharma / Sigma NZ, Decision 417, February 2001

special requirements designed to make sure the consumer is properly informed about the safe and correct use of the medicine.

Other OTC products, which are not specifically designated as pharmacy-only, can be sold in any retail outlet, such as supermarkets, service stations and department stores. These products are typically referred to as 'open' or grocery products. As certain pharmacy-only products become more widely used and consumers become aware of the effects of the medicine, there is a tendency for these products to be reclassified as grocery products...

Pharmacies may now be co-located with direct access between the pharmacy and other businesses. For example, a pharmacy may now operate within a specified area of a supermarket. Both Progressive and Foodstuffs Auckland have recently introduced pharmacies in some of their stores.

11.9 Having regard to the above, prescription and non prescription/OTC medicines have been treated as separate markets.

Pain Relief

11.10 The Commission has considered the pain relief market as recently as November 2005 (in Decision 567). In that Decision, the Commission noted as follows (at paragraphs 35 – 39):

Analgesics are medicines used in the treatment of pain and, if they contain an antipyretic ingredient, to reduce fever. Industry participants advised that most everyday pain can be easily controlled with an over-the-counter medicine. The three common active ingredients used in the treatment of everyday pain are paracetamol, aspirin and ibuprofen. All industry participants advised the Commission that there is a strong degree of substitutability between these active ingredients in the treatment of common pain. However, as the severity of the pain increases, the treatment is more specialised and the active ingredient is stronger. This is described in the table below.

Table 1 Pain Relief Treatments

Pain Scale	Examples	Active ingredients
Mild-to-moderate	Headache, backache, toothache, period pain	Paracetamol, Aspirin, Ibuprofen
Moderate-to-strong	Migraine, muscle cramps, severe post-operative pain	Codeine in combination with paracetamol or ibuprofen
Strong-to-severe	Burns, bone fractures and other serious injuries	Prescription Medicines such as Morphine

Source: <http://www.unichem.co.nz/>

Mild-to-moderate pain is typically treated with a grocery medicine, whereas moderate-to-strong pain may be treated with a pharmacy-only or prescription product. The Commission notes that each active ingredient has its own properties that restrict its use to certain consumers. For example, ibuprofen is not advised for use by pregnant women and currently codeine is only available in a pharmacy-only product.

However, industry participants advised that all these products are used in the treatment of pain and there is not a separate market for the specific active ingredient, such as either paracetamol or aspirin. Rather, a consumer may choose or be advised by a pharmacist to use a particular type of product based on the person's symptoms. Nevertheless, all these products are used for the treatment of pain.

Accordingly, the Commission considers the appropriate product to be non prescription medicines for the treatment of pain (analgesics).

11.11 The Applicant agrees with the Commission's approach to pain relief markets in Decision 567 and has adopted that approach in this application. Consequently there is no horizontal aggregation in the pain relief sector.

Cough colds and flu

11.12 Under the ATC level classification, cough, cold and flu products are classified under:

- (a) R5: which includes cold and flu preparations, cough relievers and expectorants;
- (b) R1: which includes nasal decongestants (nasal congestion being one of the symptoms of cold and flu); and
- (c) R2: sore throat medication.

Cold and Flu treatments

11.13 A cold is caused by a viral infection of the upper respiratory system. The cold virus attaches itself to the lining of the nasal passages and sinuses. This causes the infected cells to release histamine. Histamine increases the blood flow to the infected cells, causing swelling, congestion, and increased mucus production. Cold symptoms include a runny nose, possibly fever, coughing, sneezing, nasal congestion, headache, muscle ache, chills, sore throat, hoarseness, watery eyes and tiredness.

11.14 The flu is a more severe respiratory illness caused by various strains of the influenza virus. Symptoms of the flu (headache and other body aches, fever, cough, congestion) are similar to those of a common cold and are treated with the same medication.

11.15 Because of the multiple symptoms associated with a cold and flu, cold and flu medications are often combination products. They could combine:

- (a) an analgesic/antipyretic, relieving pain and fever;
- (b) an antihistamine, reducing the histamine production;
- (c) a cough reliever, suppressing the cough; and/or
- (d) a decongestant, clearing the respiratory tract and facilitating breathing.

Cough Relievers and Expectorants

11.16 There are three types of cough: a dry (non-productive) cough, a chesty (productive) cough and an allergic cough.

11.17 Each of these coughs is treated differently:

Non-productive cough

- (a) A dry cough is caused by an irritation of the throat and is not productive, i.e. it does not remove congestion (mucus in the airways). Antitussives are medications that suppress a dry cough. One of the most common active ingredients is dextromethorphan. This ingredient suppresses an area in the brain that causes coughing.

Productive cough

- (b) A productive cough is a cough that is accompanied with the secretion of mucus and relieves the respiratory tract. It removes or reduces chest congestion and allows the patient to breathe more easily. A productive cough should not be suppressed. Expectorants are medications to break up congestion and mucus and to help the patient breathe more easily.

Allergic cough

- (c) An allergic cough is medicated by treating the allergy. These medications fall under the category of anti-allergics.

Nasal decongestants

11.18 Nasal decongestants are a broad class of medications used to relieve nasal congestion. Generally, they work by reducing swelling of the mucous membranes in the nasal passages. By decreasing blood flow to these membranes, these drugs decrease congestion and open up the air passage.

11.19 The effects are not limited to the nose and these medicines can increase hypertension (blood pressure). These are normally paired with antihistamines to lessen this effect. These medications help clear a stuffy, blocked or runny nose, making it easier to breathe freely.

11.20 Common causes of nasal congestion are cold and flu, sinusitis (sinus infection), hay fever and other allergies and non-allergic rhinitis.

11.21 Nasal decongestants come in the form of systemic nasal decongestants (tablets and syrups) and nasal decongestant sprays or drops. Both types of medication have the same broad indication – removing nasal congestion. However, nasal sprays and drops are applied directly into the nose and provide immediate relief. Systemic medications are taken orally and have about a 30-45 minute delay before they provide relief.

Sore Throat

11.22 A sore throat is another common symptom of cough and cold diseases. Sore throat medications are often combination preparations formulated for infections of the throat, nose/throat and mouth/throat. They include tablets, lozenges, drops, sprays, gargles and suppository forms.

Anti-allergy products

11.23 An allergy occurs when the body's natural defence system identifies a substance (e.g. pollen, dust, food) as potentially harmful and reacts in an attempt to protect the body from that substance.

11.24 Allergens are the substances that cause the body to react. They may be inhaled (e.g. dust) or eaten (e.g. fruits) or may come in direct contact with the skin (e.g. latex) or penetrate through the skin (e.g. insect sting venoms).

11.25 Allergy-related conditions generally involve the head (eyes, nose, mouth, throat); the lungs (shortness of breath/asthma); the gastrointestinal tract (e.g. diarrhoea); or the skin (dermatitis and hives).

11.26 One type of medication used to prevent or reduce an allergic reaction is called antihistamines. Histamine is a natural chemical in the body that is released when the body tries to protect itself against allergens, causing the allergic reaction. Antihistamines block the action of histamine in the body, thus avoiding or reducing the body's allergic symptoms.

11.27 Anti-allergy products can be classified into different categories:

- (a) systemic antihistamines;
- (b) nasal anti-allergic agents, including combinations of a nasal decongestant and an anti-allergic; and
- (c) ocular anti-allergics.

11.28 Topical anti-allergic drugs are administered in the form of eye or nose drops or a nasal spray. They have only a localized application and have almost no absorption into the blood stream.

11.29 Systemic anti-allergy drugs are taken orally and affect the whole body (they enter the blood stream). Accordingly, they are indicated to relieve a broad range of allergic symptoms - not only those nasal or ocular symptoms.

11.30 Systemic and topical anti-allergics do not properly belong to the same market.

Gastrointestinal remedies

11.31 Both J&J and PCH sell a range of non prescription medicines, which can broadly be classed as gastrointestinal remedies. Products in this category include:

- (a) laxatives: used for the treatment of constipation;
- (b) heartburn and indigestion remedies;
- (c) worm treatments (for worms in humans);
- (d) diarrhoea treatments; and
- (e) heartburn.

Heartburn

11.32 Heartburn is caused either by a lack of acid to digest the food that has been eaten or the production of excess acid in the stomach. When food is eaten the stomach produces acidic gastric acids (hydrochloric acid) to break down the food and turn it into a liquid from which the nutritional value is extracted. This causes irritation of the lining of the stomach and can weaken the lower oesophageal sphincter, a small valve between the stomach and the oesophagus, which prevents food, and therefore stomach acid, from flowing back into the throat.

11.33 Heartburn can result from a number of causes: lifestyle choices, dietary habits, medical history and certain body positions which put pressure on the stomach and cause acid to leak back into the oesophagus (known as gastroesophageal reflux). Sufferers may experience any one or a combination of the following symptoms: (i) a sore/burning sensation in the stomach or behind the breastbone; (ii) a rising pain in the oesophagus (food pipe); (iii) a bitter taste in the back of the mouth or throat; (iv) a feeling that food or liquid is coming back into the mouth or throat.

11.34 OTC drugs are usually used to treat episodic heartburn, the most common form of heartburn. More serious manifestations (frequent or persistent heartburn) will usually be treated with prescription drugs, including proton pump inhibitors (*PPIs*).

Worm treatments

11.35 Worm treatments are used in the treatment of intestinal worms – threadworms (also known as pinworms), roundworms, hookworms and whipworms.

11.36 The common active ingredients in worm treatments are pyrantel embonate and mebendazole (the latter prevents worms from absorbing glucose, causing death).

Pyrantel embonate is dosed by bodyweight at 10mg/kg, for threadworm, roundworm and hookworm. It is ineffective against whipworm.⁵ The mebendazole dose for threadworm is 100mg, regardless of bodyweight. Higher doses are used for roundworm, hookworm and whipworm.⁶

11.37 PCH's worm treatment product is COMBANTRIN and its active ingredient is pyrantel embonate (although the new "COMBANTRIN-1" product contains mebendazole rather than pyrantel embonate). J&J's worm treatment product is VERMOX and its active ingredient is mebendazole. COMBANTRIN and VERMOX both treat threadworm, roundworm and hookworm. J&J's product VERMOX and PCH's product COMBANTRIN-1 also treat whipworm.

Anti-fungal treatments

11.38 Both J&J and PCH sell non prescription medicines that are used to treat fungal infections.

11.39 Antifungals are pharmaceuticals used to treat infections caused by a fungus or yeast, such as athlete's foot, ringworm and candidiasis (thrush). Fungus can grow almost anywhere on or inside the body. It can grow on the skin, nails, organs, mouth or throat. Antifungal medication works by killing the fungus or yeast or preventing its growth. They can be either prescription or non prescription.

11.40 Antifungals can be classified by reference to the location of the disease, i.e.:

- (a) mouth antifungals;
- (b) dermatological (skin) antifungals;
- (c) dermatological (scalp) antifungals; and
- (d) gynaecological antifungals.

11.41 Antifungals can also be classified by their form:

- (a) topical ointments, lotions, creams or gels;
- (b) shampoos; and
- (c) tablets.

AREAS OF AGGREGATION BETWEEN J&J AND PCH

Product markets

11.42 The tables at the end of this section identify the products in the PCH portfolio that are to be purchased under the proposed transaction and whether, having regard to the above commentary, any horizontal aggregation will occur in any market in

⁵ <http://www.everybody.co.nz/OTCGuide-Classification-40.aspx>

⁶ <http://www.everybody.co.nz/OTCGuide-Classification-40.aspx>

the New Zealand. In summary, the transaction will give rise to horizontal aggregation in the following markets in New Zealand:

- (a) allergy medication;
- (b) products for the treatment of worms; and
- (c) thrush treatments.

Functional market definitions

11.43 Neither J&J nor PCH manufactures product in New Zealand. All products are manufactured offshore and imported by the New Zealand subsidiaries.

11.44 Both J&J New Zealand and PCH New Zealand import their products. Depending on the nature of the particular product, they supply supermarkets, grocery retailers, pharmaceutical wholesalers, retail chemists, doctors, public and private hospitals, and rest homes.

11.45 In some instances the relevant distribution network includes only pharmacies and in the case of some products, both pharmacies and grocery channels (as well as other channels). The following table identifies the distribution channel for each of the above product markets where the proposed acquisition gives rise to horizontal aggregation.

Distribution channels

Product	Channel
Allergy medication	Pharmacy only
Worm treatments	Pharmacy only
Thrush treatments	Pharmacy only

Geographic Markets

11.46 All the main suppliers of the products affected by the proposed transaction supply their product on a national basis and promote their products nationally.

Identification of areas of overlap between PCH and J&J products

Product Category	PCH	J&J	Comment
Smoking cessation	PCH sells a range of smoking cessation products under the NICORETTE brand in New Zealand and in offshore markets.	J&J does not sell smoking cessation products.	No horizontal aggregation in the New Zealand market.
Vitamins and mineral supplements	PCH sells a range of vitamin and mineral supplements in offshore markets, including calcium, iron complex, multivitamins, peppermint oil, selenium, Vitamin B complex, Vitamin C, Vitamin E and Vitamin P. PCH's calcium supplement is sold under the CALCIOZIUM brand. None of these products are sold in the New Zealand market.	J&J sells a multi-vitamin product in offshore markets, but not in New Zealand. J&J also sells a calcium product called VIACTIV CALCIUM SOFT CHEW in offshore markets. J&J is looking to bring this product on to the New Zealand market potentially in later 2007.	No horizontal aggregation in the New Zealand market.
Sleeping medication	PCH sells sleeping medication in New Zealand under the brands UNISOM and DOZILE.	J&J sells a sleeping medication under the brand SIMPLY SLEEP in offshore markets but not in New Zealand.	No horizontal aggregation in the New Zealand market.
Antiseptics	PCH sells hydrogen peroxide solutions in some offshore markets but not in New Zealand.	J&J may sell hydrogen peroxide solutions in offshore markets but does not do so in New Zealand.	No horizontal aggregation in the New Zealand market.
Hair loss treatment	PCH sells hair loss treatments under the ROGAINE brand in New Zealand and in offshore markets.	J&J does not sell hair loss products.	No horizontal aggregation in the New Zealand market.
Urinary disorders	PCH sells products for urinary disorders in some offshore markets but not in New Zealand.	J&J sells products for urinary disorders in some offshore markets but not in New Zealand.	No horizontal aggregation in the New Zealand market.
Anti-haemorrhoidals	PCH sells anti-haemorrhoidal products in New Zealand (and offshore) under the ANUSOL brand.	J&J sells anti-haemorrhoidal products in some countries but not in New Zealand.	No horizontal aggregation in the New Zealand market.
Headlice and scabies treatments	PCH sells products for the treatment of headlice and scabies in some countries but not in New Zealand.	J&J may sell products for the treatment of headlice or scabies in some offshore markets but not in New Zealand.	No horizontal aggregation in the New Zealand market.

Product Category	PCH	J&J	Comment
Sting/bite treatments	PCH sells products for the treatment of stings and bites under the STINGOSE brand in New Zealand.	J&J may sell products for the treatment of stings or bites in some offshore markets but not in New Zealand.	No horizontal aggregation in the New Zealand market.
Motion sickness prevention/treatment	PCH sells products for the prevention and treatment of motion sickness in New Zealand under the DRAMAMINE and MARZINE brands.	J&J does not sell products for the prevention and treatment of motion sickness.	No horizontal aggregation in the New Zealand market.
Topical antibiotic treatments	PCH sells topical antibiotic treatments in some offshore markets but not in New Zealand.	J&J may sell topical antibiotic treatments in some offshore markets but not in New Zealand.	No horizontal aggregation in the New Zealand market.

Gastrointestinal			
Product Category	PCH	J&J	Comment
Laxatives	PCH sells laxative products (MICROLAX enema and GLYCERIN suppositories) in New Zealand.	J&J sells laxative products in some countries but not in New Zealand.	No horizontal aggregation in the New Zealand market.
Heartburn and indigestion remedies	PCH sells non prescription heartburn and indigestion remedies in New Zealand under the MYLANTA brand (Mylanta, Mylanta Double Strength, Mylanta Heartburn Relief and Mylanta Rolltabs). ⁷ PCH also supplies a number of other heartburn and indigestion remedies outside New Zealand.	J&J sells non prescription heartburn and indigestion remedies in some countries but not in New Zealand. J&J sells a prescription only product under the MOTILIUM brand in New Zealand.	No horizontal aggregation in the New Zealand market (on the basis that prescription and non prescription medicines are separate markets.) (Refer product information in Appendix 1).
Worm treatment	PCH sells a worm treatment product in New Zealand under the brand name COMBANTRIN.	J&J markets a worm treatment product in New Zealand under the brand name VERMOX.	There is horizontal aggregation in the market for products for the treatment of worms. (Refer product information in Appendix 2). Further consideration of these products is set out in section 17.
Diarrhoea treatments	PCH sells products for the treatment of diarrhoea in offshore markets (including under the LOMOTIL brand) but not in New Zealand.	J&J sells a product for the treatment of diarrhoea under the IMODIUM brand in New Zealand.	No horizontal aggregation in the New Zealand market.
Gas relief	PCH sells infant gas relief products in some countries (MYLICON DROPS) but not in New Zealand.	J&J sells products for the relief of gas in some offshore markets but not in New Zealand.	No horizontal aggregation in the New Zealand market.

⁷ J&J owns the Mylanta brand in the United States but PCH has the licence to sell products under the brand in New Zealand.

Pain relief			
Product Category	PCH	J&J	Comment
Pain relief – prescription	The assets to be acquired by J&J include PCH's anti-migraine drug MIGRALEVE which is prescription bound in some countries but available without prescription in others. This product is not available in New Zealand.	<p>J&J, via Janssen-Cilag, also sells DUROGESIC, which is a transdermal patch used for chronic pain relief.⁸ This product is available in New Zealand on prescription only.</p> <p>J&J, also via Janssen-Cilag, sells an anti-migraine drug SIBELIUM. This product is not available in New Zealand.</p> <p>J&J also sells other prescription pain relief products in some offshore markets but not in New Zealand.</p>	<p>MIGRALEVE and SIBELIUM are not in direct competition. SIBELIUM is a prophylactic (preventive) medication, meant to avoid or reduce the occurrence of migraine attacks in patients suffering from frequent and severe attacks. SIBELIUM is only indicated where other preventive treatments have failed and/or are not well tolerated. It is medication that needs to be taken continuously - not when a migraine attack occurs. It is not suitable to abort a migraine attack or to relieve the symptoms.</p> <p>MIGRALEVE is a symptomatic treatment indicated to relieve the symptoms (headache, nausea) of a migraine attack when it occurs.</p> <p>No horizontal aggregation in the New Zealand market for prescription bound pain relief.</p>
Pain relief – non prescription	PCH sells non prescription pain relief products in New Zealand under the PAMOL, CALPOL and PIROPHEN brands. The active ingredient in these products is paracetamol.	J&J sells paracetamol based non prescription pain relief products in offshore markets (including under the TYLENOL brand) but not in New Zealand. ⁹	No horizontal aggregation in the New Zealand market.
	PCH sells non prescription ibuprofen based pain relief products in offshore markets but not in New Zealand.	J&J sells non prescription ibuprofen based (including under the MOTRIN brand) in offshore markets but not in New Zealand.	
	PCH sells topical analgesics in some offshore markets.	J&J may sell topical analgesics in some offshore markets but not in New Zealand.	

⁸ Transdermal patches are applied to the skin and serve as a mechanism for the controlled release of a drug, for instance pain relievers, hormones or nicotine

⁹ J&J has registrations in New Zealand for Tylenol and Tylox but has never sold them in the New Zealand market.

	PCH sells products specifically for earache relief in some offshore markets.	J&J may sell products specifically for earache relief in offshore markets but not in New Zealand.	
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Upper respiratory			
Product Category	PCH	J&J	Comment
Cold & Flu medications	PCH sells non prescription cold and flu medications in New Zealand under the CODRAL brand.	J&J marketed a cough and flu medication in New Zealand under the ORTHOXICOL brand until mid 2006. That product has been withdrawn from the New Zealand market. J&J does not supply any other cold and flu medications in New Zealand. J&J markets cold and flu medications in a number of other countries.	No horizontal aggregation in the New Zealand market. (Refer product information in Appendix 3).
Nasal decongestant	In New Zealand, PCH sells non prescription medicines for treating nasal and sinus congestion under the SINUTAB and SUDAFED brands. PCH also sells a "plug in" nasal decongestant, which is designed to clear the air in a whole room.	J&J sells nasal decongestant products in offshore markets but not in New Zealand.	
Cough relief medication	PCH sells non prescription cough relief medications in New Zealand under the CODRAL, BENADRYL and BRONDECON brands.	J&J sells cough relief products in offshore markets but not in New Zealand.	
Sore throat	PCH sells non prescription sore throat medications in offshore markets but not in New Zealand.	J&J sells sore throat medications in offshore markets but not in New Zealand.	
Allergy relief	PCH sells non prescription products for the relief of colds, hayfever and allergies under the ACTIFED brand in New Zealand and has a sinus pain and allergy relief product under the SINUTAB and SUDAFED ranges. PCH sells a range of non prescription ocular decongestants (eye drops) under the VISINE brand in New Zealand. These include eye drops for sore eyes, red eyes and red, allergy eyes (the latter containing a decongestant and antihistamine).	J&J does not have a product similar to ACTIFED (which is for colds and allergies) in New Zealand. J&J sells a non prescription anti-allergy nasal spray and eye drops under the LIVOSTIN brand in New Zealand. J&J sells ocular decongestants in some offshore markets.	

Antifungals			
Product Category	PCH	J&J	Comment
Topical antifungals	PCH sells topical antifungal treatments in offshore markets but not in New Zealand. It used to sell topical antifungal treatments in New Zealand under the TROSYD brand but no longer does so.	<p>J&J sells topical antifungal treatments under the DAKTARIN, DAKTAGOLD, DAKTACORT and NIZORAL brands. DAKTAGOLD and DAKTACORT are cream based. NIZORAL is available as a shampoo or cream. NIZORAL is also available as a tablet on prescription only. DAKTARIN is sold in the following formulations:</p> <ul style="list-style-type: none"> ▪ DAKTARIN tincture, for the treatment of fungal infections of the nails (a prescription only product). ▪ DAKTARIN cream, used for the general treatment of skin mycosis due to certain fungi. ▪ DAKTARIN emulsions, which are liquid creams indicated more particularly for the treatment of mycosis in hairy parts of the body. ▪ DAKTARIN powder, used to treat fungus on parts of the body where maceration/perspiration is especially significant, like athlete's foot. ▪ DAKTARIN sachets, used instead of normal soap by those people who have mycotic infections. 	No horizontal aggregation in the New Zealand market.

Product Category	PCH	J&J	Comment
Thrush treatments	<p>PCH sells non prescription thrush treatments in New Zealand under the DIFLUCAN ONE brand. These are in tablet form.</p>	<p>J&J sells non prescription thrush treatments in New Zealand under the DAKTARIN and DAKTAGOLD brands. DAKTARIN and DAKTAGOLD are topical treatments.</p> <p>J&J sells a thrush treatment cream, and a prescription only thrush tablet under the NIZORAL brand, which are both available in New Zealand.</p> <p>J&J also sells a prescription thrush treatment under the SPORANOX brand.</p>	<p>Some degree of horizontal aggregation in the New Zealand market.</p> <p>(Refer product information in Appendix 5). Further consideration of these products is set out in section 18.</p>

Personal Care			
Product Category	PCH	J&J	Comment
Mouthwash	PCH sells a range of mouthwash products under the LISTERINE and LISTERMINT brands.	<p>J&J no longer sells a mouthwash product in New Zealand. It sells daily mouthwashes under the ACT and REACH brands in offshore markets.</p> <p>J&J discontinued supply of the REACH product into New Zealand (the last distribution was early-mid July 2006).</p> <p>J&J has considered bringing its ACT (anti-cavity treatment) mouthwash into New Zealand, but has determined that Medsafe's unique packaging requirements for New Zealand do not make it economically viable.¹⁰ Specifically, New Zealand regulations require the sodium fluoride content to be stated on the front of the packaging. This is not a requirement in offshore markets and the small size of the New Zealand market does not make it sufficiently attractive to produce packaging specifically for the market.</p>	No horizontal aggregation in the New Zealand market.
	In offshore markets, PCH also sells a range of medicated mouthwashes containing hexetidine as their active ingredient. Hexetidine is an antiseptic. It kills bacteria and fungi and is used to treat mouth infections.	J&J does not sell mouth infection treatments of this kind.	No horizontal aggregation in the New Zealand market.

¹⁰ Medsafe (the New Zealand Medicine and Medical Devices Safety Authority) is the responsible regulatory body.
See: <http://www.medsafe.govt.nz>

Personal Care			
Product Category	PCH	J&J	Comment
Teeth whitening products	PCH sells a pre-brush whitening mouthwash rinse (under the LISTERINE brand) in New Zealand.	J&J sells a whitening toothbrush under the REACH brand in New Zealand, and sells a whitening floss (under the REACH brand) in offshore markets. J&J also sells a whitening pen product and whitening strips (under the REMBRANDT brand) in offshore markets.	The PCH rinse and the J&J toothbrush and floss comprise different steps in a teeth whitening regime: rinse with a pre-brush whitening mouthwash rinse; brush with a whitening toothbrush and/or toothpaste; floss with a whitening floss. No horizontal aggregation in the New Zealand market.
Toothpaste	PCH sells toothpaste under the LISTERINE brand in New Zealand. PCH sells toothpastes under a variety of brands in offshore markets.	J&J does not sell a toothpaste product in New Zealand. It sells whitening toothpaste (under the REMBRANDT brand) in some offshore markets.	No horizontal aggregation in the New Zealand market.
Toothbrushes	PCH sells offshore under the DENTOSAN brand. PCH has supplied a promotional pack which included a toothbrush, travel bag, rinse cup and mouthwash, and which was sold under the ESSENTIALS brand. The pack was available for a limited time only, and the individual items were not available separately. The toothbrushes in the ESSENTIALS pack were supplied by a third party manufacturer.	J&J sells toothbrushes under its REACH brand.	No current horizontal aggregation in the New Zealand market.
Breath Freshener	PCH sells breath fresheners in New Zealand under the LISTERINE brand.	J&J does not sell breath freshener products in New Zealand.	No horizontal aggregation in the New Zealand market.
Shampoo	PCH sells shampoo in New Zealand under the PREGAINE brand. This is a specialised volume-enhancing shampoo specifically designed to care for thinning hair and is designed for use in association with PCH's ROGAINE range of products with the active ingredient minoxidil which helps prevent hair loss.	J&J sells shampoos in New Zealand under the following brands: <ul style="list-style-type: none"> ▪ NEUTROGENA (which includes regular shampoos and therapeutic (e.g., anti-dandruff) varieties ▪ JOHNSON'S. J&J also sells a medicated anti-dandruff/antifungal shampoo under the NIZORAL brand in New Zealand.	PREGAINE is a specialised shampoo that is not substitutable for J&J's NEUTROGENA, JOHNSON'S or NIZORAL products. (Refer product information in Appendix 6.) No horizontal aggregation in the New Zealand market.

Personal Care			
Product Category	PCH	J&J	Comment
Hand/Body moisturisers	PCH sells moisturising hand and body lotions and creams under the LUBRIDERM brand in offshore markets but does not sell them in the New Zealand market.	J&J sells hand and body creams and lotions in New Zealand the following brands: <ul style="list-style-type: none"> ▪ NEUTROGENA; ▪ CLEAN & CLEAR ▪ JOHNSON'S; ▪ AVEENO; and ▪ RETINOVA (available on prescription). 	No horizontal aggregation in the New Zealand market.
Hand hygiene	PCH sells a hand sanitiser in New Zealand under the PURELL brand. PURELL is a consumer brand sold through the grocery and pharmacy channel.	J&J sells anti-microbial hand sanitiser under the MICRO SHIELD brand for use in hospitals.	The PURELL and MICRO SHIELD products are not substitutable in terms of use or price. (Refer product information in Appendix 7.) No horizontal aggregation in the New Zealand market.
Acne treatments	PCH may sell acne treatment products in offshore markets but does not do so in New Zealand. PCH used to sell a pharmacy only acne treatment lotion under the brand DALACIN T brand in New Zealand but no longer does so.	J&J sells a range of anti-acne and acne treatment products in New Zealand under the NEUTROGENA and CLEAN & CLEAR brands. J&J also sells the prescription product RETIN-A.	No horizontal aggregation in the New Zealand market.
Product Category	PCH	J&J	Comment
Nappy rash	PCH sells a range of nappy rash products under the DESITIN and ZINCOFAX brands in offshore markets. These products are not available in New Zealand.	J&J sells nappy rash products in New Zealand under the DAKTOZIN and JOHNSON'S brands.	No horizontal aggregation in the New Zealand market.
Baby powder	PCH sells a baby powder called DESITIN CORNSTARCH BABY POWDER in offshore markets but not in New Zealand.	J&J sells JOHNSON'S BABY POWDER in New Zealand.	No horizontal aggregation in the New Zealand market.

Differentiated Product Markets

12 **Please indicate whether the products in each market identified in question 11 are standardised (buyers make their purchases largely on the basis of price) or differentiated (buyers make their purchases largely on the basis of product characteristics as well as price).**

12.1 The three product markets in section 11 where there will be some horizontal aggregation are, in general, differentiated product markets. While the J&J and PCH products within each market are designed to treat similar conditions, they come in different forms, can be of different strengths and/or contain varying ingredients or combinations of ingredients. In particular, in the case of PCH's products in the allergy treatment category, the products are combination products that include an allergy treatment element. The degree of differentiation in relation to each product market is discussed below.

13 **For differentiated product markets:**

- Please indicate the principle characteristics of products that cause them to be differentiated one from another.**
- To what extent does product differentiation lead firms to tailor and market their products to particular buyer groups or market niches?**
- Of the various products in the market, which are close substitutes for the products of the proposed combined entity? - which are more distant substitutes?**
- Given the level of product differentiation, to what extent do you consider that the merged entity would be constrained in its actions by the presence of other suppliers in the market(s) affected?**

Allergy medication

13.1 As discussed in more detail at section 16, the PCH products that have an allergy relief element to them are ACTIFED, SINUTAB, SUDAFED and VISINE ALLERGY. With the exception of VISINE ALLERGY, these are all *systemic* anti-allergics, i.e. they affect the entire body and are typically taken orally in the form of tablets or syrup.

13.2 J&J's allergy product is LIVOSTIN. LIVOSTIN is a *topical* (nasal and ocular) anti-allergics, relying on an antihistamine mode of action. As discussed further in section 16, topical anti-allergics are those that have a localised effect and are applied locally.

13.3 The range of ACTIFED products are promoted for colds, hayfever as well as allergies. VISINE is a range of “ocular decongestants”, which treat some of the symptoms that may be caused by an allergic reaction (or another cause), but in general do not treat the cause of the irritation. Only one of the VISINE products, the VISINE ALLERGY product, contains an antihistamine.

13.4 One of the SINUTAB range of nasal decongestants, SINUTAB SINUS, ALLERGY & PAIN RELIEF, also has an antihistamine in it. The product is promoted for the temporary relief of sinus headaches, congestion and allergic symptoms such as a runny nose and sneezing. One of the products in the SUDAFED range of nasal decongestants, SUDAFED SINUS PAIN AND ALLERGY RELIEF, is promoted for the relief of allergy and hayfever symptoms such as sneezing, watery eyes, itchy and runny nose as well as providing relief from sinus pain.

13.5 Specific details relating to each of the products is contained in the table below:

Brand	Primary purpose	Active ingredients	Form and dosage
ACTIFED	Colds, hay fever, allergies	Pseudoephedrine and triprolidine hydrochloride (an antihistamine)	Systemic - 1 tablet, 3 times daily
SINUTAB SINUS, ALLERGY & PAIN RELIEF	Sinus headaches, congestion and allergic symptoms such as runny nose and sneezing.	Pseudoephedrine hydrochloride, paracetamol and chlorpheniramine maleate	Systemic - Adults: 2 tablets every 6 hours Children: 1 tablet every 6 hours
SUDAFED SINUS PAIN AND ALLERGY RELIEF	Sinus pain and allergy relief	Pseudoephedrine hydrochloride, paracetamol and triprolidine hydrochloride	Systemic - 2 tablets, 3-4 times daily
VISINE ALLERGY RELIEF	Relief from itching, soreness, pain and redness of the eye, due to hay fever and other allergens (including pollen, grass, animal hair, dust mites, feathers and air pollutants).	Naphazoline hydrochloride (decongestant) and pheniramine maleate (antihistamine)	Topical - 1 or 2 drops in affected eye, up to 4 times daily
LIVOSTIN NASAL SPRAY	Seasonal and perennial allergic rhinitis, conjunctivitis and rhinoconjunctivitis	Levocabastine	Topical - 2 puffs, 2 times daily
LIVOSTIN EYE DROPS	Seasonal and perennial allergic rhinitis, conjunctivitis and rhinoconjunctivitis	Levocabastine	Topical - 1 drop in each eye, 2-4 times daily

Worm treatments

13.6 As discussed in more detail at section 17, PCH markets OTC worm treatment products under the brand name COMBANTRIN. J&J markets OTC worm treatment products under the VERMOX brand.

13.7 Specific details relating to each of the products is contained in the table below:

Brand	Primary purpose	Active ingredients	Form and dosage	Other relevant feature
COMBANTRIN	<p>Pyrantel Embonate products treat threadworm, roundworm and hookworm.</p> <p>Mebendazole product (COMBANTRIN-1 only) treats threadworm (but taking multiple doses can treat hookworm, whipworm and roundworm).</p>	Pyrantel embonate / mebendazole	<p>Single dose</p> <p>e.g. one square for every 10kg of body weight (taken once); one square of Combantrin-1; one liquid dose; or one tablet.</p> <p>Available in chocolate squares, pineapple/blackcurrant liquid (either adult strength or regular strength), or tablet form</p>	(Approximately) \$15.50 for 24 chocolate squares
VERMOX	Threadworm (but taking multiple doses can treat hookworm, whipworm and roundworm).	Mebendazole	Single dose - liquid or tablet form	(Approximately) \$16.10 for 6 tablets

Thrush treatments

13.8 As discussed in more detail at section 18, PCH markets OTC thrush treatment products in New Zealand under the DIFLUCAN ONE brand. J&J markets OTC thrush treatment products in New Zealand under the DAKTARIN, DAKTAGOLD and NIZORAL brands.

13.9 Specific details relating to each of the products is contained in the table below:

Brand	Primary purpose	Active ingredients	Form and dosage
DIFLUCAN ONE	Vaginal thrush	Fluconazole	One tablet only
DAKTARIN (cream)	Common fungal and candidal infections including athlete's foot, jock itch, ring worm and other tinea or candidal ¹¹ infections.	Miconazole, benzoic acid and butylated hydroxyanisole	Thin layer of cream, twice daily. Continue use for up to two weeks after signs of infection have cleared.
DAKTARIN (gel)	Oral and gastrointestinal candidiasis.	Miconazole	Infants – 20mg per kg of body weight per day. Adults – 2.5mls four times daily.
DAKTAGOLD (cream)	Fungal infections such as athlete's foot, ring worm, jock itch and candidal infections.	Ketoconazole	Apply to the infected area once or twice daily, depending on severity. Continue treatment for 14 days after symptoms disappear.
NIZORAL (cream)	Athletes' foot, tinea, ringworm and thrush infections of the skin; seborrheic dermatitis	Ketoconazole	Once daily for 2-4 weeks. Continue use for a few days after signs of infection have cleared.

¹¹ Candidal infections are rashes caused by candida (a type of fungus).

14 **Will the proposal result in vertical integration between firms involved at different functional levels?**

14.1 The proposal will not result in vertical integration in New Zealand.

Nicotine replacement therapy

14.2 PCH is a manufacturer of nicotine patches. In New Zealand, PCH markets nicotine patches, along with other nicotine replacement therapy (*NRT*) products, under its NICORETTE and NICOTROL brands. These other products include chewing gums, sublingual tablets, nasal sprays and inhalators. J&J does not market NRT products (or smoking cessation products more generally) in New Zealand or elsewhere in the world. Thus, there is no horizontal relationship between the parties in respect of NRT.

14.3 A J&J subsidiary company, ALZA Corporation, develops and manufactures "transdermal" drug delivery patches, including a nicotine patch. Transdermal patches are applied to the skin and serve as a mechanism for the controlled release of a drug, for instance pain relievers, hormones or nicotine.

14.4 ALZA supplies nicotine patches (under exclusive long-term agreements) to:

(a) [], for sale in [] (in turn, [] has entered into an agreement with [], granting [] the right to market the product in []) [CONFIDENTIAL];

(b) [], for sale in [] [CONFIDENTIAL]; and

(c) GlaxoSmithKline for sale [] [CONFIDENTIAL] in New Zealand where it is marketed under GlaxoSmithKline's brand NICABATE.¹² Under its agreement with ALZA, GlaxoSmithKline has full control over the marketing and pricing of its products.

14.5 [] [CONFIDENTIAL] or GlaxoSmithKline. Thus, ALZA's production is [] and it is

¹² In the 1980s, when the product was developed, ALZA was a small, independent, research-based company focused on the development of drug delivery solutions (often in partnership with third parties) [

[CONFIDENTIAL]. Through a subsequent merger and an assignment, these retained rights ended up with [

[CONFIDENTIAL]. In 1997, ALZA entered into an agreement with SmithKline Beecham p.l.c. [

[CONFIDENTIAL]. Via SmithKline's merger with Glaxo Wellcome, these rights ended up with GlaxoSmithKline. J&J acquired ALZA in 2001.

not a direct, or even a potential, competitor as regards the supply of nicotine patches marketed in New Zealand [] [CONFIDENTIAL]. The agreement with [] specifies that [] (i.e. ALZA would be [] following the acquisition) [CONFIDENTIAL].

- 14.6 Nicotine patches are not manufactured in New Zealand. Manufacturing of transdermal patches tends to take place mainly in the United States and Europe and, to some extent, in Asia. For example, GlaxoSmithKline's NICABATE patches are manufactured in California and Ireland. PCH manufactures its patches in Sweden. Other nicotine patch manufacturers worldwide include Lohmann Therapy Systems, Aveva DDS, Watson and Samyang Corporation. In New Zealand, the only nicotine patches available are the PCH, GlaxoSmithKline and Novartis brands.
- 14.7 A J&J subsidiary company in Australia, Tasmanian Alkaloids, produces a range of analgesic products. These products are sold to intermediate companies who refine the products further and on-sell to pharmaceutical companies, to be refined into a state in which they are capable of inclusion in pharmaceutical products.
- 14.8 About []% of Tasman Alkaloids' Australian sales of codeine phosphate are to [], although Tasman Alkaloids does not sell to Pfizer in New Zealand [CONFIDENTIAL]. Tasman Alkaloids has exported to other businesses in New Zealand in the past but the market is very small – less than 100 kilograms of codeine per year.

15 **In respect of each market identified in questions 11 identify briefly:**

- **all proposed acquisitions of assets of a business or shares involving either participant (or any interconnected body corporate thereof) notified to the Commission in the last three years and, in each case,**
 - **the outcome of the notification (e.g. cleared, authorised, declined, withdrawn)**
 - **whether the proposed acquisition has occurred.**
- **any other acquisition of assets of a business or shares which either participant (or any interconnected body corporate) has undertaken in the last three years.**

J&J

15.1 Other than internal restructuring of businesses within the wider J&J group, J&J has not acquired any assets of a business (or any brands) or shares in New Zealand in the last three years.

Pfizer

15.2 As noted in Decision 496, in 2003, Pfizer Laboratories Limited acquired the business assets of Pharmacia Limited (as part of an international merger whereby Pfizer Inc. acquired Pharmacia Corporation in a stock-for-stock transaction).¹³

¹³ Pfizer Laboratories / Pharmacia, Decision 496, April 2003

**THE FOLLOWING SECTIONS ADDRESS PARTS III, IV AND V:
CONSTRAINTS ON MARKET POWER BY EXISTING AND POTENTIAL
COMPETITION AND OTHER POTENTIAL CONSTRAINTS IN RELATION TO
EACH OF THE IDENTIFIED PRODUCT MARKETS**

J&J and PCH products

- 16.1 There are four products in the PCH portfolio that have an allergy relief element to them. These products are ACTIFED, SINUTAB, SUDAFED and VISINE ALLERGY.
- 16.2 The allergy product sold by J&J in New Zealand is LIVOSTIN.

Overlap between LIVOSTIN, ACTIFED, SUDAFED, SINUTAB and VISINE ALLERGY

- 16.3 The LIVOSTIN range contains specific anti-allergy products relying on an antihistamine mode of action. They come in a nasal spray and eye drop form. LIVOSTIN contains levocabastine, an antihistamine that actually prevents or halts the allergic reaction, by blocking the body's histamine receptor/mast cell. LIVOSTIN is typically used in the morning to ensure day-long protection should the eye come into contact with pollen or another allergen. LIVOSTIN is specifically indicated for the long-lasting relief of ocular inflammation due to hay fever and, according to the patient information leaflet, "is used to relieve runny nose or irritation of the nose *caused by allergies*".
- 16.4 LIVOSTIN products are topical anti-allergics, i.e. those that have a localised effect and are applied locally. In contrast (with the exception of the VISINE ALLERGY product), PCH sells systemic anti-allergics, which are products that affect the entire body as they are typically taken orally (usually in the form of tablets or syrup).
- 16.5 If a person suffers mild allergic rhinitis (for example due to hayfever), he or she would be likely to use a nasal spray as a first choice since people tend to avoid loading their body with systemic drugs. When a nasal spray is not likely to provide sufficient relief, the person would take a systemic drug. Switching does not occur as a result of relative price changes but rather as a means to establishing what suits the patient's needs in a particular situation. Therefore, as noted in section 11, systemic and topical anti-allergics do not belong to the same market as they are typically used in different situations (and are also classed in different ATC categories).
- 16.6 PCH's range of ACTIFED products are promoted for the use of colds, hayfever and allergies. The SINUTAB and SUDAFED ranges of nasal decongestants both contain an allergy relief element. One of the products within the SINUTAB range, SINUTAB SINUS, ALLERGY & PAIN RELIEF has an antihistamine in it. This product temporarily relieves sinus headache, congestion and allergic symptoms such as runny nose and sneezing. One of the products in the SUDAFED range of nasal decongestants, SUDAFED SINUS PAIN AND ALLERGY RELIEF, relieves allergy and hayfever symptoms such as sneezing, watery eyes, itchy and runny nose as well as providing relief from sinus pain.

- 16.7 PCH's VISINE products are a range of "ocular decongestants" promoted for sore eyes, red eyes and red, allergy eyes. VISINE products contain tetrahydrozoline or tetryzoline. This is a vascular constrictor, which narrows the blood vessels of the eye, reducing redness of the conjunctive (the white part of the eye). VISINE products mimic substances like adrenaline, providing immediate relief for eye irritation caused by environmental factors (wind, dust, smoke) or allergic reactions. VISINE only provides temporary relief of red for irritated eyes. While it treats some of the symptoms that may be caused by an allergic reaction (or another cause), it does not treat the cause of the irritation, by blocking the action of the histamine in the body that is responsible for the allergic reaction.
- 16.8 However, one of the products in the VISINE range, VISINE ALLERGY (referred to above), contains an antihistamine.
- 16.9 Ocular decongestants and eye allergy relief (ocular anti-allergics) do not belong in the same market. Accordingly, the only area of overlap between LIVOSTIN and the VISINE range is the VISINE ALLERGY product.

Other suppliers of allergy treatments

- 16.10 There are a variety of non prescription allergy products available in the New Zealand market, including those listed in the following table:

Allergy treatments

Brand	Application	Owner
ACTIFED	Systemic	PCH
SINUTAB SINUS, ALLERGY AND PAIN RELIEF	Systemic	PCH (but a controlled drug) ¹⁴
SUDAFED SINUS PAIN AND ALLERGY RELIEF	Systemic	PCH (but a controlled drug)
APO – CETIRIZINE	Systemic	Apotex
TELFAST	Systemic	Aventis
HISTAFEN	Systemic	Douglas Pharmaceuticals
GOOD HEALTH ALLERGY CHECK	Systemic	Good Health
KORDELS	Systemic	Kordels
PERIACTIN	Systemic	MSD
NUTRALIFE ANTI-ALLERGY	Systemic	Nutralife
LORA-TABS	Systemic	Pacific Pharmaceuticals
RAZENE	Systemic	Pacific Pharmaceuticals
CLARATYNE	Systemic	Schering-Plough

¹⁴ "Controlled drugs" are narcotics and certain psychotropic agents regulated under the Misuse of Drugs Act 1975. The Act defines three categories of controlled drugs, and the controlled drugs in each class are listed in the Schedules to the Act: <http://www.medsafe.govt.nz/reg.htm>

Brand	Application	Owner
DEMAZIN	Systemic	Schering-Plough
POLARAMINE	Systemic	Schering-Plough
ZADINE	Systemic	Schering Plough
DIMETAPP ELIXIR	Systemic	Wyeth Consumer Health
ZYRTEC	Systemic	Pharmabroker
VISINE ALLERGY	Topical	PCH
LIVOSTIN NASAL	Topical	J&J
LIVOSTIN EYE DROPS	Topical	J&J
CROMOLUX	Topical	AFT Pharmaceuticals
LOMIDE	Topical	Alcon
RYNACROM	Topical	Aventis
TELNASE	Topical	Aventis
ATROVENT NASAL	Topical	Boehringer Ingelheim
AT-EZE	Topical	Douglas Manufacturing
AZEP NASAL SPRAY	Topical	Douglas Pharmaceuticals
BECONASE HAYFEVER	Topical	GlaxoSmithKline
FLIXONASE	Topical	GlaxoSmithKline
NARIUM NASAL DROPS NON-MEDICATED	Topical	Hamilton (NZ)
NATURO PHARM SINUMED RELIEF SPRAY	Topical	Naturo Pharm
NEILMED SINUS RINSE	Topical	NeilMed Pharmaceuticals
OTRISAL NASAL SPRAY	Topical	Novartis
OTRIVINE ADULT	Topical	Novartis
OTRIVINE PEDIATRIC	Topical	Novartis
ZADITEN	Topical	Novartis
BUTACORT	Topical	Pacific Pharmaceuticals
ALANASE	Topical	Pacific Pharmaceuticals
NAPHCON A	Topical	Pacific Pharmaceuticals
CLEAR EYES ACR	Topical	Pharmabroker Sales
VICKS INHALER	Topical	Procter & Gamble
VICKS SINEX	Topical	Procter & Gamble
OPTREX HAY FEVER ALLERGY DROPS	Topical	Reckitt Benckiser
DRIXINE NASAL SPRAY	Topical	Schering Plough
WELEDA RHINODORON NASAL SPRAY	Topical	Weleda
DIMETAPP 12 HOUR NASAL SPRAY	Topical	Wyeth Consumer Health
DIMETAPP INFANT DROPS	Topical	Wyeth Consumer Health

16.11 J&J estimates the market shares of the major suppliers of allergy treatment products, including systemic and topical products, to be as follows:

Estimated market shares by company [CONFIDENTIAL]

Supplier	\$ value estimate	Market share estimate
PCH	\$[]	[]%
PCH	\$[]	[]%
GlaxoSmithKline	\$[]	[]%
Novartis	\$[]	[]%
Procter & Gamble	\$[]	[]%
Reckitt Benckiser	\$[]	[]%
Other	\$[]	[]%
Total	\$[]	100.00%
Combined J&J/PCH market shares	\$[]	[]%

Source: Janssen-Cilag Management based on IMS data

16.12 J&J estimates the market shares of the major suppliers of allergy treatment products, based on a market for topical products only, to be as follows:

Estimated market shared by company (topical only) [CONFIDENTIAL]

Supplier	\$ value estimate	Market share estimate
PCH	[\$]	[]%
J&J	[\$]	[]%
AFT Pharmaceuticals	[\$]	[]%
Alcon	[\$]	[]%
Aventis	[\$]	[]%
Boehringer Ingelheim	[\$]	[]%
Douglas Pharmaceuticals	[\$]	[]%
GlaxoSmithKline	[\$]	[]%
Hamilton (NZ)	[\$]	[]%
Novartis	[\$]	[]%
Pacific Pharmaceuticals	[\$]	[]%
Pharmabroker Sales	[\$]	[]%
Procter & Gamble	[\$]	[]%
Reckitt Benckiser	[\$]	[]%
Schering Plough	[\$]	[]%
Wyeth Consumer Health	[\$]	[]%
Naturo Pharm	[]	Not available
NeilMed Pharmaceuticals	[]	Not available
Weleda	[]	Not available
Total Market Size	[\$]	100%
Combined J&J/PCH market shares	[\$]	[]%

Source: Janssen-Cilag Management based on IMS data

- 16.13 The table at paragraph 16.11 above indicates that, post-acquisition, the combined entity would have a market share, based on a wider allergy treatment market (including both systemic and topical products) of []% [CONFIDENTIAL] and the three firm concentration ratio would be []% [CONFIDENTIAL].
- 16.14 The table at paragraph 16.12 indicates that, post-acquisition, the combined entity would have a market share of a market that includes topical products only, of []% [CONFIDENTIAL]. The three firm concentration ratio would be []% [CONFIDENTIAL] (the combined entity clearly not being one of these three firms).
- 16.15 Regardless of how the market is defined, the combined entity's market share would be within the Commission's safe harbours. The degree of aggregation, the combined market shares and the size of the other competitors indicates that the impact of the acquisition in the factual compared to the counterfactual is likely to be minimal. Accordingly, no further comment on this market is made.

17 Products for treatment of worms

J&J and PCH products

- 17.1 PCH markets a worm treatment product in New Zealand under the brand name COMBANTRIN.
- 17.2 J&J markets a worm treatment product in New Zealand under the brand name VERMOX.

Existing competitors

- 17.3 The following table lists the OTC worm treatment products available in the New Zealand market and sales data for the 2004 and 2005 years:

Estimated market shares by company [CONFIDENTIAL]

	VERMOX	COMBANTRIN	DEWORM	
2004				
Unit Sales	[]	[]	[]	[]
Unit Market Share	[]%	[]%	[]%	100%
\$ Sales	[\$]	[\$]	[\$]	[\$]
\$ Market Share	[]%	[]%	[]%	100%
2005				
Units Sales	[]	[]	[]	[]
Unit Market Share	[]%	[]%	[]%	100%
\$ Sales	[\$]	[\$]	[\$]	[\$]
\$ Market Share	[]%	[]%	[]%	100%

Source: Janssen-Cilag Management based on IMS data

- 17.4 Post acquisition, the combined entity would have a market share in terms of unit sales of around []% [CONFIDENTIAL] and a market share in terms of revenue of around []% [CONFIDENTIAL]. This is outside the Commerce Commission's safe harbour guidelines. While on its face there would appear to be a fairly high degree of aggregation between the COMBANTRIN and VERMOX products, there are several points to be noted about the worm treatment market, which are not apparent from market shares alone.

VERMOX and DEWORM

- 17.5 VERMOX's present market share is approximately []% [CONFIDENTIAL], whereas COMBANTRIN is clearly the third player in a market where the real competition is between VERMOX and DEWORM. DEWORM is a well

established and popular brand, and from online and in-store inquiries, proved to be the cheapest of the three major brands available.¹⁵

- 17.6 As the table at paragraph 17.13 below illustrates, VERMOX and DEWORM contain the same active ingredient (mebendazole). The products in the COMBANTRIN range contain the active ingredient pyrantel embonate, although there is a new product called COMBANTRIN-1, which contains mebendazole.
- 17.7 VERMOX is available in liquid or tablet form and DEWORM is available in chewable tablet form only. COMBANTRIN is available in both liquid and tablet form, and as chocolate squares. PCH's new product, COMBANTRIN-1 (which is the only product in the COMBANTRIN range that contains the same active ingredient as VERMOX) is only available as chocolate squares. Accordingly, although there are similarities across each suppliers range, there is some differentiation between each of the available products. This is particularly true in the case of COMBANTRIN's chocolate squares, which are a unique product, obviously designed to make the product more appealing to children.
- 17.8 Cipla Limited (*Cipla*), which manufactures DEWORM, supplies a broad range of pharmaceutical and chemical products, including (in the pharmaceutical sector) antihistamines, anti-inflammatories, anti-depressants and oncology treatments.¹⁶ Cipla's products are sold in more than 160 countries located in North America, South America, Europe, Asia, Africa and Australasia.
- 17.9 Cipla's New Zealand sponsor and distributor for DEWORM is Multichem Limited, a privately owned New Zealand company. Multichem operates in New Zealand and in the Pacific region, supplying hospitals, dentists and pharmacies with OTC products, pharmaceuticals, medical disposables, vaccines and dental supplies.¹⁷ Multichem has direct accounts with over 80% of New Zealand pharmacies.

Thompson's

- 17.10 One product that is not included in the table is Thompson's HIGH POTENCY GARLIC AND PARSLEY PERLES, which J&J understands has a small (less than 1%) share of the market. Thompson's product is used as a broad-spectrum immunity booster, but is promoted for the treatment of worms.¹⁸
- 17.11 While Thompson's at present has a small market share, it is well established in New Zealand and distributes its products worldwide. The

¹⁵ The pharmacy visited had VERMOX (only the liquid/suspension was available) at \$16.10, Combantrin chocolate squares at \$15.50 and DEWORM at \$12.90 (Thompson's Garlic and Parsley Perles were priced at \$12.60). A comparison of online pharmacies including Pharmacy Direct, Unichem and Life Pharmacy, confirmed the relative prices of the products with DEWORM being the cheapest.

¹⁶ <http://www.cipla.com/>

¹⁷ <http://www.multichem.co.nz/>

¹⁸ <http://www.thompsons.co.nz/afa.asp>

Thompson's Group includes Life-Span, Australasia's largest distributor of complementary medicine products, and Thompson Nutrition Limited, a market leader in New Zealand complementary medicine products.¹⁹

Thompson's Nutrition products are exported worldwide to Germany, United Arab Emirates, Indonesia, Korea and Japan. Thompson's is well placed to expand should the merged J&J / PCH entity attempt to raise prices above competitive levels.

17.12 As the Commission observed in the Reckitt Benckiser / Boots Healthcare decision, "the barriers to expansion from existing competitors, notably Bayer, are relatively low". The same would be true of Cipla, Multichem and Thompson's.

Potential entry

17.13 The following table lists suppliers of worm treatment products available in New Zealand and Australia, and shows the type(s) of worm each is designed to treat and its active ingredient.

Brand	Country / Region	Owner	Primary purpose	Active ingredient
VERMOX	New Zealand Australia	J&J	Threadworm, roundworm, hookworm and whipworm	Mebendazole
COMBANTRIN	New Zealand Australia	PCH	Threadworm, roundworm and hookworm and whipworm	Pyrantel embonate / mebendazole
DEWORM	New Zealand	Cipla Limited	Threadworm, roundworm, hookworm and whipworm	Mebendazole
AMCAL WORM TREATMENT	Australia	Amcal (pharmacy housebrand)	Threadworm and hookworm	Mebendazole
ANTHEL	Australia	Alphapharm	Threadworm, roundworm and hookworm	Pyrantel embonate
CHEMMART WORMING TABLETS (Pharmacy housebrand)	Australia	Symbion Pharmacy Services Pty Limited	Product is not listed in the MIMS Online database but J&J believes that it treats threadworm, roundworm, hookworm and whipworm (given that the active ingredient is mebendazole) ²⁰	Mebendazole

¹⁹ Natural healthcare products are those that complement conventional medicine.

²⁰ The MIMS database contains information on prescription and non prescription (including OTC) treatments available in Australia.

Brand	Country / Region	Owner	Primary purpose	Active ingredient
CHEMISTS' OWN DE WORM	Australia	Chemists' Own Pty	Product is not listed in the MIMS Online database but J&J believes that it treats threadworm, roundworm, hookworm and whipworm (given that the active ingredient is mebendazole)	Mebendazole
EARLY BIRD	Australia	Mentholatum Australasia Pty Limited	Threadworm	Pyrantel embonate
ESKAZOLE (prescription medication) ²¹	Australia	GlaxoSmithKline	Threadworm, roundworm, whipworm, tapeworm and hookworm, and is effective in parasitic conditions such as hydatid disease and neurocysticercosis.	Albendazole
GUARDIAN WORM TREATMENT (Pharmacy housebrand)	Australia	Guardian Pharmacies Australia Pty Limited	Product is not listed in the MIMS Online database but J&J believes that it treats threadworm, roundworm, hookworm and whipworm (given that the active ingredient is mebendazole)	Mebendazole
PHARMACIST WORM RID	Australia	Pharmacare Laboratories Pty Limited	Product is not listed in the MIMS Online database but J&J believes that it treats threadworm, roundworm, hookworm and whipworm (given that the active ingredient is mebendazole)	Mebendazole
RIDWORM	Australia	Douglas Pharmaceuticals	Threadworm	Mebendazole
STROMEKTOL (prescription medication) ²²	Australia	Merck Sharp and Dohme	Threadworm	Ivermectin

²¹ ESKAZOLE was registered in New Zealand but the registration has lapsed, as it has not been marketed in NZ since 1999.

²² STROMEKTOL is already registered (but not marketed) in New Zealand.

Brand	Country / Region	Owner	Primary purpose	Active ingredient
TERRY WHITE CHEMISTS WORMING TABLETS (Pharmacy housebrand)	Australia	Symbion Pharmacy Services Pty Limited	Product is not listed in the MIMS Online database but J&J believes that it treats threadworm, roundworm, hookworm and whipworm (given that the active ingredient is mebendazole)	Mebendazole
ZENTEL (prescription medication)	Australia	GlaxoSmithKline	Threadworm, roundworm, whipworm, tapeworm and hookworm, and is effective in parasitic conditions such as hydatid disease and neurocysticercosis.	Albendazole
PHARMACY CHOICE (Pharmacy housebrand)	Australia	Symbion Pharmacy Services Pty Limited	Product is not listed in the MIMS Online database but J&J believes that it treats threadworm, roundworm, hookworm and whipworm (given that the active ingredient is mebendazole)	Mebendazole

17.14 Further information about these products is contained in Appendix 8.

17.15 The following products are also registered in Australia but are not (yet) for sale:

Brand	Country / Region	Owner	Active ingredient
MEBAZOLE	Australia	Sanofi-Aventis Australia Pty Limited	Mebendazole
PRS DYN MEBENDAZOLE	Australia	Cardinal Health Australia t/a R P Scherer	Mebendazole
RID-WORM	Australia	Genepfarm Pty Limited	Mebendazole

Similarities between New Zealand and Australian products

17.16 Any of these 16 suppliers might represent a source of potential competition in New Zealand, especially as the vast majority of the Australian products contain similar active ingredients to the New Zealand products, and treat the same type of worm(s).

- 17.17 As the Commission has previously noted, registration of new products is a requirement for entry that a new entrant would be required to meet.²³ New medicines and “therapeutic” products are subject to regulatory approval in New Zealand and a new entrant or a supplier wishing to expand would need to submit an application to Medsafe to have the product approved. Worm products would fall within the “therapeutic” category. Evaluations by Medsafe have set fees, with the fee depending on the nature of the medicine / product.
- 17.18 Because products containing mebendazole and pyrantel embonate as their active ingredient have already been registered in New Zealand, new products containing these ingredients can be registered here relatively easily. This is because, as Medsafe’s Regulatory Guidance for Medicines publication notes, “Reduced data requirements and evaluation fees apply to New Medicine Applications for products that are closely related to an existing approved product”.²⁴
- 17.19 Products with either mebendazole or pyrantel embonate would be reviewed as new lower-risk medicine application (*NMA-L*). *NMA-Ls* are applications to distribute a new medicine that may be supplied without a prescription, contains an active ingredient(s) that is/are already available in New Zealand products, and that comes in a dosage forms that already exists in New Zealand (e.g. as a tablet or liquid).²⁵
- 17.20 On this basis, it would not be difficult for an Australian supplier wishing to introduce a product containing either mebendazole or pyrantel embonate as its active ingredient.²⁶
- 17.21 Additionally, as of 15 August 2006, Medsafe introduced a new streamlining process, which makes it easier for Australian suppliers to introduce products that are already registered in Australia into New Zealand. Such products are granted a reduced review timeline, provided certain specified documentation is provided with the application.²⁷
- 17.22 Furthermore, the New Zealand and Australian governments are working towards further harmonisation of each country’s medical regulatory

²³ Pfizer Laboratories / Pharmacia, Decision 496, April 2003

²⁴ <http://www.medsafe.govt.nz/reg.htm> (refer report at Appendix 10 – excerpt from the New Zealand Regulatory Guidelines for Medicines, Volume 1: Guidance notes for applicants for consent to distribute new and changed medicines and related products.)

²⁵ <http://www.medsafe.govt.nz/reg.htm> (refer Appendix 10)

²⁶ ESKAZOLE (containing Albendazole) is a GlaxoSmithKline product, which is available in Australia and which was previously registered in New Zealand. On this basis, and although an Albendazole product is not currently available for purchase in New Zealand, other Albendazole products (such as GlaxoSmithKline’s ZENTEL) could be registered in New Zealand without any great difficulty, although they would be registered here as a prescription medicine (as ZENTEL is in Australia).

²⁷ <http://www.medsafe.govt.nz/reg.htm>

regime.²⁸ The “trans Tasman therapeutic products agency project”, under the organisation of the Australia New Zealand Therapeutic Products Authority, involves New Zealand and Australia giving consideration to establishing a joint agency to regulate therapeutic product (medicines, medical devices and complementary medicines/dietary supplements that have therapeutic uses) in both countries. The new agency would replace Medsafe and the Australian Therapeutic Goods Administration and would be responsible for the regulatory functions currently undertaken by each body.

- 17.23 The final details of the regulatory framework, the legislation underpinning the joint agency (the treaty between New Zealand and Australia) and the transitional arrangement to create a new agency are yet to be concluded. However, the establishment of the trans Tasman agency would effectively create a single market for therapeutic products and would greatly facilitate trade and reduce compliance costs for trans-Tasman suppliers. Most significantly, products such as Douglas Pharmaceuticals’ RIDWORM would not face any regulatory barriers to entry.

Pharmacy groups

- 17.24 As the table above indicates, four of the Australian products are pharmacy housebrands. In Australia, pharmacy housebrands are already a key feature of the market, especially with paracetamol and ibuprofen products. This is a trend that is emerging in New Zealand with products such as AMCAL PARACETAMOL and UNICHEM PARACETAMOL. The pharmacy chains that are active in New Zealand, such as Life Pharmacy and Amcal, do not have a housebrand worm treatment product, but given the trend, pharmacies represent a very real potential source of entry into the market.
- 17.25 The Amcal pharmacy chain is also present in New Zealand and Amcal’s housebranded worm treatment product would appear to be a particularly likely entrant into the New Zealand market. Again, its active ingredient, mebendazole, is the same as VERMOX and DEWORM. In New Zealand, the Amcal chain has over 60 members, which are located nationwide.²⁹

Potential entrants

- 17.26 Large multinational suppliers such as Douglas Pharmaceuticals and GlaxoSmithKline are well placed to introduce their worm treatments into the New Zealand market if the merged entity were to attempt to price anti-competitively. As they already market and have registered a broad range of products in New Zealand, they are familiar with Medsafe’s registration process and have existing relationships in the distribution channels.³⁰ For example, Douglas Pharmaceuticals, which supplies the Rid Worm product,

²⁸ <http://www.anztpa.org/about.htm> (refer Australia New Zealand Therapeutic Products Authority report at Appendix 11 – “About the trans Tasman therapeutic products agency project”)

²⁹ <http://www.amcal.co.nz/>

³⁰ See information from the websites of several large multinational suppliers included in Appendix 9.

would not encounter significant regulatory barriers should it wish to register and market this product in New Zealand.

Countervailing power of purchasers

17.27 Worm treatment products are at present pharmacy only products in New Zealand. As the Commission has previously observed, many pharmacies in New Zealand are members of either formal or informal buying groups.³¹ By virtue of their membership of buying groups, members are able to negotiate more favourable terms and will inevitably favour the supplier able to offer the best terms. Completely aside from the potential of pharmacies to compete head on as suppliers of worm treatment products, their role as purchasers of the products and the countervailing power this would give them would constrain any attempt by the merged J&J / PCH entity to act anti-competitively in the worm treatment market.

Co-ordinated Market Power

17.28 The following tables assess the various factors of the worm treatment market against the various factors that the Commission considers indicate the scope of coordinated conduct (i.e. "collusion" and "detection") and whether the proposed transaction is likely to increase that scope.

Scope for collusion

Factor	Present	Effect of J&J / PCH transaction
High concentration of sellers	Yes (for worm treatments)	Increases concentration
Undifferentiated product	Some	Unlikely to change
Price inelastic market demand	Yes	Unlikely to change
Entry by new firms is slow	No	Unlikely to change
Few fringe competitors	Yes	Unlikely to change
Loss of an aggressive competitor	PCH does not have a particularly large market share	PCH has not been aggressive in this market
Static production technology	Yes	Unlikely to change
History of anti-competitive behaviour	No	Unlikely to change
Purchasers have countervailing power	Yes	Countervailing power of supermarkets and pharmacies

³¹ Sigma Company Limited / Amcal Chemists Marketing, Decision 350, April 1999

Scope for detection

Factor	Present	Effect of J&J / PCH transaction
High concentration of sellers	Yes (for worm treatments)	Increases concentration
Frequent sales	No	Unlikely to change
Stable, slow growth in demand	No	Unlikely to change
Price transparency	Yes	Unlikely to change
Cost similarities between businesses	Possibly	Unlikely to change
Multi-market contact	Possibly	Unlikely to change
Lack of vertical integration	Yes	Unlikely to change

17.29 The only feature of the worm treatments market that will change as a result of the transaction is the increase in supplier concentration. There are a number of points to be made here:

- (a) the remaining suppliers, J&J / PCH and Multichem, both supply a range of products into the OTC sector;
- (b) there is a range of other suppliers in this sector; and
- (c) the products are differentiated in a several respects.

17.30 Consequently, there would be little incentive or indeed, opportunity, for Multichem and J&J / PCH to engage in coordinated conduct.

Conclusion for worm treatment products

17.31 The combined effect of:

- (a) the presence of the DEWORM and HIGH POTENCY GARLIC AND PARSLEY PERLES products;
- (b) the potential for entry by an Australian supplier;
- (c) the potential for entry by a pharmacy housebrand product; and
- (d) countervailing power in the hands of pharmacies

would prevent the merged J&J / PCH entity from acting anti-competitively in the worm treatment products market, either alone or in coordination with others.

18 Thrush treatment

J&J and PCH Products

- 18.1 PCH markets OTC thrush treatment products in New Zealand under the DIFLUCAN ONE brand.
- 18.2 J&J markets OTC thrush treatment products in New Zealand under the DAKTARIN, DAKTAGOLD AND NIZORAL brands.

Existing competition

- 18.3 The following table lists a range of competing OTC thrush treatment products available in New Zealand.

Thrush treatment products

Brand	Owner
DIFLUCAN ONE	PCH
DAKTARIN	J&J
NIZORAL CREAM	J&J
NIZORAL TABLETS (prescription only)	J&J
SPORANOX (prescription only)	J&J
CLOTRIMADERM	AFT Pharmaceuticals
CANESTEN ONCE CREAM TREATMENT	Bayer Healthcare
CANESTEN 3 DAY CREAM TREATMENT	Bayer Healthcare
CANESTEN 6 DAY CREAM TREATMENT	Bayer Healthcare
CANESTEN 6 DAY PESSARY TREATMENT	Bayer Healthcare
CANESTEN ONCE PESSARY TREATMENT	Bayer Healthcare
CANESTEN ANTI-FUNGAL CREAM	Bayer Healthcare
CANESTEN ONCE PESSARY + CREAM	Bayer Healthcare
RESOLVE THRUSH	Ego
KOLOREX INTIMATE CARE CREAM	Forest Herbs
KOLOREX CAPSULES	Forest Herbs
LAMISIL TABS (prescription only)	Novartis
CLOCREME	Pacific Pharmaceuticals
FLUCAZOLE 150	Pacific Pharmaceuticals
TERBAFIN TABS (prescription only)	Pacific Pharmaceuticals
MICREME	Pacific Pharmaceuticals
PEVARYL PESSARY	Pacific Pharmaceuticals
NILSTAT CREAM	Sigma
NILSTAT PESSARY	Sigma

18.4 J&J estimates the market shares of the major suppliers to be as follows:³²

Estimated market shares by company [CONFIDENTIAL]

Supplier	\$ value estimate	Market share estimate
J&J	\$[]	[]%
PCH	\$[]	[]%
Pacific Pharmaceuticals	\$[]	[]%
AFT Pharmaceuticals	\$[]	[]%
Bayer Healthcare	\$[]	[]%
Total Market Size	\$[]	100.00%
Combined J&J and PCH market shares	\$[]	[]%

Source: Janssen-Cilag Management based on IMS data

18.5 The tables at paragraphs 18.3 and 18.4 above indicates that, based on a market, which due to an information shortfall has been limited to major suppliers only, post-acquisition, the combined entity would have a market share of just over []% [CONFIDENTIAL]. The actual market size will be larger once sales of Ego, Forest Herbs and Sigma are taken into account and consequently, the combined J&J / PCH market share will be smaller. While the J&J / PCH market share is outside the Commission's safe harbour threshold, Bayer Healthcare would remain a strong competitor, with a market share [] [CONFIDENTIAL] that of PCH's current market share. There are two other competitors in the form of Pacific Pharmaceuticals and AFT Pharmaceuticals which would both impose a constraint on the combined J&J / PCH entity's pricing.

Potential Competition

18.6 Potential entrants are most likely to be generic suppliers of other pharmaceutical products not listed above as existing competitors, such as GlaxoSmithKline or Douglas Pharmaceuticals. A generic supplier would not need to carry out any R&D, could register the product in a relatively short period of time, and would not necessarily need to establish production facilities since contract arrangements can be easily put in place. A generic supplier would need to approach pharmacists who are already encouraged by public authorities to recommend the use of lower priced products. This is unlikely to represent a significant barrier for an existing supplier into the New Zealand market.

Other considerations

18.7 The commentary at paragraphs 17.27 to 17.30 apply equally in relation to thrush treatments and are not repeated here.

³² Data relating to Forest Herbs, Sigma and Ego's products was not available.

GENERAL

- 18.8 J&J is happy to provide further information in relation to any of the product groups identified in the Notice, should the Commission so require.