PUBLIC VERSION

COMMERCE ACT 1986: BUSINESS ACQUISITION SECTION 66: NOTICE SEEKING CLEARANCE

23 September 2014

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

Pursuant to section 66(1) of the Commerce Act 1986 notice is hereby given seeking **clearance** of a proposed business acquisition.

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SUMMARY OF APPLICATION

1.1 GlaxoSmithKline plc ("**GSK**") seeks clearance for Leo Constellation Ltd (a majority owned subsidiary of GSK to be renamed GlaxoSmithKline Consumer Healthcare Holdings Ltd on or before closing ("**GSKCH**")) to acquire sole control of Novartis AG's ("**Novartis**") consumer healthcare ("**over-the-counter**" or "**OTC**") pharmaceuticals business (the "**OTC Transaction**").

1.2 GSK and Novartis ("**the Parties**") are global healthcare companies. The purpose of the OTC Transaction is to combine the Parties' complementary OTC businesses to enable the combined entity to compete more effectively against the multitude of competitors active today across global OTC markets, including those in New Zealand.

1.3 The only areas of material aggregation are in:

(a) OTC topical cold sore management products; and

(b) OTC systemic pain relief products.

1.4 In relation to those:

(a) In OTC topical cold sore management products:

(i) the overlap between GlaxoSmithKline NZ Ltd's (**"GSK NZ's"**) topical Zovirax product and Novartis Consumer Health Australasia Pty Ltd's ("**Novartis ANZ's**") topical Vectavir product is de minimis as Vectavir has a share of only [ ]; and

(ii) there is a range of strong existing competitors in that market, including Johnson & Johnson's Compeed, Multichem's Viratac (that had sales growth of almost [] in the last year), AFT's Viraban, Sanofi's Betadine Cold Sore Ointment, Valeant's Virasolve, and many others.

(b) In OTC systemic pain relief products:

(i) GSK NZ's systemic pain relief products, which are Panadol, Panadeine and Panafen Plus, are by no means close competitors to Novartis ANZ's Voltaren Rapid:

(aa) Panadol, Panadeine and Panafen Plus are marketed as being general pain relievers, and GSK's two main brands, Panadol and Panadeine are not non-steroidal anti-inflammatory drugs ("**NSAIDs**"); and

(bb) by contrast, Voltaren Rapid is primarily marketed as treating "back pain" because it contains the active NSAID ingredient diclofenac, which works to relieve pain by reducing inflammation.

(ii) There is a large range of strong existing competitors with a range of pain relief products on the market, including:

(aa) Reckitt Benckiser with Nurofen, Nuromol, and Disprin. Post-transaction Reckitt Benckiser will still be the largest competitor in the OTC systemic pain relief market.

(bb) Pfizer's Advil, marketed in New Zealand as the "World's Number 1 Pain Relief Brand" and experiencing growth of approximately [] in New Zealand between 2013 and 2014.

(cc) Private label products, which make up [] of the market (and almost [] of grocery sales).

(dd) Many other local and multinational players with an established presence in the New Zealand market, including Bayer (Aspro, Naprogesic), AFT (Maxigesic), and generic suppliers such as Dr Reddy's and Apotex's respective generic diclofenac products (which are direct substitutes for Voltaren Rapid), Multichem, and API.

(iii) In both product markets:

(aa) There are no barriers to imports, as evidenced by the fact that both GSK NZ and Novartis ANZ import all their products into New Zealand, and a range of other well-known competing brands overseas.

(bb) []

1.5 The OTC Transaction also results in aggregation of products from each party within the following Anatomical Therapeutic Chemical ("**ATC**") classification system ATC3 codes:

(a) R1A "topical nasal preparations";

(b) N7B "anti-smoking products";

(c) D1A "anti-fungals dermatological"; and

(d) J5B "anti-virals (excluding HIV)".

1.6 However, the product aggregation within these ATC code classifications does not give rise to any actual overlaps of competing products. In addition, as in the OTC markets described above, the Parties face significant competition from a range of international and local competitors in all other OTC product markets []

1.7 Accordingly, the Parties are confident that the OTC Transaction will not substantially lessen competition in any market in New Zealand.

REQUIRED INFORMATION

1. Provide the name of the applicant(s) for clearance, and the name of the individual(s) responsible for the notice. In addition, please include the:

- **Postal address, physical address, telephone number and web address of the applicant(s);**
- **Email address, telephone number and position of the contact person(s); and**
- **Names of any relevant related entities (showing shareholdings).**

1.1 This notice seeking clearance is given by GSK or one of its related companies.

1.2 Contact details for GSK are:

GlaxoSmithKline plc
980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom
Telephone: +44 020 8047 5000
Fax: +44 20 8047 7807
Website: www.gsk.com

1.3 The contact person for GSK is:

[]
Assistant General Counsel, Legal Department

GSK
5 Crescent Drive
Philadelphia, PA 19112
Mailstop 0200
United States

Email: []
Website: www.gsk.com

1.4 GSK is a global healthcare company, incorporated in England and Wales, and listed on the London and New York Stock Exchanges. GSK has commercial operations in more than 150 countries worldwide. GSK's principal business units are pharmaceuticals, vaccines and consumer healthcare. GSK NZ operates via two divisions: consumer healthcare and prescription pharmaceuticals. Further information about:

(a) GSK can be found on its website: www.gsk.com

(b) GSK NZ can be found on its website: www.gsk.co.nz

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

Russell McVeagh
Barristers & Solicitors
PO Box 8
AUCKLAND 1140

Attention: Sarah Keene / Troy Pilkington
Telephone: 09 367 8133 / 09 367 8108
Fax: 09 367 8595 / 09 367 8596

Email: sarah.keene@russellmcveagh.com /
troy.pilkington@russellmcveagh.com

1.6 Relevant related entities of GSK include:

(a) Leo Constellation Ltd (UK) (to be renamed GlaxoSmithKline Consumer Healthcare Holdings Ltd on or before closing – described further below);

(b) GlaxoSmithKline NZ Ltd (100% owned by Setfirst Ltd); and

(c) Setfirst Ltd (UK) (a subsidiary of GlaxoSmithKline Finance plc).

1.7 A diagram showing the structure of GSK as it relates to New Zealand is set out in **Confidential Appendix One**.

2. Provide the other merger party's (parties') name(s) and provide the:

- **Postal address, physical address, telephone number and web address of the party;**
- **Email address, telephone number and position of the contact person(s) for that party.**

2.1 The other party is Novartis. Contact details for Novartis are:

Novartis AG
Lichtstrasse 35
CH-4056 Basel
Switzerland
Telephone: +41 61 324 11 11
Fax: +41 61 324 80 01
Website: www.novartis.com

2.2 The Novartis Group is a global group of healthcare companies. Novartis is currently active in six broad areas of healthcare: pharmaceuticals, eye care, generics, animal health, consumer health and vaccines. The Novartis Group includes Novartis New Zealand Ltd, which operates the marketing, sales and distribution of Novartis' pharmaceutical and animal health products in New Zealand ("**Novartis Pharma NZ**"). The Novartis Group includes two other divisions that relate to New Zealand – CIBA Vision and Novartis ANZ (consumer healthcare) – which are operated from Australia, separately from Novartis Pharma NZ. A diagram showing the structure of Novartis is set out in **Confidential Appendix Two**. The Novartis Group also includes the Sandoz Division which is a leading global generic pharmaceuticals company that develops, manufactures, distributes and sells drugs which are not protected by valid and enforceable third-party patents, along with pharmaceutical and biotechnological active substances. Further information about Novartis is contained on its website www.novartis.com.

2.3 The Contact Person for Novartis is:

[]
Head Corporate Legal Antitrust, Novartis International AG
Postfach CH-4002, Basel, Switzerland
Telephone:[]
Mobile: []
Email: []
Fax: []

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

Simpson Grierson
Barristers & Solicitors
Private Bag 92518
AUCKLAND 1141

Attention: James Craig
Telephone: 09 977 5125 / 021 497 713
Fax: 09 307 0331
Email: james.craig@simpsongrierson.com

3. Set out the transaction details including, where relevant:

- **The type of transaction (such as a merger or joint venture), what is to be acquired and how the transaction is structured (such as whether assets or shares are to be purchased);**
- **The rationale for the merger;**
- **How this transaction changes the control of the company, and a diagram(s) of how the structure of ownership and affiliated companies are to change; and**
- **A description of relevant ancillary agreements associated with the merger, such as long-term supply agreements between the target and the acquirer.**

The OTC Transaction

3.1 The OTC Transaction is part of a three-part inter-conditional international transaction announced on 22 April 2014.

3.2 As the Commission is aware, the other two parts of the inter-conditional international transaction are:

(a) GSK's acquisition of Novartis' global human vaccines business (excluding Novartis' influenza vaccines business)[1] (the "**Vaccines Transaction**").

(b) the acquisition by Novartis of a portfolio of GSK's oncology products (excluding manufacturing) covering eleven marketed and two pipeline pharmaceuticals, together with future product expansions of any of these products (the "**Oncology Transaction**").

3.3 GSK's and Novartis' press releases announcing the transactions, which provide additional information are available at:

(a) GSK: gsk.com/en-gb/media/press-releases/2014/gsk-plc-announces-major-three-part-transaction-with-novartis-to-drive-sustainable-sales-growth-improve-long-term-earnings-and-deliver-increasing-returns-to-shareholders/

(b) Novartis: novartis.com/newsroom/media-releases/en/2014/1778515.shtml

3.4 Only the OTC Transaction is the subject of this clearance application.

3.5 Through the OTC Transaction GSK will effectively acquire sole control of Novartis' consumer healthcare business by obtaining a controlling stake of a new global consumer healthcare entity, GSKCH, to which both Parties will contribute their existing consumer healthcare businesses through a mixture of asset and share sales.[2] Novartis ANZ, which is responsible for supplying Novartis' consumer healthcare products in Australia and New Zealand, will be sold to GSKCH by way of share sale.

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[1] With the exception of the flu vaccines manufactured for the Chinese domestic market as part of the product range offered by Zhejiang Tianyuan Bio-Pharmaceutical Co Ltd ("**Tianyuan**") in which Novartis has an 85% shareholding acquired in 2011 (www.novartis.com/newsroom/mediareleases/ en/2011/1498805.shtml). The shareholding will be acquired by GSK as part of the Vaccines Transaction. Tianyuan's products bear Tianyuan's branding and are not currently sold under Novartis brand names. Tianyuan is not currently WHO approved. It therefore does not currently export vaccines from China to any UN body. In fact, in the last two years, Tianyuan has not had any export sales.

[2] GSK will contribute its global consumer healthcare business (excluding GSK's consumer healthcare business in India and Nigeria and products that are managed by, and reported for financial purposes within, GSK's Pharmaceutical Division).

3.6 Globally, Novartis will contribute all global consumer healthcare products and related assets for which financials are consolidated within Novartis' OTC business (excluding products that are managed by, and reported for financial purposes within, Novartis' Pharmaceutical Division, Alcon Division, and Sandoz Division, therefore generally excluding generic products and prescription products). A list of the products sold by the Parties in New Zealand that will be contributed to GSKCH is set out at **Confidential Appendix Three** to this application**.**

3.7 GSK will own 63.5% of the shares of GSKCH and appoint 7 of 11 directors on the entity's board of directors. Novartis will own 36.5% of the shares of the entity and appoint 4 of 11 directors. GSK will have sole control of the entity, while Novartis will have standard minority shareholder protection rights.

3.8 The other, retained aspects of the Parties' businesses will also continue to operate in New Zealand:

(a) GSK NZ's consumer healthcare business is one of two divisions of GSK NZ, the other division being GSK NZ Pharmaceuticals, which handles prescription pharmaceuticals.

(b) Novartis Pharma NZ, which is responsible for Novartis human pharmaceuticals business in New Zealand, will continue to be owned and operated by Novartis.

The rationale for the OTC Transaction

3.9 In bringing together GSK's and Novartis' consumer health businesses to form GSKCH, the Parties are combining two highly complementary businesses that will enable the combined entity to compete more effectively against the dozens of competitors active today in the OTC consumer healthcare industry in New Zealand.

3.10 The specific benefits the Parties have identified include:

(a) The new GSKCH business will better serve OTC customers through combining their respective mass market, pharmacy and expert selling capabilities and personnel worldwide.

(b) The Parties have highly complementary product portfolios and their complementary geographic footprint opens multiple new growth opportunities.

(c) The transaction enables combined access to world-leading science capabilities from both GSK's and Novartis' respective businesses.

(d) The Parties will achieve cost savings that can be reinvested in additional R&D through reduction in manufacturing costs, reduced third-party contracting, removal of infrastructure overlaps and reductions in administrative costs. The Parties estimate total annual cost savings from the three transactions of GBP£1 billion by year 5 (with approximately 40% of those savings arising from the OTC Transaction).

3.11 Similar pro-competitive benefits from concentration in the pharmaceutical industry have previously been recognised by the Commission:[3]

> Internationally, there is increasing concentration in the pharmaceutical industry. The European Community Commission (EC Commission) has identified three

[3] Decision No 398 *Glaxo Wellcome plc / SmithKline Beecham plc* (1 September 2000) at [25]–[28]: www.comcom.govt.nz/business-competition/mergers-and-acquisitions/clearances/clearances-register/detail/314.

main forces driving this merger activity: research and development, a wider range of products, and extended geographical markets.

Research and development is essential for the future of pharmaceutical companies. Patent protection for pharmaceutical products is limited in time while the approval procedures for new products are becoming more stringent and time consuming. In addition the cost of research is escalating. It appears generally agreed by industry parties that only very large companies can now support the costs of research necessary to ensure a continued flow of products.

The second reason is related and concerns the desire for companies to provide a wider range of products and enables the merged company to become a more competitive supplier to wholesalers, hospitals and pharmacy chains. A wider product range also reduces the risk that the demise of a single product has a disproportionate effect on the company's future.

Control and structure of GSKCH

3.12 The transaction does not alter the control or ownership of either GSK or Novartis.

3.13 A diagram showing the structure of GSKCH is set out in **Confidential Appendix Four**.

Description of relevant agreements

3.14 []

4. Provide copies of the final or most recent versions of any documents bringing about the proposed merger such as the sale and purchase agreement, contracts, or offer documents.

Transaction documents

4.1 Copies of the following agreements are attached:

(a) []

(b) []

5. If this merger forms part of an international transaction, list the other competition agencies that are being notified and the date on which those agencies were or will be notified.

Other notified regulators

5.1 Please find below the list of jurisdictions where at least one of the mentioned transactions entered into by the Parties is subject to notification to the respective competition authority:

Figure 1 - Overseas regulators notified of the Merger

[]

6. If the merger results in horizontal aggregation, outline the overlapping products and/or services and provide the following for each:

- **A copy of, or link to, the most recent annual report, audited financial statements and management accounts for the relevant business unit(s);**
- **Each party's total sales revenues, volumes, and, where relevant, capacity and excess capacity figures;**
- **The names and contact details for the parties' main competitors, and any trade or industry associations in which one or both of the merging parties participate; and**
- **For a merger between competing sellers, the names and contact details for each party's key customers, and the revenue earned from each in the last financial year.**

The overlapping products

6.1 The OTC Transaction results in the following competitive overlaps:

(a) overlap in the national wholesale supply of OTC topical cold sore management products; and

(b) overlap in the national wholesale supply of OTC systemic pain relief products.

6.2 The reasons these competitive overlaps do not give rise to a substantial lessening of competition in these OTC product markets is set out further in this application (at paragraphs 7.21 to 7.67).

6.3 The OTC Transaction also results in aggregation of products from each party within the following ATC3 codes:

(a) R1A "topical nasal preparations";

(b) N7B "anti-smoking products";

(c) D1A "anti-fungals dermatological"; and

(d) J5B "anti-virals (excluding HIV)".

6.4 The product aggregation within these ATC3 code classifications does not, however, give rise to any material competitive product overlaps and, therefore, do not have any effect on competition in any OTC product markets. A description of why this is the case is set out in more detail in this application at paragraphs 7.68 to 7.89.

Financial statements

6.5 A copy of GSK's 2013 annual report is available at: www.gsk.com/media/325156/annual-report-2013.pdf.

6.6 A copy of the audited financial statements for the year ended 31 December 2013 of GSK NZ is available from the Companies Office at: www.business.govt.nz/companies/app/service/services/documents/B945B22D4A04DE4E960A6FA0B0F203A6.

6.7 GSK NZ's revenue for the 2013 financial year, as set out in its audited financial statement, was $141,323,000.

6.8 A copy of Novartis' annual report is available at www.novartis.com/downloads/investors/reports/novartis-annual-report-2013-en.pdf

6.9 Novartis ANZ's revenue in New Zealand for the 2013 financial year was []. A copy of Novartis ANZ's audited financial statement, and the audited financial statement of Novartis ANZ's New Zealand branch, are included in **Confidential Appendix Five**.

Names and contact details of key competitors

6.10 The Parties' key competitors in the product categories discussed in this clearance application are set out in **Appendix Six**.

Trade or industry associations

6.11 GSK NZ and Novartis ANZ are both members of:

(a) Medicines New Zealand;[4] and

(b) The New Zealand Self-Medication Industry Association Inc. ("**NZSMI**").[5]

6.12 GSK NZ is also a member of the New Zealand Food and Grocery Council ("**NZFGC**").[6] Contact details for these organisations are set out in **Appendix Seven.**

Key customers

6.13 The following are GSK NZ's key OTC customers:

Figure 2 - GSK NZ's key OTC customers

Channel	Channel as approximate proportion of GSK's OTC sales	Customer	Proportion of GSK's sales through the channel that the customer represents	Revenue earned from customer in GSK's last financial year
Pharmacy	[] [] [] []	[]	[]	[]
		[]	[]	[]
		[]	[]	[]
		[]	[]	[]
Grocery / general merchandise	[] [] [] []	[]	[]	[]
		[]	[]	[]
		[]	[]	[]
		[]	[]	[]

6.14 In addition, GSK NZ supplies those products included on the PHARMAC schedule to the Ministry of Health.

[4] See www.medicinesnz.co.nz/about-us for further information.
[5] See: www.nzsmi.org.nz/home/default.aspx for further information.
[6] See www.fgc.org.nz/about for further information.

6.15 The following are Novartis ANZ's key OTC customers:

Figure 3 - Novartis ANZ's key OTC customers

Channel	**Channel as approximate proportion of Novartis' OTC sales**	**Customer**	**Proportion of Novartis' sales through the channel that the customer represents**	**Revenue earned from customer in Novartis' last financial year**
Pharmacy	[]	[]	[]	[]
	[]	[]	[]	[]
	[]	[]	[]	[]
	[]	[]	[]	[]
	[]	[]	[]	[]
	[]	[]	[]	[]
Grocery / general merchandise[7]	[]	[]	[]	[]
	[]	[]	[]	[]
	[]	[]	[]	[]
[]	[]	[]	[]	[]

6.16 As with GSK NZ, Novartis ANZ supplies those products included on the PHARMAC schedule to the Ministry of Health.

6.17 [].

6.18 The contact details for these GSK NZ and Novartis ANZ customers are set out in **Confidential Appendix Eight**.

[7] [].

7. Describe why you consider the merger is unlikely to result in a substantial lessening of competition in any market having regard to the factors set out in the merger and acquisition guidelines. You should address:

- **The merging parties' existing competitors, including approximate market shares, and the extent to which they will constrain the merged firm;**
- **The likelihood, extent and timeliness of entry and expansion by potential competitors (including conditions of entry and expansion) and the extent to which such entry or expansion will constrain the merged firm;**
- **The countervailing power of customers and the extent to which that countervailing power will constrain the merged firm; and**
- **Any other relevant factor.**

7.1 In this section, the Parties deal with the following issues:

(a) the relevant approach to market definition;

(b) background on supply and distribution channels and government funding;

(c) why the merger will not result in a substantial lessening of competition in relation to:

(i) OTC topical cold sore management products;

(ii) OTC systemic pain relief; and

(iii) other ATC code product aggregation (namely, topical nasal preparations, smoking cessation, anti-fungal dermatological, and anti-virals).

Market definition

Product market

7.2 In previous pharmaceutical mergers the Commission has taken the approach of defining markets by considering the condition requiring treatment, rather than defining markets based on ATC codes:[8]

> The Applicant based these market definitions on the European Pharmaceutical Marketing Research Association's classifications. The Commission has previously considered the appropriateness of using this classification system when analysing pharmaceuticals and medicines. However, the Commission also noted that there may be instances where broader or narrower classifications are necessary, dependent upon the particular circumstances of the medicines and **the condition requiring treatment**. (Emphasis added)

7.3 The Commission has also consistently taken the approach that OTC pharmaceuticals fall into separate product markets from prescription-only medicines due to the differences in the severity of conditions prescription medicines are used to treat, the differences in clinical risk, and the differences in regulation:[9]

> Although a doctor can prescribe OTC medicines, these are generally not substitutable for prescription-only medicines for three main reasons:

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[8] *Glaxo Wellcome plc / SmithKline Beecham plc*, above n 3, at [52].

[9] Decision No 594 *Johnson & Johnson / Pfizer Consumer Healthcare* (8 December 2006): www.comcom.govt.nz/business-competition/mergers-and-acquisitions/clearances/clearances-register/detail/594.

- Severity. Prescription-only medicines are typically used to treat more severe illnesses than OTC medicines.

- Clinical Risk. In instances where prescription-only and OTC medicines are indicated for the treatment of the same ailment, generally prescription-only medications are used only when OTC products have failed to provide relief. Prescription-only medications are often used in this way, as a 'measure of last resort', as these typically carry a greater level of clinical risk (i.e., contraindications, interaction with other medicines, and risk of overdose).

- Regulation. Given the higher clinical risks associated with prescription-only products, these are generally more heavily regulated than OTC products. For example, Medsafe classifies OTC products as 'low-risk medicines'. The registration fees and clinical data requirements for these are significantly lower than those for prescription-only products ('high-' or 'intermediate-risk' medicines). Further, OTC products are more accessible to consumers as these may either be self-selected or sold through pharmacist-referral. In contrast, prescription-only products can only be accessed on the advice of a medical doctor.

7.4 The Parties agree that the Commission's previous approach to market definition in the pharmaceutical industry is correct based on its commercial experience in New Zealand, namely it is appropriate to:

(a) define OTC product markets based on the conditions those products treat, as that market definition captures the range of products that consumers can and do readily switch between as a matter of practical commercial reality; and

(b) define separate product markets for OTC products, as distinct from prescription-only medicines, given the factors referred to in the Commission's previous decisions that reflect that OTC products are generally not substitutable for prescription-only products.

Functional market

7.5 As both GSK NZ and Novartis ANZ import all of their OTC pharmaceutical products to supply wholesalers, retail groups, hospitals, and grocery retailers (as allowed by the pharmaceutical regulations), the appropriate functional level to consider the OTC Transaction is the wholesale supply of the relevant OTC products. This is consistent with the previous approach of the Commission in considering transactions in the OTC pharmaceutical industry.[10]

National market

7.6 As previously observed by the Commission, all the main suppliers of OTC pharmaceuticals in New Zealand supply their products on a national basis and advertise those products nationally. Accordingly, the relevant geographic scope of the markets is national.

Summary

7.7 Applying this approach, as set out at paragraph 6.1, the OTC Transaction results in the following competitive overlaps:

(a) overlap in the national wholesale supply of OTC topical cold sore management products; and

[10] *Reckitt Benckiser plc / Boots Healthcare International Ltd*, above n 8, at [62].

(b) overlap in the national wholesale supply of OTC systemic pain relief products.

Supply and distribution channels

7.8 Section 3 of the Medicines Act 1981 sets out three categories of medicine:

(a) **Prescription medicines** which may be sold, supplied or administered only in accordance with a prescription given by an authorised prescriber.

(b) **Restricted medicines** (also known as "**pharmacist-only medicines**"), which may be sold or supplied only by a registered pharmacist in a pharmacy or hospital. These medicines are not available for self-selection from the pharmacy shelves; they are usually stored behind a counter or in the dispensary.[11] Details of the sale must be recorded.

(c) **Pharmacy-only medicines** which may be sold or supplied only in a pharmacy or hospital. The sale may be made by any salesperson.

7.9 Medicines in each of these categories are listed in the Schedule 1 to the Medicines Regulations 1984. Medicines not listed in the classification schedules are deemed to be unclassified, and are referred to as **general sale medicines**. General sale medicines may be sold from any outlet (for example, supermarkets, convenience stores / dairies, service stations, etc).

7.10 The Parties understand the Commission is familiar with the main grocery/supermarket channels in New Zealand. That channel represents almost [] of GSK's OTC business.

7.11 The Parties also understand the Commission is familiar with pharmaceutical supply and distribution channels to pharmacies given its recent decision in respect of the joint clearance application by CDC Pharmaceuticals Ltd ("**CDC**") and Pharmacy Wholesalers (Central) Ltd ("**PWL Central**") to merge their respective pharmaceutical wholesaling businesses.[12]

7.12 The Parties are subject to strong countervailing buyer power in the supply of OTC pharmaceuticals through both the grocery and pharmacy channels:

(a) []

(b) []

7.13 In summary, in both the grocery and pharmacy channels the merged entity will continue to be subject to considerable countervailing power from its customers, who will continue to have a range of suppliers to choose from in every OTC product market.

Government funding

7.14 As the Commission will be aware, certain medicines in New Zealand are available with partial or full government funding. This programme of funding is administered by PHARMAC, the Pharmaceutical Management Agency ("**PHARMAC**"), a Crown entity established by the New Zealand Public Health and Disability Act 2000. PHARMAC is directly accountable to the Minister of Health. Further background on PHARMAC can be found on its website, www.pharmac.govt.nz.

[11] See Medsafe "Pharmacist-only Medicines" (11 April 2013): www.medsafe.govt.nz/consumers/PharmOnly.asp.

[12] *CDC Pharmaceuticals Limited / Pharmacy Wholesalers (Central) Ltd* [2014] NZCC 21: www.comcom.govt.nz/business-competition/mergers-and-acquisitions/clearances/clearances-register/detail/827.

7.15 PHARMAC manages the "purchase" of a list of subsidised pharmaceuticals, the Pharmaceutical Schedule, on behalf of the Crown. Pharmaceutical suppliers may apply to PHARMAC to have a medicine listed on the Pharmaceutical Schedule for subsidy, usually following Ministry of Health approval of the product. Decisions on listing, subsidy levels, and prescribing guidelines and conditions, are made by the PHARMAC Board with input from independent medical experts.

7.16 As the single Government purchaser, with the ability to offer a supplier significant volumes, PHARMAC has significant countervailing power in its negotiations with suppliers. This monopsony power has been acknowledged by the Supreme Court in *AstraZeneca Ltd v Commerce Commission*, where it was stated:[13]

> Parliament plainly recognises that in establishing Pharmac it was creating a sole or predominant purchaser (monopsonist) for particular pharmaceutical products.

7.17 The Court of Appeal has described PHARMAC's position in the following terms:[14]

> Pharmac determines which pharmaceuticals should be listed, which subsidies are payable for each and negotiates the terms upon which the subsidised pharmaceuticals are supplied. In short, Pharmac has a substantial degree of power in the markets for the supply of subsidised pharmaceuticals in New Zealand. As a monopsonist, Pharmac has the ability to control the entry of different pharmaceuticals onto the pharmaceutical schedule.

7.18 PHARMAC's countervailing power is enhanced by the fact that negotiations and agreements involving PHARMAC are expressly excluded from the operation of the Commerce Act by s 53 of the New Zealand Public Health and Disability Act 2000. This means that, in the process of negotiations and entering into agreements with drug companies, PHARMAC is legally able to engage in conduct that, if engaged in by another purchaser, might breach the restrictive trade practices provisions in the Commerce Act.

7.19 Although the PHARMAC schedule generally only covers prescription products, some OTC products may also be available on prescription, e.g. paracetamol, often in larger quantities or different dosages to that available OTC, and Flixonase when prescribed by a doctor. In some other rare cases, OTC products may be funded despite being available without prescription, as is the case for Nicotine Replacement Treatment products, although these are only funded without prescription for people registered with the Government supported anti-smoking trust Quitline.

7.20 The Commission has previously concluded that subsidised and non-subsidised smoking cessation products come within the same market,[15] and as a broader principle consumers are able to substitute between funded and non-funded OTC products where these are available. Accordingly, while prescription-only products are considered to fall within separate product markets, for completeness prescription purchases of OTC products that are also available without a prescription have been included in GSK NZ's analysis of the relevant OTC market shares.[16]

TOPICAL COLD SORE MANAGEMENT PRODUCTS

7.21 The Commission previously considered topical cold sore management products in 2000 in *Glaxo Wellcome Plc / SmithKline Beecham Plc*,[17] in which it defined the relevant

[13] *AstraZeneca Ltd v Commerce Commission* [2009] NZSC 92, [2010] 1 NZLR 297 at [5].
[14] *AstraZeneca Ltd v Commerce Commission* [2008] NZCA 479, (2008) 12 TCLR 302 at [19].
[15] *Johnson & Johnson / Pfizer Consumer Healthcare*, above n 9, at [66].
[16] The retail sales value of those prescription sales of OTC products included in GSK's market share data reflect the price paid by the consumer to the pharmacy (and does not include a value attributable to the subsidy paid by PHARMAC for those prescription purchases).
[17] *Glaxo Wellcome plc / SmithKline Beecham plc*, above n 3.

market as being the market for the wholesale distribution of topical anti-viral products for the treatment of cold sores, with the Commission noting that "the normal treatment for cold sores is self-medication with OTC products".[18]

7.22 GSK NZ and Novartis ANZ sell the following OTC topical cold sore management products in New Zealand that will be contributed to GSKCH:[19]

Figure 4 – The Parties' OTC topical cold sore products in New Zealand

Entity	Product	Description
GSK		Zovirax Cold Sore Cream Tube 2g Active ingredient: Aciclovir 5%
		Zovirax Cold Sore Cream Pump 2g Active ingredient: Aciclovir 5%
		Zovirax invisiSeal patches Non-medicated cold sore patches
Novartis[20]		Vectavir Cold Sore Cream Tube 2g Active ingredient: Penciclovir 1%

7.23 Since the Commission's decision in *Glaxo Wellcome Plc / SmithKline Beecham plc* the market has evolved noticeably. While at the time OTC topical cold sore treatments consisted almost exclusively of anti-viral treatments, since then cold sore patches have made significant inroads (taking share from traditional topical anti-virals), lip balm manufacturers have expanded their portfolio into the cold sore space by directly marketing their products in competition with topical anti-virals, and alternative topical

[18] In *Glaxo Wellcome plc / SmithKline Beecham plc* the Commission reached the view that Aciclovir and Penciclovir based cold sore treatments fall within the same product market.

[19] GSK's prescription-only Zovirax systemic tablet products will not be contributed to the GSKCH and, in any event, are indicated for other viral conditions in New Zealand, such as shingles and genital herpes, (see Medsafe factsheets: www.medsafe.govt.nz/consumers/cmi/z/zoviraxtab200mg.pdf and www.medsafe.govt.nz/consumers/cmi/z/zoviraxtab800mg.pdf). There are a number of other prescription products with similar indications, such as Douglas's Lovir, Baxter's Ganciclovir and Pfizer's Aciclovir.

[20] Photo retrieved from: www.rivertonpharmacy.co.nz/vectavir_cream_1_2g.

treatments such as heat and light therapy devices have been launched.[21] This has sparked innovation by the traditional anti-viral cream manufacturers (such as GSK) to combine anti-viral creams with competing products – such as patches and lip balms.

7.24 As demand-side substitutes, these new topical cold sore products could all be considered as part of the same topical cold sore management market as topical anti-virals.

7.25 To the extent the Commission were to treat some of these new competing products (such as heat and light therapy devices and lip balms that are marketed with cold sore claims) as falling into a separate product market, these products should still be viewed as exerting a notable competitive constraint on other cold sore management products, including topical anti-virals.

7.26 Cold sore patches, in particular, are widely recognized as an effective substitute for topical anti-virals and are marketed as such. For example, Compeed's New Zealand website specifically promotes itself as being a competitive alternative to aciclovir cream, with claims it heals cold sores at a "comparable speed":[22]

> COMPEED® TOTAL CARE™ Invisible Cold Sore Patch is clinically proven to lessen scabs for faster healing, effective from the moment of application. The patches heal your cold sore at a comparable speed to acyclovir 5% cream.

7.27 The competition from Johnson & Johnson's Compeed patch had led to GSK introducing its own Zovirax invisiSeal patches (which are sold by GSK NZ in New Zealand).

7.28 Like anti-viral creams, patches treat the symptoms, accelerate the healing process and physically shield the cold sore, preventing further contamination. Patches also counteract itching, burning or swelling, reduce pain, and prevent the formation of crust or scars just as topical anti-virals do. In addition to treating the cold sore symptoms, patches provide the added benefit of concealing the sore while it heals. This feature, in particular, has been key to patches' rapid growth in recent years (and their predicted continued rapid growth) as cold sore sufferers are often most concerned with the appearance of the sores.

7.29 The Parties view cold sore patches, and Johnson & Johnson's Compeed cold sore patch in particular, as a serious competitive threat. As a result, the Parties include cold sore patches in their customer surveys and market share analyses, and therefore consider that the market for OTC cold sore management products includes at least topical anti-viral and topical cold sore patch products (with heat/light therapy devices and lip balms exerting additional notable competitive constraint on those products).

7.30 Adopting this approach to market definition, namely a market that includes topical anti-viral and topical cold sore patch products, the aggregation in the OTC topical cold sore management market arising from the OTC Transaction will be de minimis. That is because Novartis ANZ's topical Vectavir product, which will be contributed to the GSKCH venture:

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[21] Heat treatment products are also now sold in New Zealand as topical treatments for cold sore management - see www.hotkiss.co.nz/index.html:

> The Hotkiss is a medical device which is capable of preventing the development of lip herpes when used at the appropriate time.
>
> No uncomfortable, unattractive blisters and no sensation of sores will occur in the lip area. The instrument in lipstick form is small and compact and can be easily carried around for handy use any time.

[22] See www.compeed.co.nz/compeed-coldsore.

(a) comprises just [][23] of wholesale sales of OTC topical products for the treatment of cold sores in New Zealand; and

(b) [] Vectavir's market share has continued to decline in recent years. [][24]

7.31 The market shares in the market for the wholesale distribution of topical OTC products for the treatment of cold sores are set out in Figure 5 below:

Figure 5 – Retail sales of OTC topical cold sore products in New Zealand

		CY2012		CY2013	
Company	**Brand**	**Sales $ value MAT to 30/12/12**	**Sales share**	**Sales $ value MAT to 31/12/13**	**Sales share**
[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]

Source: GSK combination of Aztec (pharmacy) and Nielsen (grocery) data. []

Famvir Once

7.32 In the area of cold sore management, Novartis ANZ also introduced, in 2010, its Famvir Once systemic oral tablet in New Zealand, which contains the active ingredient famciclovir.[25] Famvir Once is a pharmacist-only OTC medicine for the treatment of recurrent cold sore outbreaks and will be contributed to GSKCH. Famvir Once was reclassified as a pharmacist-only (rather than prescription-only) product in New Zealand in September 2010 [].[26]

7.33 Neither of the Parties consider GSK NZ's OTC topical Zovirax products and Novartis ANZ's pharmacist-only Famvir Once product to be close competitors, given:

(a) their different mechanism of action – it is typically only severe or frequent cold core sufferers that would consider switching to a systemic product such as Famvir Once;

(b) their frequency of use - Famvir Once is a 'once-only', which is taken in a very large dose orally at the start of an outbreak (which is different to topical products that are applied repeatedly during a cold sore outbreak);

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[23] GSK estimates based on Aztec and Nielsen data.
[24] GSK estimates based on Aztec and Nielsen data.
[25] See: www.famvironce.co.nz/home.php
[26] See Medsafe "Medicines classifications update" (February 2010) www.medsafe.govt.nz/profs/PUArticles/Medicines%20classification%20update.htm.

(c) their different channel availability – GSK NZ's OTC Zovirax product is available in both pharmacies and supermarkets whereas Famvir is only available in pharmacies;

(d) their different shelving requirements – as a pharmacist-only product Famvir will typically be stored behind the counter or in a pharmacy, and not on the same shelf as other OTC cold sore products for a customer to choose between and, therefore, a consumer's decision to use Famvir will often be based on a pharmacist or doctor's recommendation, or other prior knowledge, rather than as a result of browsing the shelves looking for a cold sore treatment; and

(e) their different side effect profile - the large dose of anti-viral active ingredient in systemic anti-virals result in these products having a different side effect profile to topical anti-virals (see Medsafe's Famvir Once Datasheet).[27] Because of this different side effect profile, systemic anti-virals are better suited for more acute cold sore outbreaks than topical cold sore management products.

7.34 Novartis, through its generic Sandoz Division, also sells a generic equivalent of Famvir Once in Australia (called Elovax One Dose), which will not be contributed to GSKCH (as Sandoz products are not forming part of the OTC Transaction).[28]

7.35 Even if systemic products such as Famvir Once were to be included in the same product market as topical cold sore management products, the Parties estimate that the market share of Famvir Once would be less than [] once other systemic cold sore management products are also included (according to GSK's Aztec data, retail sales of Famvir Once were worth [] in 2012 and [] in 2013).

There is a range of vigorous existing competitors

7.36 Furthermore, GSKCH will continue to be constrained by the multitude of different competing options that are already in the New Zealand OTC topical cold sore market:[29]

(a) Cold sore patches such as Johnson & Johnson's Compeed have made substantial inroads into the market share of traditional products since being launched in New Zealand in around 2005. The Parties consider Compeed to be a significant – and rapidly expanding – competitor, with Compeed already holding [] of the topical cold sore management market in New Zealand. As noted above:

(i) Compeed's New Zealand website specifically promotes itself as being a competitive alternative to aciclovir cream, with claims it heals cold sores at a "comparable speed";[30] and

(ii) the competition from Johnson & Johnson's Compeed patch has led to GSK introducing its own Zovirax invisiSeal patches (which are sold by GSK NZ in New Zealand).

(b) Generic products, which were relatively new to the market when *Glaxo / Smithkline* was considered, have consolidated their position in the market, substantially increasing their sales volumes by taking share from established brands. Both of the anti-viral formulations being contributed to GSKCH (aciclovir and penciclovir) are now off-patent, and there are a number of

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[27] See: www.medsafe.govt.nz/profs/datasheet/f/famvironcetab.pdf
[28] See: www.betterhealth.vic.gov.au/bhcv2/bhcmed.nsf/pages/szcelova/$File/szcelova.pdf
[29] See a list of the cold sore treatment options available in New Zealand at: www.pharmacylive.co.nz/common-conditions-detail?cid=E0B74145-E90F-4B09-BB0A-7632BD738E7E.
[30] See www.compeed.co.nz/compeed-coldsore.

generic aciclovir products in the market in New Zealand. AFT's generic aciclovir product Viraban and Multichem's generic Viratac together now account for almost [] of the cold sore management market, with Viratac enjoying sales growth of almost [] between 2012 and 2013.

Figure 6 - Generic cold sore creams in the New Zealand OTC topical cold sore management market

Entity	Product	Description
AFT[31]		Viraban Cold Sore Cream Tube 5g Active ingredient: Aciclovir 5%
Multichem[32]		Viraban Cold Sore Cream Tube 5g Active ingredient: Aciclovir 5%

Similarly, generic aciclovir products now account – either individually or collectively – for the highest value shares in the OTC segment in a number of European countries (for example, []).[33] Both PHARMAC[34] and Medsafe[35] have run campaigns in New Zealand promoting awareness of the benefits of generic prescription drugs, as has Consumer NZ.[36] The Parties expect continued growth from generic cold sore products in New Zealand and the launch of private label generic products (for example, a private label aciclovir product under the "Your Pharmacy" private label has been launched in Australia).[37]

(c) In addition to these generics, there are also a number of other topical products available in the New Zealand market that have other (non-aciclovir or penciclovir) active ingredients or modes of action, including DTC Healthcare Ltd's Herstat propolis-based product, which is claimed to be "clinically proven to be more effective than any other remedy on the market today"[38]. These products include:

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31 Photo retrieved from: www.aftpharm.com/nz-products/viraban-cold-sore-cream

32 Photo retrieved from: www.lifepharmacy.co.nz/p/Viratac-Cold-Sore-Treatment-Cream-5-5g-Tube-with-FREE-Lipbalm?i=101000.

33 GSK data.

34 Pharmac "The facts about generic medicines – Information Sheet" www.pharmac.govt.nz/2011/09/16/06GENERIC_MEDS.pdf.

35 Medsafe "Generic Medicines and Bioequivalence" (March 2013) www.medsafe.govt.nz/Profs/PUArticles/Mar2013GenericMedBioqueivalence.htm.

36 Consumer "Generic medicines" (4 September 2012) www.consumer.org.nz/articles/generic-medicines

37 See product data sheet: www.perrigo.com.au/upload/product/document/YOU02262F_MSDS.pdf.

38 See www.herstat.com.

Figure 7 – Other topical cold products in the New Zealand OTC topical cold sore management market

Entity	**Product**	**Description**
Sanofi[39]		Betadine Cold Sore Ointment 7.5g Active ingredient: 10% w/w Poviodine-Iodine
DTC Healthcare Ltd[40]		Herstat Cold Sore Cream Tube 2g Active ingredient: Propolis ACF
Valeant Pharma[41]		Virasolve Cold Sore Cream Tube 5g Active ingredient: Each gram contains Idoxuridine 5mg, Lignocaine Hydrochloride 20mg, Benzalkonium Chloride 5mg

(d) Outside of the market as identified above, there are now also a number of other cold sore treatment products such as heat/light therapy devices, lip balms marketed as having cold sore treatment properties, and natural/nutritional alternatives that will continue to place notable constraint on the products in the OTC topical cold sore management market. Examples of such products currently available in New Zealand are set out in Figure 8 below.

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39 Photo retrieved from: www.lifepharmacy.co.nz/search?q=%22cold+sore%22.
40 Photo retrieved from: www.lifepharmacy.co.nz/search?q=%22cold+sore%22.
41 Photo retrieved from: www.lifepharmacy.co.nz/search?q=%22cold+sore%22.

Figure 8 – Alternative cold sore treatments available in New Zealand that constrain OTC topical cold sore management products

Entity	Product	Description
Kenwick Labs, Inc. [42]		Savex Medicated Ingredients: Waxes, Lanolin, Fragrance or Parfum, Menthol, Camphor or Camphre, Isopropyl, Palmitate, Salicylic Acid or Acide, Salicylic
Carmex[43]		Carmex Ointment 7g for cold sores, fever blisters and chapped lips[44] Ingredients: Petrolatum, Lanolin, Cocoa Butter, Seed Butter, Beeswax, Camphor, Menthol, Salicyclic Acid, Vanillin.
Thursday Plantation[45] **(Integria Healthcare)**		Tea Tree Cold Sore Cream 10g tube[46] Ingredients: Melaleuca (Tea Tree), Camphor 5 mg/g, Menthol, Phenol

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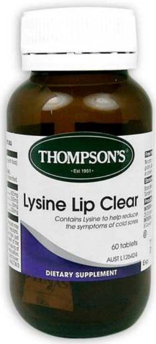
[42] Photo retrieved from: www.healthexpress.co.nz/savex_cold_sore_cream_7g_tub.html#.VA_AIdLNu70.
[43] Photo retrieved from: www.mainstreettaupo.co.nz/shop-online/details/_cat2_/2518/Cold-Sore-Treatments/_prod_/Carmex-Ointment-7g-Pot.
[44] www.mainstreettaupo.co.nz/shop-online/details/_cat2_/2518/Cold-Sore-Treatments/_prod_/Carmex-Ointment-7g-Pot.
[45] Photo retrieved from: www.thursdayplantation.com/product-categories/australia/mouth-care/tea-tree-cold-sore-cream.
[46] www.thursdayplantation.com/product-categories/australia/mouth-care/tea-tree-cold-sore-cream.

Light-Office NZ Ltd[47]		Hotkiss heat application device for treating cold sores[48] "The treatment of herpes with the Hotkiss takes place with the help of a concentrated heat in the range of 50-51°C which, when applied at the proper time, prevents the formation of the blisters and allows the further symptoms (prickly sensation, burns, itchiness, feeling of tightness, pain) to subside quickly."
Clinicians[49] **(Douglas)**		Cold Sore Ease Nutrients to support the body's natural defences for the lips and skin.
Nature's Own **(Sanofi)**[50]		Cold Sore Relief L-Lysine is one of the eight essential amino acids needed for human development. It helps reduce the frequency and severity of outbreaks of cold sores and provides relief for the

[47] Photo retrieved from: www.herpotherm.co.nz.
[48] See: www.hotkiss.co.nz
[49] Photo retrieved from: www.clinicians.co.nz/special-nutrients/products/ColdSore%20Ease.
[50] Photo retrieved from: www.naturesown.com.au/cold-sore-relief-l-lysine-500mg.

		symptoms of cold sores.
Nutra Life[51]		Lysine 1000 "Helps reduce the incidence of cold sore infections by helping to restrict the growth and development of virus involved."[52]
Ethical Nutrients[53]		Lysine Viral Cold Sore Defence "Help reduce the frequency and severity of outbreaks of cold sores."[54]
Thompson's[55] **(Integria Healthcare)**		Lysine Lip Clear "Lysine Lip Clear doesn't just work to reduce the risk of cold sores it can also be used in the management of an outbreak."[56]

There are no barriers to imports and new products from overseas

7.37 All of GSK NZ's and Novartis ANZ's existing products are imported – there are no transport cost barriers to any pharmaceutical company importing generic or branded products from overseas.

7.38 Indeed, there are a number of topical cold sore management products marketed overseas, but not yet in New Zealand, under brands that are well known in New Zealand and, therefore, could readily be launched in New Zealand. For example:

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[51] Photo retrieved from: www.healthchemist.co.nz/mm5/merchant.mvc?Screen=CTGY&Category_Code=cold-sores&Sort_By=newest&Store_Code=HC&Offset=10#.VBdYbtLNu70.

[52] See: www.healthchemist.co.nz/cold-sores/nutralife-lysine-1000mg-tablets-60-p2361469.html#.VBdYedLNu70.

[53] Photo retrieved from: www.healthchemist.co.nz/mm5/merchant.mvc?Screen=CTGY&Category_Code=cold-sores&Sort_By=newest&Store_Code=HC&Offset=10#.VBdYbtLNu70.

[54] See: www.healthchemist.co.nz/cold-sores/ethical-nutrients-lysine-viral-cold-sore-defence-tablets-60-p918882.html#.VBdYZdLNu70.

[55] Photo retrieved from: www.healthchemist.co.nz/mm5/merchant.mvc?Screen=CTGY&Category_Code=cold-sores&Sort_By=newest&Store_Code=HC&Offset=10#.VBdYbtLNu70.

[56] See: www.healthchemist.co.nz/cold-sores/thompsons-lysine-lip-clear-tablets-60-p916273.html#.VBdYaNLNu70.

(a) Blistex Antiviral Cold Sore Cream, which contains aciclovir, is available in Australia[57] and has market share of [];[58]:

(b) Beiersdorf manufactures markets a cold sore patch under the Elastoplast brand in Europe (launched in 2009).

7.39 There are also popular products in Australia that have not been launched in New Zealand, for example Nyal's Antiviral Cold Sore Cream has a market share of more than [] in topical cold sore products in Australia.[59]

7.40 These products are as set out in Figure 9 below.

[57] See www.blistex.com.au/cold_sores.php.
[58] GSK data.
[59] GSK data.

Figure 9 – Topical products available overseas that have not entered the New Zealand market

Entity	Product	Description
Blistex[60]		Antiviral Cold Sore Cream 5g tube Active ingredient: Aciclovir 5%
Beiersdorf[61]		Elastoplast Cold Sore Patch Includes a hydrocolloid formulation to maintain a moist healing condition
Nyal[62]		Nyal Antiviral Cold Sore Cream 5g tube Active ingredient: Aciclovir 5%

Significant overseas developments are likely to occur in New Zealand

7.41 Developments overseas demonstrate that new products are likely to enter or develop further in New Zealand in the near future:

(a) In the USA and Canada, for example, an alternative antiviral (docosanol) has entered the OTC topical cold sore management markets and become the most popular cold sore treatment, with over USD$120 million in sales.[63] Docosanol

[60] Photo retrieved from: www.blistex.com.au/cold_sores.php.
[61] Photo retrieved from: www.amazon.co.uk/Nivea-Elastoplast-Cold-Sore-Patch/dp/B003JHNAKS.
[62] Photo retrieved from: www.shop.coles.com.au/online/national/nyal-antiviral-cold-sore-cream
[63] GSK.

products are now available across Europe as well (for example, Blistex now offers docosanal based cold sore treatments products in the UK).[64]

(b) Lip balms (e.g. Blistex) and topical pain relievers (e.g. Blistex medicated Lip Ointment) are increasingly important in cold sore management.[65] GSK estimates that 18% of all lip balm sales can be attributed to cold sore sufferers.[66] While these products do not stop the spread of cold sores, they do play an important role in treatment and management of cold sore symptoms. In Australia lip balm manufacturers have launched products with cold sore claims,[67] and as noted above these products are offered in New Zealand with similar claims (for example, Carmex and Blistex Lip Balm).[68]

(c) Internationally (as recently occurred in New Zealand in 2012 with HotKiss), alternative cold sore treatments, including light/heat therapy devices have also been launched overseas and are marketed as working faster than cold sore creams.[69]

Purchasers have significant countervailing power

7.42 As noted at paragraph 7.12 above, pharmacy wholesalers and grocery retailers, as purchasers of OTC pharmaceuticals, will continue to have significant countervailing power in their dealings with GSKCH after the OTC Transaction. []

The transaction will not result in coordinated effects

7.43 The risk of coordinated effects after the OTC Transaction in the topical OTC cold sore management market is low. Consistent with the approach taken by the High Court in *Brambles New Zealand Ltd v Commerce Commission*,[70] the conditions for concluding that there would be effective and sustainable coordinated behaviour as a result of the acquisition simply do not exist in the OTC topical cold sore management market. The OTC topical cold sore management market is characterised by a number of features that condition against prospects for coordinated effects as per the tests in the Commission's Guidelines:

(a) Pricing structures in the OTC topical cold sore management market are not transparent (suppliers negotiate individually and confidentially).

(b) Innovation is a key feature of the market.

(c) Products are off-patent, which limits barriers to entry and expansion.

(d) There is significant countervailing buyer power from both pharmacy buying groups and supermarkets, which is able to disrupt any hypothetical coordination.

(e) The transaction does not eliminate a maverick []

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[64] Blistex "How docosanol works" www.blistexcoldsorecream.co.uk/How-blistex-works-how-docosanol-works.
[65] See, for example: www.shop.countdown.co.nz/shop/ProductDetails?Stockcode=716931&name=blistex-lip-balm-medicated-relief.
[66] Internal GSK presentation "Abreva/Zovirax – Global Hydro Target Research" (April 2014) (based on GSK market research study).
[67] See, for example: www.blistex.com/products/medicated-lip-ointment and www.mycarmex.com/solutions.
[68] See, for example: www.shop.countdown.co.nz/shop/ProductDetails?Stockcode=716931&name=blistex-lip-balm-medicated-relief.
[69] See, for example: www.boots.com/en/Boots-Avert-Electronic-Cold-Sore-Machine_1129542/.
[70] *Brambles New Zealand Ltd v Commerce Commission* (2003) 10 TCLR 868 (HC).

(f) There are large numbers of actual and potential competitors, and other products that exert notable constraint (such as heat/light therapy devices and lip balms marketed with cold sore claims), which rules out the viability of tacit coordination.

OTC SYSTEMIC PAIN RELIEF

7.44 The Parties sell the following OTC systemic pain relief products in New Zealand:

(a) GSK NZ supplies OTC systemic pain relief products under the following brands:

(i) *Panadol*: GSK NZ supplies a number of different Panadol products (see www.gsk.co.nz/panadol.html), with the active ingredient being paracetamol. Some Panadol products also contain caffeine (Panadol Extra – "for extra pain relief) or Diphenhydramine HCI (Panadol Night – "effective on night pain"). Panadol products are available in both pharmacy and grocery channels.

GSK NZ also supplies paracetamol based pain relief products for children, in lower doses, under the Panadol Children's brand.

Paracetamol is a general purpose non-narcotic analgesic, providing analgesic (pain-killing) and antipyretic (fever reducing) effects. Paracetamol is considered an analgesic as it works by reducing the pain signals in the brain.[71] It is not considered a NSAID as it has only a limited anti-inflammatory effect.

(ii) *Panadeine*: GSK NZ supplies several different Panadeine products (see www.gsk.co.nz/panadeine.html), with the active ingredients being paracetamol in combination with codeine. GSK NZ offers two different active ingredient strengths in New Zealand:

(aa) Panadeine: Paracetamol 500mg, Codeine phosphate 8mg;

(bb) Panadeine Plus: Paracetamol 500mg, Codeine phosphate 15mg;

Both Panadeine and the Panadeine Plus strengths are classed as pharmacist-only medicines in New Zealand (as with all OTC products that contain codeine and are labelled for analgesic use).[72]

Codeine is an opiate used inter alia for its analgesic properties, which works on pain at the level of the brain/nerves. It is contained in combination products with NSAIDs or paracetamol to provide greater pain relief than either agent alone.

(iii) *Panafen Plus*: GSK NZ supplies several different Panafen products (see: www.gsk.co.nz/panafen-plus.html), with the active ingredients being ibuprofen and codeine (Ibuprofen 200mg, Codeine phosphate 12.8mg). As with Panadeine and Panadeine Plus, Panafen Plus is a pharmacist-only medicine.

Ibuprofen is a NSAID pharmaceutical. Different to paracetamol and codeine (which act on the brain/nerves), NSAIDs provide pain relief

[71] See: www.everybody.co.nz/page-5809d133-a2c8-4411-b2e1-3cda779e7fbb.aspx

[72] New Zealand Pharmacy Network "Restrictions on sale of codeine-containing meds" (1 October 2010) www.nzpharmacy.wordpress.com/2010/10/01/restrictions-on-sale-of-codeine-containing-meds.

by blocking certain enzymes to reduce inflammation and, thereby, reduce inflammatory pain.[73]

(b) Novartis ANZ supplies OTC systemic pain relief in New Zealand under the *Voltaren Rapid Muscle & Back Pain* brand ("**Voltaren Rapid**"). The Voltaren Rapid products contain the active ingredient dicolenfac. Systemic diclofenac products, such as Voltaren, are available OTC as:

(i) a pharmacy-only medicine when offered with 12.5 mg of diclofenac per tablet/capsule; and

(ii) a pharmacist-only medicine when offered with 25 mg of diclofenac per tablet/capsule.

Diclofenac is a NSAID pharmaceutical and, therefore, treats inflammation in order to alleviate pain.

7.45 Novartis ANZ also offers OTC topical pain relief products (M2A "Topical Anti-Rheumatics and Analgesics") under the Voltaren Emulgel and Voltaren Osteo Gel brands in New Zealand. GSK NZ does not offer OTC topical pain relief products in New Zealand, and accordingly no overlap arises in the topical pain relief space in New Zealand.[74]

7.46 The European Commission has previously concluded that topical pain relief products fall within a separate product market from systemic pain relief products.[75] Adopting separate topical and systemic pain relief markets is consistent with the previous approach of the Commission.[76]

7.47 The Parties agree with this market definition given that not only their mode of application, but also the classes of pain and potential side effects, differ significantly. While systemic pain relievers are taken through central intake irrespective of the pain location, topical products are only suitable for specific pain (e.g. musculoskeletal pain) and are applied locally for specific pain where it occurs.

7.48 Systemic and topical pain relief products are also often taken as complementary products (e.g. a consumer taking a pain relief tablet as well as applying a topical rub)

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[73] See: www.everybody.co.nz/page-5809d133-a2c8-4411-b2e1-3cda779e7fbb.aspx.

[74] [] the topical pain market in New Zealand is a highly competitive market that includes a range of competitors with well-known brands, such as:

- Ebos with Deep Heat, Nature's Kiss, Mentholatum (www.online.ebos.co.nz/default.cfm?action=list&by=brand&brand_id=1092);
- Douglas Pharmaceuticals with its Rheumon Gel (www.douglas.co.nz/viatris/products/rheumon-gel/);
- Haw Par Healthcare with its Tiger Balm range (www.tigerbalm.com/sg);
- Weleda with its Arnica and Heat Rub ranges (www.weleda.co.nz/heat-rub-36ml/w3/i1004288/);
- AFT with Zostrix (www.aftpharm.com/nz-products/zostrix and www.aftpharm.com/nz-products/zo-rub-for-muscles);
- Reckitt Benckiser with Nurofen Gel and Nurofen Back Pain Heat Patches (www.nurofen.co.nz/pain-relief/products/topicals.php);
- Blackmores with Flexagil Pain Relief Cream (www.blackmoresnz.co.nz/products/flexagil);
- Naturo Pharm Ltd with its Arnica Cream (www.naturopharm.co.nz/products/TopicalProducts/ArnicaCream.asp);
- As well as many others.

[75] Case No COMP/M.6705 *Procter & Gamble / Teva Pharmaceuticals OTC II* (9 November 2012): www.ec.europa.eu/competition/mergers/cases/decisions/m6705_20121109_20310_2788198_EN.pdf. In previous decisions, the Commission considered that assessing all ATC3 products classified under M2A together was appropriate for market definition.

[76] The Commission's decision in *Reckitt Benckiser plc / Boots Healthcare International Ltd* (above n 8) did not consider topical pain relief as part of the OTC medicines for the treatment of pain considered in that clearance process.

rather than in substitution for one another. Given there is no overlap in topical pain relief products, they are not discussed further in this application.

7.49 In relation to OTC systemic pain relief products, in *Reckitt Benckiser / Boots* in considering an overlap between those parties' OTC systemic pain relief products, the Commission defined a product market that combined all OTC systemic medicines for the treatment of pain, regardless of active ingredient:[77]

> 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.

7.50 Assuming consumers do still generally regard the products as substitutes, the Parties do not consider that GSK NZ's paracetamol-based products and Novartis ANZ's diclofenac-based products are close competitors. GSK NZ's paracetamol-based products are marketed to cover a range of pain conditions, and, importantly, only have a limited anti-inflammatory action. GSK's products are "general" pain relievers while Voltaren Rapid Muscle & Back Pain, as the name suggests, is specifically marketed for muscular and back pains.

7.51 The Parties acknowledge that there is nevertheless an extent to which consumers can, and do, switch between all of the various different types of systemic pain relief products for different types of pain and different levels of pain severity:

(a) While Voltaren Rapid is marketed for back and muscle pain, it is indicated to also treat post-operative pain (inflammation and swelling) and period pain.[78] Paracetamol, ibuprofen, aspirin and codeine based products are similarly marketed as treating a range of different types of pain, including muscular and back pain, for example:

(i) Reckitt Benckiser's New Zealand Nurofen website markets Nurofen, which is an ibuprofen based product, as being:[79]

> effective in the relief of inflammation and/or pain associated with headaches, backache, muscular aches, arthritic pain, rheumatic pain, neuralgia, some cold and flu symptoms, period pain, dental pain, and it reduces fever.

(ii) Pfizer's New Zealand website for Advil markets Advil, also an ibuprofen based product, as being for:[80]

> Headache, Back Pain, Muscle Pain, Arthritis Pain, Period Pain, Dental Pain

(iii) Reckitt Benckiser's aspirin based product, Disprin, is marketed as offering:[81]

> …rapid, effective relief from pain associated with: Headaches and migraine headaches, Rheumatic and arthritic pain, Neuralgia (nerve pain), Toothaches, Cold and flu symptoms, Sore throats, Period pain, Fibrositis,

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[77] Ibid.
[78] See Medsafe datasheet: www.medsafe.govt.nz/profs/datasheet/v/VoltarenRapidtabandcap.pdf.
[79] See www.nurofen.co.nz/pain-relief/pain-killers/ingredients.php.
[80] See www.advil.co.nz/.
[81] See www.onlinepharmacynz.com/product/613/Disprin.html.

> Relieves inflammation associated with back and muscular pain, and strains and sprains, Reduces fever

(iv) AFT's combination paracetamol/ibuprofen product, Maxigesic, is marketed as offering relief from:[82]

> Headache, Toothache, Arthritis, Rheumatic pain, Migraine headache, Dental procedures, Tennis elbow, Tension headache, Backache, Period pain, Sinus pain, Sore throat, Muscular pain, Aches and pains associated with cold and flu

(v) Pfizer's Ponstan, a mefenamic acid product (which is another form of NSAID), is marketed as offering relief from period pain but is also indicated to offer relief from:[83]

> muscle and bone injuries such as sprains, strains, low back pain (lumbago), rheumatism and tendonitis, after setting broken or dislocated bones, dental pain, headache

(b) As each and every consumer feels pain in his or her own way, there is no clear delineation from a consumer's perspective between the different strengths of pain relief products. While some consumers may consider that a particular severity of pain requires a pharmacist-only medicine (such as codeine, diclofenac, naproxen or mefenamic acid), other consumers with the same pain condition will treat that pain using products available through both grocery and pharmacy channels.

7.52 In addition, given that OTC systemic general pain relief products are often marketed as relieving migraine symptoms, and general pain treatments with paracetamol or an NSAID as an active ingredient may be classified as "anti-migraine preparations" in the N2C ATC3 class when marketed/labelled for migraine symptom relief, the Parties consider that products within the N2C code may also properly be considered to fall within the OTC systemic pain relief market.[84]

7.53 However, in recognition of the Commission's approach of defining "markets in the way that best isolates the key competition issues that arise from the merger"[85] the parties have not included N2C products in the calculation of the market shares in the OTC systemic pain relief management market given:

(a) There will be no aggregation in the N2C "anti-migraine preparations" code: while GSK NZ offers one N2C product OTC in New Zealand, namely Paramax, which is a pharmacist-only medicine, all of Novartis Pharma NZ's N2C products in New Zealand are prescription-only products and are not being contributed to the GSKCH venture; and

(b) Including those products in the calculation of market shares would only serve to dilute the aggregated market share of GSKCH:

(i) GSK NZ accounts for only [] of N2C products in New Zealand, and Novartis Pharma NZ for only [], [];

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[82] See www.aftpharm.com/nz-products/maxigesic.
[83] See Medsafe datasheet: www.medsafe.govt.nz/consumers/cmi/p/Ponstan.pdf.
[84] Anti-migraine preparations may additionally include triptans, which relieves local swelling and inflammation in the brain, thereby specifically targeting the migraine's accompanying symptoms such as nausea, vomiting or aversion to light.
[85] At paragraph 3.10 of the Commission's Merger and Acquisition Guidelines.

(ii) There are a number of other (including significantly larger) players in the N2C category in New Zealand, such as Actavis ([]), Mylan ([]), Boehringer ([]), AFT ([]), and MSD ([]).[86]

7.54 Adopting this approach to the calculation of market shares, the market shares in the nationwide market for OTC systemic pain relief treatment products are set out in Figure 10 below.

Figure 10 – Retail sales of OTC systemic pain relief products in New Zealand

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7.55 While GSKCH's combined market share falls outside the Commission's concentration indicators, the Parties do not consider that there will be any detrimental impact on competition in the OTC systemic pain relief product market for the reasons set out below:

The Parties are not each other's closest competitors

7.56 While the Parties can be considered to overlap in the OTC systemic pain relief market generally, overall their portfolio and presence is complementary. Voltaren Rapid is not the closest competitor of GSK NZ's products, and in particular it is not the closest competitor of its paracetamol or codeine-based products (Panadol and Panadeine), which account for over [] of GSK NZ's retail pain relief sales in New Zealand.[87] This is because the active ingredient in Voltaren Rapid, diclofenac, is a NSAID product, which treats pain through an anti-inflammatory action, and, therefore, is more closely in competition with other NSAID based products. [].

7.57 There are also a range of other NSAID products in the market, for example, naproxen based products (Bayer's Naprogesic), mefenamic acid based products (Pfizer's Ponstan), other generic dicloenfac products (Apotex's generic diclofenac product Apo-Diclo) and other ibuprofen based products (AFT's Maxigesic, Pfizer's Advil).

7.58 It is well recognised that paracetamol, NSAID and codeine based products fall within different types of pain relief products:[88]

> Even though there a large number of painkillers available, there are only three main types (each works in a different way). They are:
>
> - Non-steroidal anti-inflammatory drugs (NSAIDS). Examples of NSAIDs include; ibuprofen, diclofenac, and celecoxib. Aspirin is also an NSAID but nowadays it is mainly used (in low doses) to help to keep the blood from clotting.
> - Paracetamol.
> - Weak opioids and strong opioids (sometimes called opiates). Examples of weak opioids include: codeine, and dihydrocodeine. Examples of strong opioids include: diamorphine, morphine, oxycodone, and pethidine. Many people who need strong opioids are in hospital. Tramadol is also an opioid but fits somewhere in between a weak opioid and a strong opioid.[89]

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[86] Market share figures based on IMS Midas wholesale sales data.
[87] GSK combination of Aztec (pharmacy) and Nielsen (grocery) data.
[88] See www.patient.co.uk/health/painkillers.
[89] GSK advises that the most commonly used OTC NSAIDs for pain relief are aspirin, ibuprofen and naproxen, with diclofenac being a lessen commonly used OTC NSAID for pain relief.

7.59 The different types of systemic pain relief (both OTC and prescription-only) available in New Zealand are summarised in the table below:

Figure 11 – Commonly used types of pain relief medication in New Zealand

Analgesics	Anti-inflammatories
paracetamol tramadol (eg, Tramal)	**NSAIDs (COX 1 and COX 2 inhibitors)** aspirin ibuprofen (eg, Brufen, Nurofen) naproxen (eg, Naxen, Naprogesic, Noflam, Sonaflam) diclofenac (eg, Apo-Diclo, Cataflam, Diclax, Voltaren) indomethacin (eg, Rheumacin) piroxicam [no current products NZ] sulindac (eg, Clinoril)
Opioids codeine dextropropoxyphene [no current products NZ] dihydrocodeine (eg, DHC Continus) morphine oxycodone (eg, Oxycontin)	**NSAIDs (COX 2 inhibitors)** celecoxib (eg, Celebrex) etoricoxib (eg, Arcoxia) meloxicam (eg, Mobic, Melorex)
	Steroids cortisone prednisolone

Source: Everybody.co.nz (MIMS (NZ) Ltd)[90]

7.60 This difference in action, in particular the fact that diclofenac acts as an anti-inflammatory whereas paracetamol and codeine have a significantly more limited anti-inflammatory effect, is reflected in the different ways the products are marketed, with Voltaren Rapid's marketing emphasis being on muscular, back and sporting injuries,[91] while Panadol marketing materials focus more on general pain relief not linked to activity, such as headaches.[92]

7.61 As such, both products have closer third-party competitors. [] The closest competitors to GSK NZ's paracetamol-based products, which are typically marketed as general pain relievers, are private label paracetamol products (Pams, Signature Range, Homebrand, Your Pharmacy) and the range of other paracetamol products (such as Multichem's Ethics products, and API's Paracare products).

The combined entity will continue to face vigorous competition

7.62 Competition will remain strong in the OTC systemic pain treatment market. GSKCH will be constrained by a large number of big international players, including Reckitt Benckiser, Pfizer, and Dr Reddy's, and from a number of local competitors:

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[90] See www.everybody.co.nz/page-5809d133-a2c8-4411-b2e1-3cda779e7fbb.aspx.
[91] See www.familyhealthdiary.co.nz/products/voltaren-rapid-muscle-back-pain.
[92] See www.panadol.co.nz/helpful-information/headaches/top-10-triggers.html.

(a) Reckitt Benckiser will continue to have the largest market share in the OTC systemic pain treatment product market in New Zealand through its suite of different brands and active ingredients, including Nurofen, Nuromol, Nurofen Plus and Disprin;

(b) Pfizer will continue to compete with its two NSAID products, which both, similarly to Voltaren Rapid, target inflammation to treat pain, namely:

(i) Pfizer's Advil (ibuprofen) product. While New Zealand sales of Advil are currently comparatively small in comparison to other markets worldwide:

(aa) The sales of Advil in New Zealand have increased [] between 2013 and 2014, demonstrating that this is a product experiencing strong growth in New Zealand;

(bb) Advil's New Zealand website (www.advil.co.nz) promotes Advil as being the "World's Number 1 Pain Relief Brand", which demonstrates the scope that the Advil brand has to grow in New Zealand if Pfizer identifies market opportunities in New Zealand.

(ii) Pfizer's Ponstan (mefenamic acid). As noted, while Ponstan is marketed as offering relief from period pain, it also indicated to offer relief from a range of other pain conditions (see paragraph 7.51(a)(v) above).

(c) Dr Reddy's introduced a generic diclofenac product in New Zealand in 2012, and as noted above, [].

(d) Apotex's generic diclofenac product, Apo-Diclo.[93] Apotex, a company specialising in generic pharmaceuticals, is the largest Canadian-owned pharmaceutical company with global sales companies exceeding $1 billion (Canadian $) per year.[94]

(e) AFT, which is a New Zealand-owned competitor, heavily promotes its Maxigesic product, launched in 2009, and has recently introduced Paracetamol-Osteo in New Zealand. AFT is seen as an aggressive competitor on price, leveraging both its 'locally owned' image and access to manufacturing facilities in India to build its presence in the industry.

Competition will continue, and likely increase, from generic suppliers

7.63 The active ingredients concerned (ie, paracetamol, codeine, ibuprofen and diclofenac) are not patent-protected, and there a number suppliers already active in New Zealand competing through their generic offerings. For example:

(a) Dr Reddy's generic diclofenac product, introduced in New Zealand in 2012.

(b) Apotex's generic diclofenac product, Apo-Diclo.

(c) Multichem is a New Zealand based manufacturer and importer of generic pharmaceutical products, and currently offers generic paracetamol, ibuprofen and aspirin based products that together account for [] of retail sales, with

[93] See www.apotex.com/nz/en/products/search.asp?qt=A2Z&qs=D&t=Search and www.medsafe.govt.nz/Profs/Datasheet/a/ApodicloECtab.pdf

[94] See www.apotex.com/nz/en/about/default.asp

Multichem's sales growing by more than [] between 2013 and 2014.[95] Multichem's turnover exceeds NZ$30 million, and it has relationships with a number of international generic manufacturers.

(d) Private label pain relief products account for more than [] of all pain relief sales in New Zealand, including:

(i) Both of the major supermarkets in the grocery channel, who are both currently experiencing growth in the sales of the respective private label brands; and

(ii) The largest pharmacy retailer, Green Cross Health in 2010 launched its own private label brand, called 'Your Pharmacy',[96] and supplies paracetamol-based pain relief products under this brand.[97]

7.64 There are no relevant barriers to entry or expansion of sales of these generic pain relief products increasing in response to any price increase by GSKCH. For example, API's pharmaceutical plant has been recently upgraded, doubling its manufacturing capacity.[98]

No barriers to imports

7.65 All of GSK NZ's and Novartis ANZ's existing products are imported – there are no transport cost barriers to any pharmaceutical company importing generic or branded products from overseas. In addition to competition from generics and private label products (referred to above) that can be imported from around the world, there are a number of well-known overseas pain relief brands that are not present in New Zealand that could be introduced to New Zealand if market opportunities were identified. For example:

(a) Johnson & Johnson, a company that supplies a range of consumer and pharmaceutical products in New Zealand, owns Tylenol, a well-known paracetamol based OTC pain relief treatment in the USA.[99]

(b) Bayer, a company that supplies a range of consumer and pharmaceutical products in New Zealand, owns a number of well known pain relief brands overseas that do not yet have a large presence in New Zealand, such as:

(i) Aleve, a well-known ibuprofen based OTC pain relief treatment in the USA;[100]

(ii) Aspro, an aspirin based OTC pain relief product;

(iii) Naprogesic, a NSAID containing naproxen sodium, which is marketed as providing "temporary relief for neck and Back pain, Muscle pain, and Inflammation, period pain, Migraine, headaches, post operative pain e.g following Dental or Minor surgery, Sinus pain and fever".[101]

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[95] For further information see www.multichem.co.nz.
[96] Pharmacy Today "Private label for Pharmacybrands" (3 August 2010) www.pharmacytoday.co.nz/news/2010/august-2010/03/private-label-for-pharmacybrands.aspx
[97] See www.lifepharmacy.co.nz/search?q=%22your+pharmacy%22#
[98] See www.api.net.nz/manufacturing/pharmaceutical-plant.
[99] See www.tylenol.com/products.
[100] See www.aleve.com/index.php.
[101] See www.healthchemist.co.nz/product/naprogesic-tablets-12-p756059.html#.VAzj4tLNu70.

Purchasers have significant countervailing power

7.66 As noted at paragraph 7.12 above, pharmacy wholesalers and grocery retailers, as purchasers of OTC pharmaceuticals, will continue to have significant countervailing power in their dealings with GSKCH after the OTC Transaction. []

The transaction will not result in coordinated effects

7.67 For the same reasons set out in respect of OTC topical cold sore management products (at paragraph 7.43), the risk of coordinated effects after the OTC Transaction in the OTC systemic pain treatment market is low. The OTC systemic pain treatment market is characterised by a number of features that condition against prospects for coordinated effects as per the tests in the Commission's Guidelines:

(a) pricing structures in the OTC systemic pain treatment market are not transparent (suppliers negotiate individually and confidentially);

(b) innovation is a key feature of the market (for example, new combination pain relievers entering the market such as AFT's Maxigesic product);

(c) products are off-patent, which limits barriers to entry and expansion;

(d) there is significant countervailing buyer power from both pharmacy buying groups and supermarkets, which is able to disrupt any hypothetical coordination (including the prevalence of private label products);

(e) the transaction does not eliminate a maverick []; and

(f) there are large numbers of actual and potential competitors, which rules out the viability of tacit coordination.

OTHER ATC CODE PRODUCT AGGREGATION

Topical nasal preparations

7.68 The OTC transaction gives rise to an ATC product aggregation in the R1A "topical nasal preparations" ATC3 code as both Flixonase (a GSK NZ product) and Otrivin (a Novartis ANZ product) are being contributed to GSKCH.

7.69 Flixonase and Otrivin are not really substitutable products as:

(a) Flixonase is a R1A1 "nasal corticosteroids without anti-infectives" product, which is used, like other topical corticosteroid products, as a preventative treatment for allergic and non-allergic rhinitis (irritation and inflammation of the mucous membrane). Flixonase nasal spray is marketed as being for the prevention of allergies, with GSK's marketing materials stating:[102]

> When first used, Flixonase may take up to 12 hours to provide relief from allergy symptoms but, with ongoing daily use, Flixonase can actually prevent allergies from reoccurring.

Medsafe's datasheet for Flixonase similarly records that it is used as a prophylactic and for more long term treatment of allergic rhinitis:

> Flixonase Allergy & Hayfever 24 Hour is indicated for the prophylaxis and treatment of allergic rhinitis including hay fever and that caused

[102] See www.gsk.co.nz/flixonase.html.

> by other airborne allergens such as house dust mite, mould spores and animal dander.

Other R1A1 nasal corticosteroids available in New Zealand include:

(i) Mylan's Butacort, Alanese Aqueous, and Nasaclear;

(ii) Aspen's Beconase; and

(iii) Sanofi's Telnase and Azmacort.

[][103]

(b) Otrivin is a R1A7 product, "General Nasal Decongestants*",* which is used for temporary relief of nasal congestion caused by various conditions including a cold and sinusitis (inflammation of the sinuses). Otrivin is available as nasal spray or drops and contains the active ingredient xylometazoline. Otrivin nasal spray is primarily used as a general decongestant for the treatment of cold and flu. Marketing materials for Otrivin state that it is used:[104]

> for fast relief of nasal congestion or blocked nose and running nose associated with the common cold.

Medsafe's datasheet for Otrivin similarly records that it is used as a responsive treatment for blocked noses caused by colds, flu, sinusitis, hayfever or other allergic sinusitis:[105]

> Xylometazoline is a nasal decongestant that clears blocked noses.
>
> It is used for the relief of blocked nose caused by colds, flus, sinusitis, hayfever or other allergic sinusitis.

[]

7.70 Both GSK NZ and Novartis ANZ consider that Flixonase and Otrivin are complementary products, with Flixonase used by consumers to prevent allergic rhinitis occurring and Otrivin used for temporary relief once a person has a congested nose arising from a cold, flu or sinusitis.

7.71 The Parties' view that R1A1 and R1A7 products do not fall within the same product market is consistent with the conclusions of the European Commission in previous decisions:[106]

> The parties consider ATC third level of topical nasal preparations too wide for an appropriate definition of the market. The parties submit that the third level category of topical nasal preparations comprises a number of drugs for the topical application to the nose which cover different indications and offer different modes of action. Such products, according to the parties, are not substitutable beyond the indication they are designed to treat.
>
> The parties' products include SB's "Bactroban Nasal" and "Rinazina", and GW's "Flixonase" and "Beconase". The parties submit that SB's "Bactroban Nasal" falls within category R1A3 (nasal anti-infectives without corticosteroids) and is indicated for the prevention of nasal colonisation and subsequent infections.

[103] GSK data.
[104] See www.lifepharmacy.co.nz/p/Otrivin-Blocked-Nose-Adult-Nasal-Spray-Original-10ml?i=114989.
[105] See www.medsafe.govt.nz/consumers/cmi/CoughandCold/Xylometazoline.pdf.
[106] Case No COMP/M.1846 *Glaxo Wellcome / Smithkline Beecham* (8 May 2000): www.ec.europa.eu/competition/mergers/cases/decisions/m1846_en.pdf.

> SB's other product "Rinazina" falls within category R1A7 (nasal decongestants) and is indicated for the symptomatic relief of nasal congestions. GW's "Flixonase" and "Beconase" by contrast fall within the category R1A1 (nasal corticosteroids without anti-infectives) which treat rhinitis, which is an inflammation of the nasal mucus membrane, principally caused by allergies.
>
> ...
>
> By contrast, the parties submit that nasal corticosteroids (R1A1) have no effect on bacteria of the nasal mucosa. According to the parties, these products affect the mucus membrane itself to reduce an inflammation of the nasal membrane (rhinitis) which is mainly caused by an allergy but can also be caused non-allergically (smoking, pollution, central heating). GW's "Flixonase" and "Beconase" are corticosteroids used for the treatment of allergic as well as non-allergic rhinitis. SB has no rhinitis product and "Bactroban Nasal" cannot be used for this purpose.
>
> On the basis of the foregoing, the parties submit that their activities should not be regarded as overlapping in this area. Most third parties in their replies to the Commission's enquiries support the parties' view and have confirmed that the different products discussed above are not designed to treat the same indications. Third parties have confirmed that different products will be used for decongestant purposes only and for allergies, such as hay fever.
>
> On the basis of the foregoing, the Commission considers that the parties' existing products do not overlap and, therefore, this treatment area will not be discussed any further.

7.72 Even if Otrivin is regarded as a product used for relief of allergies (which is not its primary marketed use), the Parties' view that prophylactic nasal corticosteroid sprays are not substitutable with products for immediate allergy relief is consistent with the previous conclusions of the Commission:[107]

> The extent and nature of allergy symptoms can vary significantly across individuals and so consumers use allergy treatments in myriad of ways. For example, some individuals find nasal corticosteroid sprays as the most effective form of hayfever control, and do not view other treatments as viable alternatives. ... Others will use immediate relief and prevention products together in a complementary fashion, depending on the severity of their symptoms. ... Personal preferences and individual circumstances clearly are important in forming consumption decisions.
>
> Recognising the variety of consumers' needs, suppliers of allergy treatments have developed an extensive and highly differentiated range of products in terms of, among other factors: packaging; mode of delivery; dosage and duration of effectiveness; and price. The high degree of product differentiation and the variety of ways in which users demand these make it difficult to assess whether for instance, products that provide immediate relief ought to be defined in a separate market to prophylactics.

7.73 Defining markets on the basis that R1A1 and R1A7 products are not properly substitutable from the perspective of consumers would mean that there is no overlap between the Parties in topical nasal applications, with a number of other large international players active in each of those respective R1A1 and R1A7 product categories (including Aspen, Sanofi, Mylan, Pfizer, Johnson & Johnson, MSD, Procter & Gamble).

7.74 Similarly, defining the market on the basis of what the Parties regard in their commercial operations as "allergy treatments", which is the approach:

[107] *Johnson & Johnson / Pfizer Consumer Healthcare*, above n 9.

(a) the Commission adopted in *Johnson & Johnson / Pfizer* in defining a broader market for OTC allergy relief medications; and

(b) the Parties consider is correct from a consumer substitutability perspective,

demonstrates that there is no real overlap between the parties' products, as outlined in Figure 12 below.

Figure 12 - Retail sales of all allergy treatments in New Zealand

[]

7.75 Even if the Commission were to adopt a market for OTC allergy relief that is broader than the products that the Parties consider fall within the allergy relief market (and broader than the allergy market that Aztec and Nielsen collect data for) that includes Otrivin and other general decongestant products, the OTC Transaction would not give rise to any material impact on competition given:

(a) The only overlap between GSK NZ and Novartis ANZ would be due to the inclusion of Otrivin in the allergy market, which is not how the Parties record allergy market shares internally, and Otrivin for the reasons set out above is not a close competitor to:

(i) GSK's Flixonase product; nor

(ii) GSK's Zyrtec, which is an antihistamine (containing cetirizine) and is available in systemic tablet and syrup form;

(b) There would be a large number of international players with well-known products in such an allergy market, such as:

(i) Johnson & Johnson with its Sudafed decongestant/allergy product;[108]

(ii) Sanofi with Telfast[109] and Telnase Nasal Spray;[110]

(iii) Mylan with Razene, Lora, Xergic, Alanase and Butacort;[111]

(iv) MSD with Claratyne;[112]

(v) Pfizer with Dimetapp;[113]

(vi) Aspen with Beconase;[114]

(vii) Procter & Gamble with Vicks Sinex 12-Hour Decongestant Nasal Spray;[115]

(viii) AFT with its range of products, including Maxiclear.[116]

[108] See www.sudafed.co.nz.
[109] See www.telfast.com.au.
[110] See www.telfast.com.au/antihistamines/telnase-nasal-spray.
[111] See www.mylan.co.nz/ConsumerProducts/Xergic.aspx.
[112] See www.claratyne.com.au.
[113] See www.dimetapp.co.nz.
[114] See www.aspenpharma.co.nz/products/details/index/id/1134/product/Beconase.
[115] See www.vicks.com.au/products/vicks-cold-and-flu-family/mucus-control-liquid-dm.
[116] See www.lifepharmacy.co.nz/p/Maxiclear-Hayfever-and-Sinus-Relief-Tablets-30s?i=9838466.

(c) As the Commission has previously concluded, the OTC allergy market:[117]

> is a highly fragmented market with many competitors, offering differentiated products. There are also many generic companies, such as AFT and Douglas Pharmaceuticals that have also been able to enter the market and take a small amount of market share.

(d) Green Cross Health has launched a range of "Your Pharmacy" private label products in both the topical nasal application and systemic allergy relief product categories, including:

(i) Your Pharmacy Decongestant Nasal Spray 20ml;[118]

(ii) Your Pharmacy Sinus with Antihistamine Tablets;[119]

(e) []

7.76 As Otrivin is used as a decongestant for the treatment of cold and flu (ie it is a single-symptom treatment), the Parties recognise that the Commission may wish to also consider the extent to which Otrivin competes with GSK NZ's systemic multi-symptom cold and flu products, namely its:

(a) Coldrex range of products for the treatment cold of flu symptoms (such as congestion, headache, body aches & pains, sore throat and coughs);[120] and

(b) Panadol Cold & Flu range for the treatment of cold and flu symptoms.[121]

7.77 If the Commission were to adopt a broader market for all OTC products that treat cold and flu symptoms, the Parties do not consider that the OTC Transaction would give rise to any impact on competition:

(a) As above, the Parties do not consider Novartis ANZ's Otrivin and GSK NZ's Coldrex and Panadol Cold & Flu products to be each other's closest competitors (as Otrivin is a topical single symptom product, and Coldrex and Panadol Cold & Flu are systemic multi-symptom products);

(b) The Parties will continue to face vigorous competition from well-resourced international competitors in offering cold and flu treatments such as:

(i) Johnson & Johnson with Sudafed;

(ii) Pfizer with Dimetapp;

(iii) Reckitt Benckiser with Nurofen Cold & Flu and Lemsip;

(iv) Procter & Gamble with Vicks; and

(v) AFT (a local competitor) with Maxiclear.

(c) The shares would only marginally exceed the Commission's concentration indicators in any such market, as outlined below.

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[117] *Johnson & Johnson / Pfizer Consumer Healthcare*, above n 9.
[118] See www.lifepharmacy.co.nz/p/Your-Pharmacy-Decongestant-Nasal-Spray-20ml?i=135519.
[119] Seewww.lifepharmacy.co.nz/p/Your-Pharmacy-Sinus-with-Antihistamine-PE-Tablets-48s?i=342991.
[120] See www.gsk.co.nz/coldrex.html.
[121] See www.gsk.co.nz/panadol-cold-flu.html.

Figure 13 – Retail sales of all cold & flu treatments in New Zealand

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Anti-smoking products

7.78 There will be an ATC code product aggregation between GSK NZ's retained pharmaceutical division and GSCKH in the N7B "antismoking products" ATC3 code as:

(a) Novartis ANZ's OTC nicotine replacement therapy ("**NRT**") products, sold under the Habitrol and Nicotinell brands, will be contributed to GSKCH; and

(b) GSK NZ (through its pharmaceutical division) supplies Zyban in New Zealand, which is a product, unlike Novartis ANZ's NRT products, that is available only on prescription. Zyban is an example of a nicotine de-addiction therapy ("**NDT**") product. NDTs are products that do not have nicotine in them but instead work to reduce smoking cravings by interacting with chemicals in a patient's brain.[122]

7.79 The Commission has previously considered smoking cessation products in *Johnson & Johnson / Pfizer Consumer Healthcare*.[123] In that case the Commission confirmed its earlier view that OTC medicines are not generally substitutable for prescription products:

> For these reasons, the Commission concludes that OTC products do not compete with prescription-only medicines, and therefore defined the latter as falling outside the boundaries of the markets relevant to the present Application. This is consistent with the Commission's approach in Decision 567*: Reckitt Benckiser & Boots Healthcare International Limited*.

7.80 Accordingly, the Commission considered that the relevant market was the New Zealand market for the importation and wholesale supply of OTC smoking cessation products.[124]

7.81 Adopting the Commission's previous approach to market definition, no competitive overlap will arise in smoking-cessation products and, therefore, there will be no impact on competition.[125]

7.82 [].

7.83 Accordingly, the Parties consider that the OTC smoking cessation market will remain highly competitive after the OTC Transaction, with GSKCH continuing to face the same constraints that led the Commission to determine that the market was vigorously competitive in *Johnson & Johnson / Pfizer*, namely:[126]

(a) the competition between Novartis ANZ (whose products will be contributed to GSKCH) and Johnson & Johnson (with its Nicorette branded products); and

(b) the significant constraint from PHARMAC as a substantial purchaser of NRT products.[127]

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[122] See www.medsafe.govt.nz/consumers/cmi/z/zyban.pdf.
[123] *Johnson & Johnson / Pfizer Consumer Healthcare*, above n 9.
[124] Ibid at [78].
[125] More information in relation to smoking cessation may be found at the Ministry of Health's website: (6 June 2014). The New Zealand Guidelines for Helping People to Stop Smoking. Ministry of Health www.health.govt.nz/publication/new-zealand-guidelines-helping-people-stop-smoking
[126] *Johnson & Johnson / Pfizer Consumer Healthcare* at [204].
[127] Novartis ANZ currently has a sole supply agreement with PHARMAC to be the funded brand of NRT nicotine lozenges, patches and gum. That contract is due to continue until 30 June 2017. (See PHARMAC "Approval of sole supply arrangement for nicotine replacement therapy (NRT)" (25 March 2014) www.pharmac.health.nz/news/notification-2014-03-25-nrt-sole-supply/). [] In relation to bids for contracts of this nature, the Commission has previously observed that the key determinant of competition is whether or not a party

7.84 Further to these constraints, the Parties consider the market to have become even more competitive since the Commission last considered it as nicotine free e-cigarettes have entered the market [], with those products being marketed by pharmacies alongside all other OTC smoking products.[128]

7.85 Even if the Commission were to change its previous market definition and consider that OTC and prescription-only products fall within the same market, on the basis that they both help smokers manage their nicotine cravings, the Parties do not consider that there will be any detrimental lessening of competition in a broader OTC and prescription-only smoking cessation market as:

(a) Johnson & Johnson and Elusion will continue to be significant competitors through their respective OTC products;

(b) Mylan's Norpress and Pfizer's Champix will continue to be significant prescription-only competitors. In respect of Champix:[129]

(i) Champix's sales revenue in New Zealand is [] GSK NZ's sales of Zyban in 2013, with Pfizer selling []; and

(ii) While [].

(c) PHARMAC, as previously observed by the Commission, will continue to exert significant constraint as a substantial purchaser of both OTC and prescription-only smoking cessation products;

(d) a range of other smaller competitors such as Nicobloc, Nicobrevin, and other alternative remedies such as Naturo Pharm's Quite Smoke, Medico Herbs' Quit Smoking Spray, and Acu-Quit will continue to exert competitive constraint on the larger competitors.[130]

7.86 For the reasons set out above the Parties do not consider that the OTC Transaction will have any detrimental impact on the vigorous level of existing competition in the OTC and prescription smoking cessation markets.

Anti-fungals dermatological

7.87 The OTC transaction gives rise to an ATC overlap in the D1A "anti-fungals dermatological" ATC3 code as Lamisil (a Novartis ANZ product) is being contributed to GSKCH and GSK NZ's retained pharmaceutical division supplies Stieprox.[131]

7.88 However, Stieprox is a dandruff/dermatitis shampoo while Lamisil is an anti-fungal cream used for the treatment of conditions such as athlete's foot and tinea. Accordingly,

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faces at least one well matched and aggressive challenger (Decision 569, *Energy Market Services Limited and the Marketplace Company Limited* (20 December 2005)).

[128] See: www.lifepharmacy.co.nz/search?q=smoking

[129] GSK estimates. []/

[130] See: www.naturaltherapiesltd.co.nz/products-page/acuplus-no-needle-acupunture/acu-quit

[131] [] the anti-fungal market in New Zealand is a highly competitive market that includes a range of competitors with well-known brands, such as:

- Bayer's Canesten (see: www.canesten.co.nz/en/home/index.php);
- Janssen-Cilag Pty Ltd's Daktarin (see: www.onlinepharmacynz.com/product/148/Daktarin_Powder.html) and Miconazole Cream (see: www.aliveplusspharmacy.co.nz/productinfo/Miconazole_Cream);
- Ego Pharmaceutical's SolvEasy Tinea Cream and Resolve Tinea Cream (see: www.douglas.co.nz/fungal-infections/products/resolve-tinea/);
- Thorton & Ross's Mycota Cream (see: www.aliveplusspharmacy.co.nz/productinfo/Mycota_Cream_25g_);
- Pacific Pharmaceuticals' Pevaryl Cream (see: www.aliveplusspharmacy.co.nz/productinfo/Pevaryl_1%25_Cream_20g).

there is no competitive overlap between these products. This is consistent with the European Commission's approach to products in this ATC code:[132]

> The Commission's market investigation confirmed that the D1A category includes a wide range of dermatological products based on different active ingredients and different delivery modes. It therefore appears more appropriate to further subdivide this category to ATC4 level in order to account for the non-substitutability of topical antifungals, systemic ones and scalp treatments. The relevant product market where the parties are active is the OTC segment of the D1A1 category, topical antifungals. However, even at ATC4 level, products are significantly differentiated. Thus, on the basis of the results of the market investigation and the arguments put forward by the parties, the Commission has partially adjusted the relevant product market, slightly deviating from the D1A1 category, to exclude individual products that clearly belong to a different product market for purposes of competition analysis.
>
> Therefore, products classified in the D1A1 category, which, according to the results of the market investigation, are shampoos or other scalp treatments, have been excluded from the market for topical antifungals.

Anti-virals (excluding HIV)

7.89 There is an ATC overlap in the J5B "anti-virals (excluding HIV)" ATC3 code between GSK NZ and Novartis Pharma NZ, including one product that is available without prescription. However, the OTC Transaction does not give rise to any competitive aggregation as:

(a) The GSK NZ products in the J5B "anti-virals (excl anti-HIV)" category are all prescription-only products in New Zealand supplied through GSK NZ's pharmaceutical division and are not being contributed to GSKCH;

(b) The only Novartis ANZ product in the J5B "anti-virals (excl anti-HIV)" category is Famvir Once, which has been discussed in the context of the cold sore management section.

(c) In any event, the products are indicated for different conditions, with Novartis ANZ's Famvir Once indicated for "recurrent herpes labialis (cold sores)" and GSK NZ's pharmaceutical division's J5B products indicated for the following:

(i) Zovirax: Shingles and genital herpes;[133]

(ii) Zeffix: Hepatitis B;[134]

(iii) Valtrex: Shingles and genital herpes;[135] and

(iv) Relenza: Influenza.[136]

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[132] Case No COMP/M.3544 *Bayer Healthcare / Roche (OTC Business)* (19 November 2004) at [25]–[26]: www.ec.europa.eu/competition/mergers/cases/decisions/m3544_20041119_20212_en.pdf.
[133] See Medsafe datasheet: www.medsafe.govt.nz/profs/datasheet/z/zoviraxtab.pdf
[134] See Medsafe datasheet: www.medsafe.govt.nz/profs/datasheet/z/Zeffixtab.pdf.
[135] See Medsafe datasheet: www.medsafe.govt.nz/profs/datasheet/v/valtrextab.pdf.
[136] See Medsafe datasheet: www.medsafe.govt.nz/consumers/cmi/r/relenza.pdf.

Confidentiality

8. If you wish to request confidentiality for specific information contained in or attached to the notice, please state why you consider the information to be confidential and state the reasons for your request in terms of the criteria set out in the Official Information Act 1982.

8.1 Confidentiality is sought in respect of the information in this application that is contained in square brackets and highlighted. Confidentiality is sought for the purposes of section 9(2)(b) of the Official Information Act 1982 on the grounds that:

(a) the information is commercially sensitive and valuable information which is confidential to the participants; and

(b) disclosure would be likely unreasonably to prejudice the commercial position of the participants, as the parties providing the information.

8.2 GSK requests that it be notified of any request made to the Commission under the Official Information Act 1982 for release of the confidential information. GSK also requests that the Commission seek and consider GSK's views as to whether the information remains confidential and commercially sensitive at the time responses to such requests are being considered.

8.3 The foregoing equally applies in respect of any additional information provided to the Commission that is expressed to be confidential.

9. Provide two copies of the application. One copy must be a confidential version and the other a public version both in Microsoft word format and in searchable PDF format.

- **In the confidential version of the application any information for which confidentiality is sought must be highlighted in bold and contained in [square brackets].**
- **In the public version the confidential information should be removed from within the square brackets, with the brackets remaining as [ ].**

9.1 A confidential version and a public version have been provided.

9.2 In the confidential version of the application, confidential information is contained in square brackets and highlighted.

DECLARATION

I, Victoria Whyte, have prepared, or supervised the preparation, of this notice seeking clearance.

To the best of my knowledge, I confirm that:

- all the information specified by the Commission has been supplied;
- if the information has not been supplied, reasons have been included as to why the information has not been supplied;
- all information known to me that is relevant to the consideration of this notice has been supplied; and
- all information supplied is correct as at the date of this notice.

I undertake to advise the Commission immediately of any material change in circumstances relating to the notice.

I understand that it is an offence under the Commerce Act to attempt to deceive or knowingly mislead the Commission in respect of any matter before the Commission, including in these documents.

I am a director/officer of the company and am duly authorised to submit this notice.

Victoria Whyte, Company Secretary, GlaxoSmithKline plc

Date: 23 September 2014

CONFIDENTIAL APPENDIX ONE

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CONFIDENTIAL APPENDIX TWO

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CONFIDENTIAL APPENDIX THREE

Consumer healthcare products that will form part of GSKCH in New Zealand

GSK NZ's existing OTC consumer healthcare products

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Novartis OTC consumer healthcare products to be contributed in New Zealand

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CONFIDENTIAL APPENDIX FOUR

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CONFIDENTIAL APPENDIX FIVE

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APPENDIX SIX

Contact details for key competitors referred to in the application

Name	Contact Details	Description
Actavis New Zealand Ltd	PO Box 128244 Remuera Auckland 1541 New Zealand T: +64 9 630 4488 actavis.co.nz enquiries@actavis.co.nz	Actavis New Zealand Ltd is a subsidiary of the specialty pharmaceutical company Actavis plc. Headquartered in Dublin, Ireland, Actavis plc is focused on developing, manufacturing and commercializing generic and branded pharmaceutical products.[137]
AFT Pharmaceuticals	Level 1, 129 Hurstmere Road Takapuna Auckland 0622 T: +64 9 4880232 F: +64 9 4880234 aftpharm.com/nz aftpharm.com/nz/contact	AFT Pharmaceuticals is a New Zealand based privately owned company with operations in both Australia and New Zealand. AFT focuses firmly on the pharmaceutical prescription and OTC market sectors. Since its first product launches in 1998, sales have grown every year to be on target in New Zealand to exceed NZ$36 million this year.[138]
API Consumer Brands	PO Box 76-401 14-16 Norman Spencer Drive Manukau City, Auckland T: +64 9 279 7979 F: +64 9 279 7999 www.api.net.nz sales@api.net.nz	API Consumer Brands markets itself as one of New Zealand's leading pharmaceutical companies. API Consumer Brands has pharmaceutical manufacturing plant that produces OTC and dispensary products including liquids, creams, suspensions, tablets, powders, suppositories and capsules, which are distributed to pharmacies and hospitals within New Zealand and around the world.[139]
Apotex NZ Ltd	32 Hillside Rd Glenfield Auckland 0627 T: +64 9 4442073 http://www.apotex.com/nz/en/default.asp	Apotex NZ Ltd is a subsidiary of Apotex Inc, the largest Canadian-owned pharmaceutical company. Apotex Inc. Exports to over 115 countries around the world, with its group sales exceeding $1 billion (Canadian $) per year.[140]
Aspen Pharmacare Australia Pty Ltd	*New Zealand operations c/o:* Healthcare Logistics 58 Richard Pearse Drive Airport Oaks Auckland 2022 T: +64 9 918 5100 F: +64 9 918 5101 *Aspen Australia Head Office Address:* 34-36 Chandos Street St Leonards NSW 2065	The Aspen New Zealand operation is part of Aspen PharmaCare Australia Ptd Ltd, which is a subsidiary of Aspen Pharmacare Holdings Ltd, a listed South African pharmaceutical company that is a supplier of branded and generic pharmaceuticals in more than 150 countries across the world. The Aspen Group has 26 manufacturing facilities at 18 sites on 6 continents and approximately 8200 employees.[141]

137 See: www.actavis.co.nz/en/about/default.htm.
138 See: www.aftpharm.com/nz.
139 See: www.api.net.nz/brands/pharmaceuticals.
140 See: www.apotex.com/nz/en/about/default.asp.
141 See:
- www.aspenpharma.co.nz/about
- www.aspenpharma.com/group-overview-2

	T: +61 2 8436 8300 F: +61 2 9901 3540 aspenpharma.co.nz/contact	
Bayer New Zealand	PO Box 2825 3 Argus Place Glenfield, Auckland T: +64 9 443 3093 F: +64 9 443 3094 www.bayer.co.nz/scripts/pages/en/index.php bayer.co.nz/scripts/pages/en/enquiry.php	Bayer New Zealand is part of the international Bayer group, which operates in the health care, nutrition and high-tech materials sectors. Bayer employs 112,000 people worldwide, and around 1,100 in Australia/New Zealand. Worldwide operations are managed from Group headquarters in Leverkusen, Germany. In 2013 the Bayer Group recorded sales of EUR 40.157 billion. Bayer's operations in Australia and New Zealand generated AU$1.051 billion in revenue in 2013.[142]
Blistex	PO Box 1033 North Ryde BC NSW 1670 T: +61 2 8113 6200 F: +61 2 8113 6222 blistex.com.au otc@keypharm.com.au	Blistex manufactures tests and distributes a full line of lip care products from its headquarters in Illinois, USA. Blistex's Australasian business is run via its Sydney office.[143]
Care Pharmaceuticals	Suite 6 442 New South Head Rd Double Bay Sydney 2028 New South Wales T: +61 2 9300 1900 F: +61 2 9387 6654 T(NZ): +64 9838 3265 carepharmaceuticals.com.au/contact-us ** No NZ address - NZ telephone only*	Care Pharmaceuticals was acquired by Prestige Brand Holdings Inc in July 2013. It has a diverse range of products in the following areas: cold and flu; hayfever and allergies; nasal health; eye care; pain relief; oral rehydration; constipation; conception and pregnancy; women's health; vitamin supplementation; immune system support; anal conditions.[144]
Clinicians	PO Box 45-061 Te Atatu Peninsula 0651 Auckland T:+64 9 835 0660 F: +64 9 835 0690 clinicians.co.nz clinicians.co.nz/contact-us	Clinicians is a wholly owned subsidiary of Douglas Pharmaceuticals. It produces general vitamin and mineral supplements as well as products for specific conditions.[145]
Douglas Pharmaceuticals New Zealand	Corner Te Pai Place and Central Park Drive Henderson Auckland T: +64 9 835 0660 douglas.co.nz douglas.co.nz/contact-us	Douglas Pharmaceuticals is a New Zealand based manufacturer and distributor of prescription medicines and consumer products, with manufacturing facilities in New Zealand and Fiji. Douglas Pharmaceuticals currently supplies 30 generic products in 35 countries worldwide.[146]
Dr Reddy's New Zealand Ltd	Level 6, AMI Building 63 Albert St Auckland 1142 T: +64 9 356 7000 drreddys.com/index.html drreddys.com/newzealand/contact-us.asp	Dr Reddy's New Zealand Ltd is a wholly owned subsidiary of Dr. Reddy's Laboratories Ltd, an integrated global pharmaceutical company based in India. Dr Reddy's offers active pharmaceutical ingredients, custom pharmaceutical services, generics, biosimilars, and differentiated formulations and NCEs. Its therapeutic focus is on gastro-intestinal,

142 See: www.bayer.co.nz/scripts/pages/en/about_bayer/bayer_australia_and_new_zealand/index.php.
143 See: www.blistex.com/about-blistex.
144 See: www.carepharmaceuticals.com.au/our-company/our-capabilites/.
145 See: www.clinicians.co.nz/about-us
146 See: www.douglas.co.nz/about-us.

		cardiovascular, diabetology, oncology, pain management, anti-infective and paediatrics.[147]
Elusion New Zealand Ltd	T: +64 9 443 4433 elusionelectroniccigarette.co.nz elusionelectroniccigarette.co.nz/contacts.html ** no NZ address - NZ telephone only*	Elusion manufactures and distributes electronic cigarettes within New Zealand.
Ethical Nutrients (Health World Ltd)	PO Box 675 Virginia BC Queensland 4014 Australia T: +617 3117 3300 http://ethicalnutrients.com.au/contact hworld@healthworld.com.au.	Health World Ltd is an Australian based nutritional medicine business.[148]
Foodstuffs	PO Box 5401 Lambton Quay Wellington 6145 T: + 64 4 472 6435 F: +64 4 472 6412 foodstuffs.co.nz foodstuffs.co.nz/about-foodstuffs/contact-us	Foodstuffs is New Zealand's biggest grocery distributor. It operates primarily via two regional collectives: Foodstuffs North Island Ltd and Foodstuffs South Island Ltd. Each of the regional co-operatives is owned by its retail members. Foodstuffs employs more than 30,000 people nationwide, and supplies New World, Pak n Save, Four Square, Liquorland, Write Price, Shoprite, Gilmours, Toops and Raeward Fresh stores.[149]
Integria Healthcare (New Zealand) Ltd	3 Te Kea Place Rosedale Auckland 0632 T: +64 9 978 0200 integria.com	Integria Healthcare (Australia) Pty Ltd is the parent company of the Thursday Plantation and Thompson's brands. The Integria Group is an Australasian-wide natural medicine company with more than 1,800 natural health and personal care products supports.[150]
Green Cross Health	Private Bag 11906 Ellerslie Auckland 1542 T: + 64 9 571 9080 F: +64 9 571 9081 greencrosshealth.co.nz greencrosshealth.co.nz/contact	Green Cross Health Ltd (formerly Pharmacybrands) has pharmacy, medical and community healthcare divisions and is listed on the New Zealand stock exchange (GXH). Green Cross Health represents around 300 community pharmacies throughout New Zealand under the Unichem and Life Pharmacy banners and holds equity interests in 70 of these pharmacies.[151]
Johnson & Johnson	Ground Floor Tonkin & Taylor House 105 Carlton Gore Rd Newmarket Auckland 1023 T: +64 9 523 8700 jnjnz.co.nz jnjnz.co.nz/contact-us	Johnson & Johnson has approximately 128,000 employees across more than 275 operating companies in 60 countries. It operates via three divisions: medical devices and diagnostics, pharmaceutical, and consumer. 2013 sales were approximately $71.3 billion.[152]
Merck & Co Inc ("**MSD**")	PO Box 99-851 Newmarket Auckland 1149 New Zealand T: +64 9 523 6000	Merck (known as MSD within New Zealand), produces medicines, vaccines, biologic therapies and animal health products.[153]

[147] See: www.drreddys.com/media/popups/mediakit/company_profile.html.
[148] See: www.ethicalnutrients.com.au/content/why-ethical-nutrients
[149] See: www.foodstuffs.co.nz/about-foodstuffs/.
[150] See: www.integria.com/about-us/.
[151] See: www.greencrosshealth.co.nz/about-us.
[152] See: www.jnj.com/about-jnj.
[153] See: www.msd-newzealand.com/Pages/home.aspx.

	msd-newzealand.com	
Multichem	8 Apollo Drive Rosedale Auckland 0632 T: +64 9 488 0330 multichem.co.nz	Multichem is one of New Zealand's major importers and distributors of pharmaceutical products. It has as annual turnover exceeding NZ$30 million. Multichem supplies a population base of more than 32 million including New Zealand, Australia and the Pacific Islands.[154]
Mylan New Zealand Ltd	PO Box 11183 Ellerslie, 1542 Auckland New Zealand T: +64 9 579 2792 F: +64 9 579 7072 mylan.co.nz info@mylan.co.nz	Mylan New Zealand Ltd is part of the international group Mylan of the USA. Mylan is one of the world's leading generics and specialty pharmaceutical companies, providing products to customers in approximately 150 countries and territories. Mylan New Zealand Ltd is one of the largest pharmaceutical companies in New Zealand, specialising in generic pharmaceuticals. Mylan New Zealand promotes a wide range of prescription medicines and over-the-counter medicines.[155]
Naturo Pharm Ltd	PO Box 952 Rotorua T: 0800 1 76543 F: 0800 1 76444 naturopharm.co.nz info@naturo.co.nz	Naturo Pharm is a manufacturer and supplier of homoeopathic remedies. New Zealand owned and operated, the company is based in Rotorua, where it has office, laboratory, manufacturing and warehouse facilities.[156]
Nature's Own (part of Sanofi-Aventis)	T: 1300 130 612 naturesown.com.au naturesown.com.au/contact-us/ ** No NZ address/phone*	Nature's Own is one of the longest established vitamin brands in Australia and is based in Virginia, Brisbane.[157] It is part of the Sanofi-Aventis group.
Neilmed Pharmaceutical New Zealand Pty Ltd	PO Box 27310 Mount Roskill Auckland 1440 T: +64 9 570 7279 F: +64 9 353 1430 neilmed.co.nz	Neilmed Pharmaceutical New Zealand Pty Ltd is a subsidiary of NeilMed Pharmaceuticals, Inc. NeilMed is the largest manufacturer and supplier of Large Volume Low Pressure saline nasal irrigation systems in the world.[158]
NicoBloc NZ Ltd	P O Box 108-165 Symonds Street Auckland 1150 New Zealand T: +64 9 529 4297 nicobloc.co.nz info@nicobloc.com.au	NicoBloc NZ distributes the NicoBloc product to both the New Zealand and Australian markets.
Perrigo	25 - 29 Delawney St Balcatta, Western Australia 6021 T: +61 8 9441 7800 F: +61 8 9441 7888 perrigo.com.au	Perrigo Company plc, headquartered in Ireland, develops, manufactures and distributes over-the-counter and generic prescription pharmaceuticals, nutritional products and active pharmaceutical ingredients. Perrigo, which operates in over 40 markets worldwide, markets itself

[154] See: www.multichem.co.nz/.
[155] See: www.mylan.co.nz/AboutMylan.aspx.
[156] See: www.naturopharm.co.nz/about_naturopharm/default.asp.
[157] See: www.naturesown.com.au/about-us/
[158] See: www.neilmed.co.nz.

		as an industry leader in pharmaceutical technologies.[159]
Pfizer	Level 1, Suite 1.4, Building B, 8 Nugent St Grafton Auckland 1023 T: 0800 699 276 or 09 3543065 F: 0800 735 045 or 09 3747630 pfizer.co.nz contactus.newzealand@pfizer.com	Pfizer is an international company listed on the New York and London stock exchanges. Its corporate headquarters are located in New York and its 2013 revenue was $51.6 billion. Pfizer has been active in New Zealand for the past 50 years, and now employs just under 50 personnel in New Zealand across its biopharmaceutical and consumer businesses.[160]
Procter & Gamble	Unit 3, Building I 5 Orbit Drive Rosedale North Shore City Auckland T: +64 9 415 7800 pg.com/en_ANZ/	Procter & Gamble is a global, publicly traded company headquartered in Cincinnati, Ohio. It has operations in approximately 70 countries and annual sales of approximately $84.2 billion (FY 2013). Procter & Gamble operates four global business units: beauty; baby, feminine and family care; fabric and home care; and health and grooming.[161]
Progressive Enterprises Ltd	Private Bag 93306 Otahuhu, Auckland 1640 T: +64 9 275 2788 progressive.co.nz	Progressive Enterprises, a subsidiary of Woolworths Ltd, is headquartered in Auckland. It owns and operates over 165 Countdown supermarkets in New Zealand and has approximately 18,500 employees nationwide.[162]
Pro-Health Products	59 Baddeley Ave Kohimarama, Auckland * *No NZ phone*	Pro-Health Products is the New Zealand distributor of Nicobrevin, an anti-smoking product.
Reckitt Benckiser (New Zealand) Ltd	Lincoln Manor 289 Lincoln Road Henderson, Auckland T: +64 9 839 0200 F: +64 9 839 0202 rb.com/rb-worldwide/operations-around-the-world/new-zealand	Reckitt Benckiser is a multinational consumer goods company headquartered in Slough, England. Its business is structured around the categories of health, hygiene, home, and food. Reckitt Benckiser operates in nearly 200 countries and had a 2013 net revenue of £10 billion.[163]
DTC Healthcare Ltd	St John's House St John's Street Chichester PO19 1UU United Kingdom herstat.com	DTC Healthcare Ltd is the manufacturer and retailer of the Herstat Cold Sore Care range. The company is based in Chichester, England.
Sanofi-Aventis New Zealand Ltd	PO Box 12851 Penrose, Auckland T: +64 9 580 1810 sanofi.com.au/l/au/en/index.jsp sanofi.com.au/l/au/en/layout.jsp?scat=42FA602B-8760-4104-8E0A-968E550D2D8A	Sanofi is a global healthcare company that researches, manufactures and markets pharmaceutics, vaccines, and animal health products. It operates 112 industrial sites in 41 countries, and 20 R&D sites. In 2013 net worldwide sales were approximately €32,951.[164]
Valeant Pharma	*Australasia*: Level 3, Suite 3.05 120 Bay Street Port Melbourne Victoria 3207 Australia T: +61 3 9676 1800	Valeant Pharma is a multinational specialty pharmaceutical company with a focus on branded pharmaceuticals, branded generics and over-the-counter products, and a specialisation in dermatology and eye health. It is headquartered in Quebec,

[159] See: www.perrigo.com/about/about-perrigo.aspx.
[160] See: www.pfizer.co.nz/content/about-pfizer-in-new-zealand.
[161] See: www.pg.com/en_US/index.shtml.
[162] See: www.progressive.co.nz.
[163] See: www.rb.com/home.
[164] See: www.en.sanofi.com/Images/35787_ChiffresCles_2014_EN_V3.pdf.

	F: +61 3 9676 1807 valeant.com	Canada, and has approximately 16,000 worldwide employees. 2013 revenues were approximately $5.76 billion.[165]
Vitaco Health (NZ) Ltd (Nutra Life)	PO Box 259 109 Botany, Manukau 2163 T: 0800 268 872 F: 0800 688 725 nutralife.co.nz nutralife.co.nz/contact-us	Vitaco Health is a New Zealand based company which operates the brands Nutra-Life Heath & Fitness (supplements/sports nutrition) and Healtheries (health foods). The company has approximately 400 employees and distributes products to 30 countries worldwide.[166]

[165] See: www.valeant.com/about.
[166] See: www.vitaco.co.nz/about.html.

APPENDIX SEVEN

Contact details for industry bodies

Name	Contact Details
Medicines New Zealand	PO Box 10-447 The Terrace Wellington 6143 T: +64 4 499 4277 F: +64 4 499 4276 www.medicinesnz.co.nz info@medicinesnz.co.nz
New Zealand Self-Medication Industry Association Inc	PO Box 647 Auckland T/F: +64 9 2355260 www.nzsmi.org.nz/home tim.roper@nzsmi.org.nz
New Zealand Food and Grocery Council	PO Box 1925, Wellington T: +64 4 473 9223 F: +64 4 496 6550 www.fgc.org.nz admin@fgc.org.nz

CONFIDENTIAL APPENDIX EIGHT

Contact details for key OTC customers

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