

NOTICE SEEKING CLEARANCE UNDER SECTION 66 OF THE  
COMMERCE ACT 1986 FOR A PROPOSED MERGER OF

*Novartis AG and Alcon Inc*

**1 April 2010**

**PUBLIC VERSION**

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

 **Simpson Grierson**

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## EXECUTIVE SUMMARY

The Novartis Group is a large group of healthcare companies operating in many countries throughout the world, supplying a range of both prescription and non-prescription medicines, vaccines, consumer healthcare products and animal health products.

Novartis New Zealand Limited operates the sales, marketing and distribution of Novartis' human pharmaceutical, and animal health products in this country. The Novartis Group also includes two further New Zealand divisions - "CIBA Vision" and "Novartis Consumer Health", which are operated from Australia separately from Novartis New Zealand Limited.

Novartis AG (**Novartis**) intends to acquire the majority shareholding in Alcon, Inc. (**Alcon**), which is a global medical company specialising in eye care. Alcon operates in New Zealand through Alcon New Zealand Ltd, and to a smaller extent Alcon Pharmaceuticals Ltd and Alcon Laboratories Inc.

There is minimal overlap between Novartis' and Alcon's products and they are mostly complementary. The acquisition of Alcon by Novartis will allow Novartis to expand into the eye care sector, which it sees as a growing sector given the ageing population.

In the pharmaceutical industry, products can be broken down into therapeutic classes according to the Anatomical Therapeutic Classification (the **ATC Classification**) devised by the European Pharmaceutical Marketing Research Association (**EphMRA**). The ATC Classification is hierarchical and includes 16 categories with each having up to four levels. It has been recognised by the Commerce Commission in previous decisions that the ATC3 classification is generally the appropriate classification for market definition, although this will be fact dependent in each case. In the markets identified in New Zealand, Novartis believes that the ATC3 classification is generally the appropriate market definition, based on principles of substitutability, and therapeutic indications. However, for the S1E classification narrower market definitions may be appropriate based on substitutability principles (as expanded on below).

Proceeding on this basis, there are only five categories in which there is potential overlap between Novartis' and Alcon's products in New Zealand as a result of the acquisition. These are:

- the category in New Zealand for the manufacture, import and wholesale supply of miotics and antiglaucoma preparations – (ATC3 classification S1E). The S1E

category for miotics and antiglaucoma preparations can potentially be subdivided into two sub-categories: (i) a segment for miotics for use in cataract surgery and (ii) a segment for anti-glaucoma products because these two sets of products have different uses and may not be substitutable;

- the category in New Zealand for the manufacture, import and wholesale supply of ocular anti-allergies, decongestants and antiseptics - (ATC3 classification S1G);
- the category in New Zealand for the manufacture, import and wholesale supply of artificial tears and ocular lubricants - (ATC3 classification S1K);
- the category in New Zealand for the manufacture, import and wholesale supply of lens care products - (ATC3 classification S1L); and
- the category in New Zealand for the manufacture, import and wholesale supply of ophthalmological diagnostic agents - (ATC3 classification S1T).

In some of these categories, the parties' products differ in their mode of action and therapeutic use and therefore do not overlap directly. Even where there is some aggregation in these categories, no competition issues arise because:

- post-acquisition, Novartis will continue to face intense competitive pressure from a number of large international pharmaceutical companies;
- many of Novartis' and Alcon's products in the relevant categories are off patent and face competition from a broad range of generic products;
- barriers to entry and expansion by existing participants in the human healthcare industry are not high; and
- the pricing of pharmaceutical products is highly regulated, which means the parties will not have the ability to increase profits or profit margins significantly or sustainably.

Looking at each of the categories identified separately:

- At the ATC3 level, the combined share of Novartis and Alcon post-acquisition in two of these five categories, S1E and S1G, falls within the Commerce Commission's safe harbours, based on the IMS data available.
- If the S1E sub-category for miotics for use in cataract surgery applies, the combined Novartis/Alcon entity post-acquisition will have a [ ]% share. That said, even if this is the case, there will still be one significant competitor in this category (Sigma Pharmaceuticals) with a [ ]% share, aggregation is limited as Alcon only has a [ ]% share, and the total value of this sub-category in New Zealand is very small, being only US\$[ ] .
- Although the 2009 IMS data for the S1T category shows some aggregation, Novartis discontinued its only product in this category in 2009 in New Zealand, and no longer supplies this product. It has no intention to commence re-selling into this category in future. Therefore there will not be any aggregation issues in this category going forward.
- In the S1K category, the post-acquisition combined share of Novartis and Alcon will be [ ]% (with potentially limited additional share from Novartis' CIBA Vision division). While this is outside the Commission's safe harbours, Novartis will continue to face strong competition primarily from Allergan, which is another large multi-national pharmaceutical company. Accordingly there will remain significant competitive constraints on Novartis going forward.
- In the S1L category, Novartis' share (through its CIBA Vision division) is very small, as CIBA Vision only sells its products through optometry channels (having approximately [ ]% of the sales through this channel), which amount to only around 20% of total sales in the overall category. Given the small Novartis share, aggregation will be minimal. Furthermore, there are a number of large competitors in this category, such as Bausch & Lomb and Abbott Medical. Accordingly there will remain significant competitive constraints on Novartis going forward.

Given the complementary nature of the business and products of Novartis and Alcon, a number of efficiencies will be created by the acquisition. The proposed transaction will enable Novartis to enhance its capabilities to meet demand relating to increasing vision care needs of an aging population.

Therefore Novartis submits that the proposed acquisition will not have the effect of substantially lessening competition in any of the relevant categories identified.

## PART 1: TRANSACTION DETAILS

1. Provide the name of the acquirer (person giving notice), and the name and position of the individual responsible for the notice. Please include the:

- registered office address, postal address and physical address of the acquirer;
- telephone and fax numbers and website of the acquirer; and
- email address, telephone number and position of the contact person

### The Acquirer

1.1 The acquirer is Novartis AG (**Novartis**).

1.2 This notice is given by:

Novartis AG  
Lichtstrasse 35  
4056 Basel  
Switzerland  
Telephone: 41 61 324 06 00  
Fax: 41 61 324 08 08  
Web Site: <http://www.novartis.com>

Contact Person:  
Sean Evans  
Designation: General Manager, Novartis New Zealand Limited  
Address: Private Bag 65904, Mairangi Bay 1010  
Office no.: 09 361 8112  
Fax no.: 09 361 8156  
Mobile no.: 021 796 280  
Email address: [sean.evans@novartis.com](mailto:sean.evans@novartis.com)

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

Simpson Grierson  
Lumley Centre  
Private Bag 92518  
Auckland

Telephone: (09) 977 5125  
Facsimile: (09) 977 5046  
Email: [james.craig@simpsongrierson.com](mailto:james.craig@simpsongrierson.com)  
**Attention:** James Craig/Peter Hinton



**2. Provide the name of the other merger parties, and the name/position of the relevant individual within the relevant merger parties. For each merger party, please include the:**

- **registered office address, postal address and physical address;**
- **telephone and fax number and website; and**
- **email address, telephone number and position of the contact person.**

**2.1** The target business is Alcon, Inc. (**Alcon**). The contact details are:

Alcon, Inc.  
Bosch 69  
PO Box 62  
Hunenberg, 6331  
Switzerland  
Telephone/Fax: 41 41 785 88 88 / 41 41 785 88 87  
Web Site: <http://www.alconinc.com>

Contact Person:  
Peter Slover  
Managing Director Australia/Area Director New Zealand, Alcon  
Laboratories (Australia) Pty. Ltd  
Phone - +61.2.9452.9230  
Fax - +61.2.9453.7730

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

Howrey LLP  
1299 Pennsylvania Ave NW  
Washington, DC 20004-2402  
[www.howrey.com](http://www.howrey.com)

**Attention:** Charles M. Malaise  
Telephone: +1 202.383.7058  
Fax: +1 202.318.8478  
Email: [MalaiseC@howrey.com](mailto:MalaiseC@howrey.com)

**3. With respect to the merger parties, list the relevant companies and the person or persons controlling these directly or indirectly. Please use organisational charts or diagrams to show the structure of the ownership and control of the acquirer and participant(s) to the acquisition.**

**3.1** Please see the **attached** organisational chart for Novartis AG, and the list of subsidiaries and associated "partially held" or similar companies. The Novartis Group includes Novartis New Zealand Ltd, which operates the marketing, sales and distribution of Novartis' pharmaceutical, and animal health products. The Novartis Group also includes two other New Zealand divisions - "CIBA Vision" and "Novartis Consumer Health", which are operated from Australia, separately from Novartis New Zealand Limited.

**3.2** For Alcon, please see the **attached** organisational chart, which lists the various interconnected and subsidiary companies. There are three Alcon companies with sales in New Zealand. These are:

- (a) Alcon New Zealand Ltd;
- (b) Alcon Pharmaceuticals Ltd (Switzerland); and
- (c) Alcon Laboratories Inc. (US).

**3.3** Pharmaco NZ Ltd provides distribution and warehousing services for Alcon New Zealand Ltd in New Zealand.

**4. Provide details on what is to be acquired.**

**4.1** Alcon is a company listed on the New York Stock Exchange. Prior to April 2008, 77% of the shares in Alcon were held by Nestlé S.A (**Nestlé**), with the remainder held by smaller investors.

**4.2** On 6 April 2008, Novartis entered into a Purchase and Option Agreement (**POA**) with Nestlé concerning the purchase of shares in Alcon. According to the POA, there are two distinct transactions:

- (a) Novartis first acquired 24.85% of the shares in Alcon (the **Initial Purchase**) from Nestlé, which owned approximately 77% of the shares

in Alcon prior to completion of the Initial Purchase. After completion of the Initial Purchase in 2008, Nestlé retained a majority shareholding of approximately 52.15%.

(b) The parties also agreed on a call option (for the benefit of Novartis) and a put option (for the benefit of Nestlé) regarding the remaining approximately 52.15% of Alcon's shares owned by Nestlé. The options could be exercised between 1 January 2010 and 31 July 2011.

4.3 Novartis exercised its call option on 4 January 2010.

4.4 By this notice, clearance is sought for the acquisition of Nestlé's 52.15% shareholding in Alcon (**Proposed Acquisition**). Regulatory filings have been or will be made in a number of countries.

4.5 Following the completion of the Proposed Acquisition, Novartis will hold approximately 77% of the shares in Alcon. This notice does not relate to the remaining 23% shareholding in Alcon which is currently publicly held.

**5. Fully explain the commercial rationale for the proposed merger. Specify whether this is part of an international merger.**

5.1 This is part of an international merger.

5.2 Through the execution of the notified transaction, Novartis aims to enhance its global business activities in eye care. This is a dynamic and fast-growing sector in healthcare globally, driven by high unmet needs of an aging population, innovation and emerging markets such as Asia. Alcon offers a complementary range of products focusing on the treatment of eye diseases and conditions. In particular Novartis produces contact lenses, which Alcon does not, and Alcon produces intraocular lenses and ophthalmic surgical devices, which Novartis does not. Alcon is also expected to provide a platform for future growth in eye care through its differentiated R&D portfolio.

5.3 Combining the parties' product portfolios will allow the parties to offer more innovative products that will benefit New Zealand patients.

**6. Provide copies of the final or the most recent versions of any documents bringing about the proposed merger (e.g. contracts, sales and purchase agreements, or offer documents if it is a public bid).**

**6.1** Please find attached copies of the following documents:

- (a) Shareholders Agreement between Nestle S.A. and Novartis AG dated 6 April 2008;  
[www.sec.gov/Archives/edgar/data/1114448/000110465908045488/a08-18409\\_1ex2d2.htm](http://www.sec.gov/Archives/edgar/data/1114448/000110465908045488/a08-18409_1ex2d2.htm)
- (b) Purchase and Option Agreement between Nestle S.A. and Novartis AG dated 6 April 2008  
[www.sec.gov/Archives/edgar/data/1114448/000110465908045488/a08-18409\\_1ex2d1.htm](http://www.sec.gov/Archives/edgar/data/1114448/000110465908045488/a08-18409_1ex2d1.htm)
- (c) [ ]
- (d) [ ]
- (e) [ ]

**7. If any other jurisdiction’s competition agency has been (or will be) notified of the proposed merger, please list each competition agency notified (or to be notified) and the date of the notification.**

The parties are seeking approval from a number of competition agencies across a number of jurisdictions, as follows:

<b>Country</b>	<b>Date (or anticipated date of filing)</b>
Argentina	8 February 2010
Australia	[ ]
Brazil	22 January 2010
Canada	26 January 2010
China	[ ]
Colombia	[ ]
European Union	[ ]

Israel	17 March 2010
Japan	[ ]
Mexico	17 March 2010
Russia	18 March 2010
Singapore	31 March 2010
South Africa	[ ]
South Korea	[ ]
Taiwan	[ ]
Turkey	[ ]
Ukraine	19 March 2010
United States	15 January 2010

**7.1 Please indicate whether you would be willing to provide the Commission with a waiver allowing it to exchange confidential information with competition agencies in other jurisdictions in respect of the proposed merger.**

7.1 Novartis would prefer to consider a request for a waiver in more detail if (or when) such a request is made, and the Commission has advised Novartis of the particular agency or agencies with which it wishes to exchange confidential information.

## PART 2: THE INDUSTRY

8. Describe the relevant goods or services supplied by the merger parties (it is sufficient to refer in general terms to activities in which there will be no aggregation).

### General Information about Novartis

8.1 Novartis AG (**Novartis**) is the ultimate holding company of the multinational group of pharmaceutical companies that comprise the Novartis Group (also collectively referred to as **Novartis**).

8.2 Novartis is active in the development, production, distribution and marketing of medical products, including prescription medicines, over-the-counter (**OTC**) medicines, human vaccines and animal health products. Novartis operates in over 140 countries. Novartis's product portfolio spans the following areas:

(a) Pharmaceuticals: Novartis develops and markets patent-protected prescription drugs for important health needs. Novartis' products are concentrated in five major therapeutic areas: (i) cardiovascular and metabolism; (ii) oncology and haematology; (iii) neuroscience and ophthalmics; (iv) respiratory; and (v) immunology and infectious diseases. Novartis' current product portfolio comprises 45 key marketed products, and the product development pipeline involves about 140 projects in various stages of clinical development – including potential new products, as well as potential new indications or formulations for existing products.

(b) Vaccines and Diagnostics: Novartis' Vaccines and Diagnostics Division provides products to fight more than 20 vaccine-preventable viral and bacterial diseases, as well as sophisticated blood-testing equipment. Novartis' Vaccines division focuses on creating innovative products to prevent influenza, meningitis and other diseases. Novartis' blood testing business (which operates under the Chiron name), is dedicated to preventing the spread of infectious diseases through novel blood-screening tools.

(c) Sandoz Division: The Sandoz Division 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. The Sandoz Division has activities in Retail Generics, Anti-Infectives, Biopharmaceuticals and Oncology Injectables. In Retail Generics, Sandoz develops and manufactures active ingredients and finished dosage forms of pharmaceuticals to third parties. In Anti-Infectives, the division develops and manufactures active pharmaceutical ingredients and intermediates – mainly antibiotics – for use by Retail Generics and for sale to third party customers. In Biopharmaceuticals, Sandoz develops, manufactures, distributes and sells protein or biotechnology based products (known as biosimilars or follow-on biologics) and sells biotech manufacturing services to other companies. In Oncology Injectables, Sandoz develops, manufactures, distributes and sells cytotoxic products for the hospital market. Sandoz offers approximately 1,000 compounds in more than 130 countries.

(d) Consumer Health Divisions: The Consumer Health Division researches, develops, manufactures and markets a wide range of products that restore, maintain or improve the health and well-being of consumers, as well as pets and livestock. The division consists of three business units:

- OTC (over-the-counter medicines) offers products for the treatment and prevention of common medical conditions and ailments to enhance people's overall health and well-being.
- Animal Health offers products and services to save, prolong and improve animal lives, focusing on both companion and farm animals (including cultivated fish).
- CIBA Vision researches, develops, manufactures and markets contact lenses and lens care products.

**8.3** For further information, we refer to the most recent annual report of Novartis, which can be found on the internet at [www.novartis.com](http://www.novartis.com).

## General Information about Alcon

- 8.4** Alcon is a research and development driven, global medical specialty company focused on eye care. Alcon develops, manufactures and markets pharmaceuticals, surgical equipment devices and consumer eye care products to treat diseases and disorders of the eye in more than 180 countries. Alcon conducts its business from offices located in 75 countries around the world in regions including Canada, the Far East, Europe, the Middle East and Africa, Latin America and the Caribbean, and the United States. Alcon has nearly 15,000 employees worldwide.
- 8.5** Alcon's businesses are conducted through two business segments: Alcon United States and Alcon International. Both business segments market and sell products principally in three product categories of the ophthalmic market:
- (a) Pharmaceutical: Alcon continues to advance treatments for numerous eye diseases. The principal pharmaceutical products include glaucoma products; anti-infectives, anti-inflammatories and combination therapies; and ocular allergy products. Alcon also offers otic products (anti-infective/anti-inflammatory products for ear infection); and generic ophthalmic and otic pharmaceutical products.
  - (b) Surgical equipment: Alcon manufactures and markets ophthalmic surgical products for use in all ocular surgical procedures, including cataract surgery, vitreoretinal surgery, and refractive surgery.
  - (c) Consumer Vision Care: Alcon continues to produce innovative products to meet the eye care needs of consumers globally. Alcon's "Our consumer vision care" product line includes contact lens care products such as contact lens solutions, as well as a full line of artificial tears, allergy eye drops and ocular dietary supplements.
- 8.6** For further information we refer to the most recent annual report of Alcon which can be found on the internet at [www.alcon.com](http://www.alcon.com).



**9. Describe the industry or industries affected by the proposed acquisition. Where relevant, describe how sales are made, the supply chain(s) of any product(s) or service(s) involved, and the manufacturing process. If relevant, provide a glossary of terms and acronyms.**

**9.1** Eye care is a dynamic and fast-growing sector in healthcare globally, driven by high unmet needs of an aging population, innovation and emerging markets such as Asia.

**9.2** In New Zealand both Novartis and Alcon manufacture their products overseas and import products through their parent or other related companies. There are some generic drugs manufactured in New Zealand (for example by Douglas Pharmaceuticals) and these may be exported, but generally most pharmaceutical products are imported into New Zealand.

**9.3** Both Novartis and Alcon and their competitors generally sell products to pharmaceutical and other wholesalers. About 95% of Novartis' pharmaceutical sales in New Zealand are to wholesalers. Wholesalers then supply either hospitals or pharmacies. Novartis has some limited sales directly to certain District Health Boards, very limited sales directly to pharmacies, and limited sales to targeted pharmacy distribution centres. For OTC products, products also get ranged in retail pharmacies with negotiated discounts.

**9.4** Novartis' CIBA Vision division sells its products solely through optometry channels – that is, through opticians and optometrists. In the categories in which CIBA Vision operates, these sales only account for a small portion of the overall category. CIBA Vision's competitors sell their products through pharmacy and/or grocery channels, as well as through optometry.

**9.5** Neither Novartis nor Alcon sell products directly to end users.

**9.6** The price of reimbursed prescription-based pharmaceutical products is generally set by the government funding agency, Pharmac. The government sets the budget and Pharmac controls the portion of it related to medicines. The government then reimburses pharmacists for the ex-manufacture costs of the drug, plus a controlled wholesaler mark-up (usually about 10%) and sometimes for the pharmacists' dispensing fees. This means that companies are generally constrained in the prices that they set. Pharmac also sets the "H-Schedule",

which lists the national procurement prices for products used in hospitals, to ensure DHBs across the country pay the same prices.

**10. Describe the current industry trends and developments including the role of imports and exports, emerging technologies, and/or changes in supply and demand dynamics.**

**10.1** There is an ageing population, which means that the demand for eye care products will likely increase. Many of the products in the categories identified are OTC products, where barriers to entry are low and competition is fierce. However, because prescription medicines are tightly controlled by Pharmac, prescription-based pharmaceutical products are typically low growth markets.

**10.2** As mentioned above, both Novartis and Alcon manufacture their products overseas and import products through their parent or other related companies. There are some generic drugs manufactured here (for example by Douglas Pharmaceuticals) and these may be exported, but generally most pharmaceutical products are imported into New Zealand.

**10.3** Novartis and Alcon are also involved in the development of a number of pipeline products which are not yet on the market. Some of these pipeline products are ophthalmological. In terms of the relevant categories referred to in this application, Alcon currently has pipeline products for the [ ] categories, and Novartis has pipeline products for the [ ] categories.

**11. Please highlight any relevant mergers that have occurred in this industry over the past three years.**

**11.1** Within the last three years there have been three global mergers within the wider industry, which have also affected New Zealand. These are:

- (a) Pfizer Inc and Wyeth Corp;
- (b) Schering-Plough Corporation and Merck & Co., Inc; and
- (c) Schering-Plough Corporation and Organon BioSciences N.V.

**11.2** In all of these cases, the parties applied for clearance in New Zealand and the Commission's decisions granting clearance are Decisions 678, 677 and 621.

**11.3** None of these mergers affected the categories identified for the purpose of this application. Nor did any of these mergers include the current parties to this application.

## PART 3: MARKET DEFINITION

### HORIZONTAL AGGREGATION

12. For each area of aggregation of market shares, please define the relevant market(s) for the:
- product(s) or service(s);
  - functional level;
  - geographic area; and
  - customer dimension and timeframe (if relevant).

### Market definition in the Pharmaceutical Industry

#### *ATC3 level*

12.1 Products can be broken down into therapeutic classes according to the Anatomical Therapeutic Classification (**the ATC Classification**) devised by the European Pharmaceutical Marketing Research Association (**EphMRA**). The ATC Classification is hierarchical and includes 16 categories with each having up to four levels.<sup>1</sup>

12.2 The Commerce Commission has accepted the ATC3 level as a starting point for market definition in pharmaceutical cases in New Zealand. In *Schering-Plough Corporation v Organon Biosciences N.V.* (Decision 621, 4 October 2007)<sup>2</sup> the Commerce Commission stated at paragraphs 94 and following:

"In previous decisions, the Commission has, in defining human health markets, referred to the "Anatomical Therapeutic Chemical" (ATC) classification system, which subdivides medicines into different therapeutic classes. ...

The ATC classification was used by the Commission as a starting point for the definition of markets in Decision 398 and 496. However, in the former, the Commission noted that "there may be instances where broader or narrower classifications are necessary, dependent upon the particular circumstances of the pharmaceuticals and the condition requiring treatment".

...

<sup>1</sup> <http://www.ephmra.org/PDF/ATC%20Guidelines%202009.pdf>

<sup>2</sup> See also *Reckitt Benckiser Plc v Boots Healthcare International Ltd* (Decision 567, 30 November 2005), *Pfizer Laboratories Ltd v Pharmacia Ltd* (Decision 496, 3 April 2003) and *Glaxo Wellcome Plc v SmithKline Beecham Plc* (Decision 398, 1 September 2000).

... The third level (ATC3) allows medicines to be grouped in terms of their therapeutic indications (their intended use), and can therefore be useful in defining markets on the demand-side. These groups of products generally have the same therapeutic indication and cannot be substituted for products belonging to other ATC3 classes."

- 12.3** The European Commission has also relied in previous decisions on the third level of the ATC classification (**ATC3**)<sup>3</sup> which groups medicines by therapeutic indication (i.e. their intended use) as a starting point to define the relevant product market.
- 12.4** The European Commission does, however, recognise that, in certain cases, it may be necessary to analyse pharmaceutical products at a higher or lower ATC level. An example of a situation where a higher ATC level might be appropriate is where products from different ATC classes are substitutes for the treatment of the same illness or disease. On the other hand, a lower ATC level, resulting in a narrower market definition, might be appropriate where the medicines in question have differing indications.
- 12.5** For this reason, we have provided information about the parties' products below in respect of their ATC3 classification (with the exception of the S1E category, where we have provided information on potentially narrower sub-categories), and only in areas where there is (or may be) potential overlap between the products of Novartis and Alcon.

*Prescribed (Rx) /Non-Prescribed (OTC)*

- 12.6** Pharmaceutical products may also be subdivided on the basis of demand-related criteria. A possible distinction is that between pharmaceutical products which can be issued only on prescription (**Rx products**) and those which can be sold over the counter (**OTC products**).
- 12.7** The European Commission has, in previous decisions,<sup>4</sup> defined separate product markets for OTC and Rx products based on the fact that medical indications (as well as side effects), legal framework, marketing and distributing tend to differ between the two categories. The present transaction concerns both OTC and Rx products.

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<sup>3</sup> See Case COMP/M.3544 - Bayer Healthcare/Roche, at paras 12 *et seq*; Case COMP/M.3354 – Sanofi-Synthelabo/Aventis, at paras 14 *et seq*; and Case COMP/M.2922 – Pfizer/Pharmacia, at paras 15 *et seq*.

<sup>4</sup> See Case COMP/M.3544 – Bayer Healthcare/Roche; and Case COMP/M.3394 – Johnson & Johnson/Johnson & Johnson MSD Europe, at paras 14-15.

### *Originator Medicines/ Generics*

- 12.8** Generics are in general less expensive copies of the originator drugs. In regulatory approval procedures, a generic drug manufacturer has to demonstrate that the generic version of the originator drug has identical quality and purity and is biologically equivalent to the originator drug.
- 12.9** In previous decisions, the European Commission has concluded that originator and generic drugs form part of the same product markets for any given indication.<sup>5</sup> We believe this is appropriate in the present case.

### *Pipeline products*

- 12.10** Novartis and Alcon are also involved in the development of a number of pipeline products which are not yet on the market but are in various stages of development. Where there are pipeline products for the relevant markets they are identified below.

### **Product level**

- 12.11** As discussed above, we have provided information on the basis of the ATC3 classification in New Zealand (with the exception of the S1E classification, where there are potential sub-categories). The following are the ATC3 categories where there will be some aggregation in New Zealand post-acquisition between Novartis and Alcon.

#### ***S1E – Miotics and Anti-glaucoma preparations***

- 12.12** The ATC3 classification here comprises miotics and antiglaucoma preparations.
- 12.13** Indication: Anti-Glaucoma preparations aim to reduce intraocular pressure (IOP) to treat glaucoma. Miotics are mainly used in the context of cataract surgery to induce miosis before surgical intervention.
- 12.14** Mechanism of use: antiglaucoma - variety of modes of action including prostaglandin derivatives and prostamides, beta-blockers, alpha2-adrenergic

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<sup>5</sup> See, for example, Case COMP/M.3751 – Novartis/Hexal, at para 3.

agonists, certain miotic agents and carbonic anhydrase inhibitors. For miotics, the most used miotic in surgery is acetylcholine hydroxide.

12.15 OTC/Rx: Rx.

12.16 Novartis material products: Miotics: Miochol-E. Anti-glaucoma: none

12.17 Alcon material products: Miotics: Miostat, Isopto Carpine, Isopto Carbachol; Anti-glaucoma: Travatan, Betoptic, Iopidine UD, Azopt.

12.18 Pipeline products: Novartis: [ ]

Alcon: [ ].

### ***S1G – ocular anti-allergies, decongestants and antiseptics***

12.19 The ATC3 classification for "ocular anti-allergics, decongestants and antiseptics" is S1G.

12.20 Indication: These products are eye drops that principally treat eye allergies, such as hayfever and seasonal or perennial allergic conjunctivitis. Eye allergies occur when a foreign substance, known as an allergen, enters the eye. The body's immune system reacts to the allergen by releasing histamine from mast cells. Histamine causes eye redness, as well as itching and swelling. S1G products treat these symptoms and certain products treat the underlying cause of the symptoms.

12.21 Mechanism of Action: Antihistamines relieve eye itching, decongestants reduce eye redness, mast cell stabilisers reduce eye swelling (and as a result eye redness) and multiple action products relieve all of these symptoms by acting as a mast cell stabilising antihistamine.

12.22 OTC/Rx: OTC and Rx.

12.23 Novartis material products: Zaditen.

12.24 Alcon material products: Patanol Naphcon-A, Naphcon Forte, Zincfrin, Lomide.

12.25 Pipeline Products: Novartis: [ ]

Alcon: [ ]

***S1K Artificial tears / dry eye***

12.26 The ATC3 classification for artificial tears is S1K which includes "artificial tears and ocular lubricants".

12.27 Indication: artificial tears are ophthalmic preparations (solutions or ointments) used for the relief of dry eyes (xerophthalmia) and ocular irritation.

12.28 Mechanism of Action: the surface active properties of the vehicles found in artificial tears solutions act to stabilise the tear film and increase tear viscosity to prevent tear evaporation and retard tear drainage.

12.29 OTC/Rx: All OTC.

12.30 Novartis material products: Genteal, Viscotears,

12.31 Alcon material products: Systane, Polytears, Bion Tears, Poly-visc, Poly Gel, Enuclene, Tears Naturale,

12.32 Pipeline Products: Novartis [ ].

Alcon: [ ]

***S1L - Contact lens solutions***

12.33 The ATC3 classification for contact lens solutions is S1L, which includes preparations for use with contact lenses.

12.34 Indication: (MPS and hydrogen peroxide cleaning systems): cleansing, disinfecting, rinsing protein removal, and storage of contact lenses.

12.35 Mechanism of Action:

- (a) Multi-Purpose Solutions (**MPS**): sterile aqueous solution cleans by loosening and removing accumulations of protein and other deposits and



debris from lenses and continues to clean lenses during disinfection and storage, destroys harmful micro-organisms, used to rinse and store soft contact lenses, conditions the lens surface with a layer of moisture;

- (b) Hydrogen peroxide cleaning systems (**HP**): sterile solution containing micro-filtered hydrogen peroxide cleans, disinfects, neutralizes and removes protein from lenses.

**12.36** OTC/Rx: OTC

**12.37** Novartis material products: Aosept Plus (HP), Aquify MPS (MPS).

**12.38** Alcon material products: Opti-Free replenish (MPS), Opti-Free Express (MPS), Polyclens 2 (MPS), Soalens (MPS).

**12.39** Pipeline products: Novartis: [ ];

Alcon: [ ].

Novartis also understands that Johnson & Johnson has a "major program underway" in contact lens solutions.

### ***S1T Ophthalmological Diagnostic Agents***

**12.40** The ATC3 classification for ophthalmological diagnostic agents is SIT.

**12.41** Indication: ocular diagnostic agent, used particularly in relation to the diagnosis of wet age-related macular degeneration (AMD).

**12.42** Mechanism of Action: the active ingredient in these products is Fluorescein, which is administered either by injection or by eye drops. Both Novartis' and Alcon's products are administered by injection.

**12.43** OTC/Rx: Rx

**12.44** Novartis material products: Fluorescein (discontinued in 2009).

**12.45** Alcon material products: Fluorescite.

- 12.46 Pipeline products: Novartis: [ ]  
Alcon: [ ]

### **Functional Level**

- 12.47 Novartis considers the relevant functional level in New Zealand to be manufacture, import and wholesale supply.
- 12.48 All of the parties' products supplied in New Zealand are manufactured overseas and imported into New Zealand (subject to regulatory approval from Medsafe). They are sold to wholesale and speciality distributors, hospitals, retail and specialty pharmacists, medical clinics and optometrists. There is some local manufacture of generic pharmaceuticals, including products in the affected categories.
- 12.49 Neither Novartis nor Alcon sell directly to end users in New Zealand.
- 12.50 In Decision 594 (*Johnson & Johnson / Pfizer*) the Commission accepted that the relevant functional dimension in that case was the import and wholesale supply of the various products in question (paragraphs 75-77).

### **Geographic Area**

- 12.51 In New Zealand, the Commerce Commission has held that the relevant geographic market for pharmaceutical products is national in scope. See for example *Johnson & Johnson / Pfizer Consumer Healthcare* (Decision 594, 8 December 2006) at paragraph 74, *Reckitt Benckiser Plc / Boots Healthcare International Ltd* (Decision 567, 30 November 2005) at paragraph 64, *Pfizer Laboratories Ltd / Pharmacia Ltd* (Decision 496, 3 April 2003) at paragraph 85 and *Glaxo Wellcome Plc / SmithKline Beecham Plc* (Decision 398, 1 September 2000) at paragraph 69.
- 12.52 Novartis and Alcon distribute their products nationally, and prices are set on a national basis. Therefore, in accordance with previous Commission decisions, Novartis considers the markets to be national in geographic scope.

### **Customer Dimension and timeframe**

**12.53** Not relevant.

### **Summary**

**12.54** In summary, Novartis submits that the categories for the purpose of this clearance application where aggregation issues arise post-acquisition are:

- (a) the manufacture, import and wholesale supply of miotics and antiglaucoma preparations (S1E), or potentially the S1E sub-category for miotics for use in cataract surgery in New Zealand;
- (b) the manufacture, import and wholesale supply of ocular anti-allergies, decongestants and antiseptics (S1G) in New Zealand;
- (c) the manufacture, import and wholesale supply of artificial tears (S1K) in New Zealand; and
- (d) the manufacture, import and wholesale supply of preparations for use with contact lenses (S1L).

**12.55** While aggregation issues previously arose in New Zealand for the manufacture, import and wholesale supply of ophthalmological diagnostic agents (S1T), as noted above Novartis has discontinued its product in this category and has no plans to re-enter. Hence there is no overlap between the products of Novartis and Alcon in this category, and we do not propose to deal with it further below.

**13. Where relevant, please explain how products or services are differentiated within the market(s).**

We deal with each of the above categories in turn below.

### **S1E Miotics and Antiglaucoma Preparations**

**13.1** While they are within the same ATC3 category, miotics for use in cataract surgery and anti-glaucoma products have substantially different indications. Miotics used for cataract surgery are used to induce miosis before the surgical intervention.

Anti-glaucoma preparations aim to reduce intraocular pressure (**IOP**) to treat glaucoma.

**13.2** Miotics are products such as drops that are designed for use in cataract surgery that cause the constriction of the eye's pupil after delivery of the lens. The most commonly used miotic in cataract surgery is acetylcholine hydroxide, with other miotics used including carbachol and pilocarpine. Novartis' product, Miochol E, is based on acetylcholine hydroxide and Alcon's product, Miostat, is based on carbachol. A patient's treating physician will determine which miotics product is to be used during surgery. Miosis is induced in seconds with Miochol-E, whereas it takes two to five minutes with Miostat. Due to the corrosive nature of Miochol-E, it is sold in a blister pack containing one vial and one ampoule, which means that some physicians prefer Miostat. However, because Miochol-E works faster, some physicians favour speed over convenience.

**13.3** Anti-glaucoma products are used to lower intraocular pressure damaging the optic nerve. They have a variety of modes of action including certain miotics, prostaglandin derivatives and prostamides, topical beta-adrenergic receptor antagonists (beta-blockers), alpha2-adrenergic agonists, sympathomimetics, and carbonic anhydrase inhibitors. Different therapeutical strategies can be used as first choice treatments (i.e. preferred treatments) by physicians in order to reduce IOP levels. First choice products include alpha2-adrenergic agonists, beta-blockers, carbonic anhydrase inhibitors, prostaglandin derivatives and prostamides. Treatment should always start by monotherapy; where the target IOP level cannot be reached through the selected monotherapy, physicians can switch to other first-choice monotherapy products or, alternatively, prescribe combinations of products. However, while different types of anti-glaucoma products with different modes of action are often used to treat the disease at different stages, these products have similar methods of action and indication and as such are considered to be broadly substitutable.

### **S1G Ocular Anti-allergies, Decongestants and Antiseptics**

**13.4** The key types of medication manufactured and sold in this category include ocular anti-allergics, decongestants and antiseptics for the treatment of allergic conjunctivitis. These products mainly treat ocular allergies and, in particular,

allergic conjunctivitis. There are several types of conjunctivitis, including milder seasonal or perennial allergic conjunctivitis (which can cause eye redness and itching) and several forms such as vernal keratoconjunctivitis and giant papillary conjunctivitis. Alcon and Novartis overlap only in the supply of products to manage or treat allergic conjunctivitis. There are both OTC and prescription products which are sold in New Zealand.

- 13.5** While the products sold in this category may have different formulations, modes of action and administration, they all have similar indications: relief of itching, swelling and/or redness caused by allergic conjunctivitis. As such Novartis considers them to be broadly substitutable in New Zealand and it is appropriate to consider this category at the ATC3 level.

### **S1K Artificial Tears**

- 13.6** This group of products is used for ophthalmic preparations (artificial tears) which come in the form of liquid drops, gels and ointments (in order of increasing viscosity) and are used for the relief of dry eyes and ocular irritation.
- 13.7** Artificial tear products contain varying formulations that maintain ocular tonicity. Artificial tear solutions usually consist of a vehicle to stabilize the tear film and promote wetting, although the buffering agents, preservatives, pH content and other factors may vary from product to product.
- 13.8** The surface active properties of the vehicles found in artificial tears solutions act to stabilise the tear film and increase tear viscosity to prevent tear evaporation and retard tear drainage. Agents tend to mimic the action of mucin, the inner tear film layer that promotes the wetting and adhesion of tears to the ocular surface.
- 13.9** Hydrogels (demulcents) are the viscosity enhancing ingredient of artificial tears. The following hydrogels have been used in artificial tears: Hydroxypropyl Methylcellulose (HPMC), Carboxy Methylcellulose (CMC), Polyvinyl Alcohol (PVA), Carbopol, polyvinyl pyrrolidone, polyethylene glycol, dextran, hyaluronic acid, or carbomer 940 (polyacrylic acid).
- 13.10** Artificial tears may also contain glycerine, magnesium chloride, and zinc chloride, all of which are found in natural tears. Sodium borate, a mild antiseptic, and other desirable ingredients may also be included.

**13.11** While the products sold within this group have different methods of administration, formulations and modes of action, they are each used to provide symptomatic short-term relief for dry eyes and other ocular irritations. Although consumers may take account of the active ingredient (which affects viscosity), whether preservatives are included, and suitability for use with contact lenses when making their purchasing decision, the products have similar indications and compete largely on price. On this basis, Novartis considers the products to be broadly substitutable.

## **S1L Contact Lens Solutions**

**13.12** This principally comprises products used for cleaning, disinfecting, and protein removal on contact lenses. Other contact lens care products include storage products for contact lenses and re-wetting drops for use specifically with contact lenses. The two main types of lens cleaning solution products sold to customers are:

- (a) multipurpose cleaning solutions (**MPS**), which are a sterile aqueous solution which immediately cleans the lens by loosening and removing accumulations of protein and other deposits and debris and continues to clean lenses during disinfection and storage. The solution also destroys harmful microorganisms, and is used to rinse and store soft contact lenses, and conditions the lens surface with a layer of moisture. Contact lenses may be worn immediately after using the MPS;
- (b) hydrogen peroxide cleaning systems, which use a sterile preservative-free solution containing micro-filtered hydrogen peroxide to clean, disinfect and remove protein from contact lenses; the hydrogen peroxide is then neutralized by a catalyst. This solution takes around six hours to neutralise to provide a hydrogen peroxide-free interface when inserted into the eye and is considered to provide contact lenses with a more effective and thorough cleanse.

**13.13** The parties have largely complementary product portfolios in this area, with Alcon principally selling MPS for contact lenses. Alcon does not market a hydrogen peroxide cleaning system. Novartis (through its subsidiary Ciba Vision) principally sells a hydrogen peroxide cleaning system and has small sales of an MPS product.

**13.14** The category is price sensitive, with lower levels of customer brand loyalty present. There is some difference in price, as well as inconvenience and sensitivity, between MPS and hydrogen peroxide cleaning system products. MPS products in particular are considered to be highly substitutable, with customers regularly switching between different brands of MPS.

## **VERTICAL INTEGRATION**

**14. Provide details of any creation or strengthening of vertical integration that would result from the proposed merger. Please use organisational charts or diagrams to illustrate the structure of the ownership and/or control of the participants and the vertical relationships in question.**

**14.1** The proposed transaction will not result in vertical integration in the markets identified.



## PART 4: COUNTERFACTUAL

**15. In the event that the proposed merger does not take place, describe what is likely to happen to the business operations of the merger parties and the market/industry.**

**15.1** If the merger did not take place, a counterfactual is likely to be the status quo, that is, that Novartis and Alcon would continue running their respective operations. However, that counterfactual would deprive the parties of the opportunity to combine the best of their respective capabilities and achieve greater efficiencies to enable Novartis to enhance its ability to meet demand relating to increasing vision care needs of an ageing population (as expanded on below).

## PART 5: COMPETITION ANALYSIS

### EXISTING COMPETITORS

**16. Identify all of the relevant competitors in the market(s), including near competitors and importers in the market(s), and describe how they all compete in the market(s).**

**16.1** Please see the table in response to question 17 below setting out competitors and market shares. All the relevant competitors for each market are listed in this table. The contact details for these competitors are included in the response to question 29 below.

**16.2** Major competitors in the relevant markets include:

**Allergan, Inc.**

**16.3** Founded in 1950, Allergan, Inc., with headquarters in California, USA, is a global technology-driven multi-specialty health care company that discovers, develops and commercializes innovative pharmaceuticals, biologics and medical devices. Allergan has leading portfolios in eye care, neurosciences, medical dermatology, medical aesthetics, obesity intervention and urologics. It also has a strong focus on Research and Development (**R & D**), employing more than 50 percent of its global work force in either R & D or sales. Allergan employs more than 8,000 people worldwide and has a presence in more than 100 countries. It has been listed on the New York Stock Exchange since 1989.

**16.4** Allergan competes primarily with Alcon and Novartis in its eye care pharmaceutical product offerings. Allergan's Eye Pharmaceutical products treat a variety of eye conditions including glaucoma, dry eye, and external eye diseases. Leading products in Allergan's eye care product portfolio include eye drops for glaucoma, OPTIVE® Lubricant Eye Drops, and the REFRESH® range of artificial tears. Allergan also has a range of other specialty pharmaceutical products including urologics, Botox and Skin care products, as well as medical devices including breast aesthetics and obesity intervention devices such as Lap Bands for use during surgery. In the last reported financial year ending 31 December 2009, Allergan reported global total revenues of US\$503.6 million.

- 16.5** Allergan currently employs over 130 people in Australia/New Zealand and is continuously growing in size to support the growth of demand for its products in the market.
- 16.6** For more information on Allergan, please see [www.allergan.com](http://www.allergan.com).

### **Pfizer**

- 16.7** Founded in 1849, with global headquarters in New York, USA, Pfizer is a diversified health care company, with product offerings in human, animal, and consumer health, including vaccines, biologics, small molecules and nutrition across the developed and emerging markets. It has medicines in numerous growing therapeutic areas, a robust pipeline, premier scientific and manufacturing capabilities and a leading global presence. Pfizer also collaborates with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. Pfizer is currently listed on the New York Stock Exchange, the London Stock Exchange, the Swiss Stock Exchange and Euronext. Pfizer has nine diverse health care businesses: Primary Care, Specialty Care, Oncology, Emerging Markets, Established Products, Consumer Healthcare, Nutrition, Animal Health and Capsugel.
- 16.8** In the last reported financial year ending 31 December 2009, Pfizer reported global total revenues of US\$50,009 million.
- 16.9** For more information on Pfizer, please see [www.pfizer.com](http://www.pfizer.com).

### **Bausch & Lomb**

- 16.10** Founded in Rochester, New York in 1853, Bausch & Lomb is currently the largest global provider of eye care products. With nearly 14,000 employees worldwide, Bausch & Lomb's products are currently available in more than 100 countries. Bausch + Lomb manages its commercial operations on a regional basis, and the research and development and product supply functions are managed on a global basis. Bausch & Lomb has been listed on the New York Stock Exchange since 1958. Bausch & Lomb has three product categories: Vision Care, Pharmaceuticals and Surgical. Its core businesses include contact lenses and lens care products, and ophthalmic surgical and pharmaceutical products. Bausch & Lomb is highly regarded for its innovation, being the first company to introduce soft contact lenses to the world in 1971.

**16.11** For more information on Bausch & Lomb, please see [www.bausch.com](http://www.bausch.com).

### **Johnson & Johnson**

**16.12** Founded in 1886, with global headquarters in New Jersey, USA, Johnson & Johnson engages approximately 117,000 employees worldwide in the R & D, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson has sales in three primary business segments: consumer health care; pharmaceuticals; and medical devices and diagnostics. Johnson & Johnson has more than 250 operating companies in 57 countries worldwide. It was listed on the New York Stock Exchange in 1944. In 2009, Johnson & Johnson's global sales were US\$61,987 million, while its total investment in R & D was US\$6,986 million.

**16.13** For more information on Johnson & Johnson, please see [www.jnj.com](http://www.jnj.com).

### **Aspen**

**16.14** Aspen Pharmacare Holdings Limited (Aspen) is the largest listed pharmaceutical company in South Africa and a major supplier of branded and generic pharmaceutical, healthcare and nutritional products to the southern African and selected international markets. Aspen has businesses in South Africa, Australia, India, Brazil, Mexico, Venezuela, Kenya, Tanzania, Uganda, Mauritius and the United Kingdom and exports to many other territories across the globe. Aspen is the largest generics manufacturer in the southern hemisphere and is also the leading supplier of generic medicines to both the private and the public sectors in South Africa. Aspen is currently listed on the Johannesburg Stock Exchange and has a market capitalisation in excess of A\$2.5 billion.

**16.15** For more information about Aspen, please see [www.aspenpharma.com](http://www.aspenpharma.com).

**17. Outline the estimated market shares in terms of sales, and, where relevant, volume and productive capacity, of the merger parties and competitors identified above. Please include:**

**17.1 the estimated total value of the domestic market; and**

**17.2 the source of the data provided.**

**17.1** The information provided in the tables below is sourced from IMS Health, an external market research company which gathers data on pharmaceutical products. The tables below contain IMS data for New Zealand for each of the relevant four categories identified (S1T is excluded as Novartis no longer sells into this category as noted above). The tables below list revenue and share information for 2009 for each of the participants in the relevant categories. (Novartis has the IMS data for 2007 and 2008, which it can provide to the Commission if that will assist.) We note that no volume information has been provided, as volume data for all market participants is not available.

**17.2** The IMS data only captures sales through pharmacies and wholesalers. It does not capture, for example, sales through the grocery and optometry channels. The optometry channel is the only channel through which CIBA Vision (a division of Novartis) distributes its products.

**17.3** While product sales through the grocery and optometry channels are much less substantial on the whole, the IMS data may none-the-less not be materially complete for some of the relevant product categories, especially the S1K and S1L categories where the majority of Novartis' sales are through the optometry channel and therefore not recorded by IMS. As such, for those categories the IMS data is better used as a general guide only. However, where possible we have checked the IMS data against the parties' internal estimates for accuracy and clearly noted where the data should be given less weight in the submission. Moreover, the IMS data remains the best source of data available to analyse the various categories.

**S1E (Miotics + antiglaucoma preparations) category**

RANK	COMPETITORS (INCLUDING MERGER PARTIES)	ESTIMATED REVENUE	ESTIMATED % OF CATEGORY SHARE BY REVENUE
<b>Combined Novartis/Alcon</b>			[ ]
1	Pfizer	US\$[ ]	[ ]
2	Allergan	US\$[ ]	[ ]
3	Merck & Co	US\$[ ]	[ ]
4	Alcon	US\$[ ]	[ ]
5	Aft Pharmaceutica l	US\$[ ]	[ ]
6	Apotex	US\$[ ]	[ ]
7	Sigma Pharmaceutica l	US\$[ ]	[ ]
8	Novartis	US\$[ ]	[ ]

**17.4** As noted above, there are potentially separate sub-categories within the S1E category between anti-glaucoma products and miotics for use in cataract surgery. If the IMS figures are broken down in this way, then no issues are raised for anti-glaucoma preparations as Novartis does not supply into this category. However in miotics for cataract surgery, the figures would be as follows:

*Sub-category – S1E -Miotics for use in Cataract Surgery*

RANK	COMPETITORS (INCLUDING MERGER PARTIES)	ESTIMATED REVENUE	ESTIMATED % OF CATEGORY SHARE BY REVENUE
<b>Combined Novartis/Alcon</b>			[ ]
1	Novartis	US\$[ ]	[ ]
2	Sigma Pharmaceutica l	US\$[ ]	[ ]

4	Alcon	US\$[ ]	[ ]
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**S1G (Conjunctivitis) category**

RANK	COMPETITORS (INCLUDING MERGER PARTIES)	ESTIMATED REVENUE	ESTIMATED % OF CATEGORY SHARE BY REVENUE
<b>Combined Novartis/Alcon</b>			[ ]
1	Aspen	US\$[ ]	[ ]
2	Bausch & Lomb	US\$[ ]	[ ]
3	Alcon	US\$[ ]	[ ]
4	Johnson & Johnson	US\$[ ]	[ ]
5	Aft Pharmaceuticals	US\$[ ]	[ ]
6	Allergan	US\$[ ]	[ ]
7	Reckitt Benckiser	US\$[ ]	[ ]
8	Novartis	US\$[ ]	[ ]
9	Sanofi-Aventis	US\$[ ]	[ ]

**S1K (Artificial Tears) category**

RANK	COMPETITORS (INCLUDING MERGER PARTIES)	ESTIMATED REVENUE	ESTIMATED % OF CATEGORY SHARE BY REVENUE
<b>Combined Novartis/Alcon</b>			[ ]
1	Allergan	US\$[ ]	[ ]
2	Alcon	US\$[ ]	[ ]
3	Novartis (NB does not)	US\$[ ]	[ ]

	include CIBA Vision)		
4	Aft Pharmaceutica l	US\$[ ]	[ ]
5	Corneal Lens Ltd	US\$[ ]	[ ]
6	Sigma Pharmaceutica l	US\$[ ]	[ ]
7	Bausch & Lomb	US\$[ ]	[ ]
8	US Medical	US\$[ ]	[ ]

**S1L (Preparations for use with Contact Lenses) category**

RANK	COMPETITORS (INCLUDING MERGER PARTIES)	ESTIMATED REVENUE	ESTIMATED % OF CATEGORY SHARE BY REVENUE
<b>Combined Novartis/Alcon</b>			[ ]
1	Bausch & Lomb	US\$[ ]	[ ]
2	Abbott Medical Optics	US\$[ ]	[ ]
3	Alcon	US\$[ ]	[ ]
4	Indpt Optical	US\$[ ]	[ ]
5	Allergan	US\$[ ]	[ ]
6	AFT Pharmaceutica l	US\$[ ]	[ ]
7	Toomac Medical	US\$[ ]	[ ]
	Novartis (NB does not include CIBA Vision)	-	0



**17.5** In summary, there is aggregation in the four categories identified as a result of the acquisition. However in two categories, being the S1E and S1G categories, the combined shares post-acquisition are within the Commission's safe harbours at the ATC3 level.

**17.6** Expanding on this, the categories where share figures (based on IMS data) in the ATC3 categories will be within the Commission's safe harbours post-acquisition are:

(a) **S1E (miotics and antiglaucoma preparations):** This is on the basis that the CR3 post-acquisition in this category would be [ ]% (comprised of Allergan at [ ]%, Merck & Co at [ ]%, and Pfizer at [ ]%). The safe harbour threshold would therefore be 20%, and Novartis/Alcon post-acquisition would be within this at [ ]%. In any event, Novartis' share of this category is only 0.4% so the aggregation issues are minimal. That said, if the category is sub-divided further into miotics for cataract surgery then the acquisition would be outside the safe harbours with Novartis having [ ]% share and Alcon having [ ]% share. However, the total annual value of this miotics for cataract surgery category is only US\$[ ], Alcon's share of this segment of the category is small ([ ]%) and there remains a significant competitor in Sigma Pharmaceuticals with [ ]% share.

(b) **S1G (ocular anti-allergics, decongestants and antiseptics):** This is on the basis that the CR3 post-acquisition in this category would be [ ]% (comprised of Aspen at [ ]%, Bausch & Lomb at [ ]%, and Novartis/Alcon at [ ]%). While this is on the border of the 70% CR3 threshold for assessing the safe harbours, Novartis/Alcon at [ ]% would be within the safe harbours, whether the resulting threshold was 40% or 20%. In addition the aggregation issues are minimal as Novartis has only a [ ]% share of this category. For completeness, if the category is defined at the ATC4 level, the combined Novartis/Alcon entity will have 100% of the S1G3 ATC4 category (although there will not be aggregation in the other S1G ATC4 categories). However, for the reasons set out in response to question 13 above, Novartis believes that the products in the ATC3 categories are broadly substitutable.

**17.7** This leaves the S1K and S1L categories. We note the following in respect of these categories:

- (a) **S1K:** In the S1K category, Alcon's share is [ ]%, and Novartis' share is [ ]% (although this could be slightly higher because of CIBA Vision products, the sales of which are not captured in the IMS data). Aggregation will be limited because of Novartis' relatively small share and Novartis and Alcon will still be subject to competitive constraint from Allergan in particular, which would remain the largest player in the post-acquisition with [ ]% share. This is expanded on in the next section.
  
- (b) **S1L:** The IMS data does not show any aggregation for the S1L category, as it shows Alcon having a [ ]% share but Novartis having no sales in this category. However, CIBA Vision (a division of Novartis) does have some sales in this category (through the optometry channel). If the CIBA Vision products are included, there will be some limited aggregation. There is some data that suggests that, in regards to sales through the optometry channel only (i.e. not including Alcon's sales through pharmacies or grocery), CIBA Vision has approximately [ ]% of this channel. Novartis estimates that sales through the optometry channel are approximately 20% of total sales in the S1L category. Assuming this is correct, this would make CIBA Vision's share approximately [ ]% of the S1L category (i.e. 20% of [ ]%) although this is a very rough indication only. Much of even these limited CIBA Vision sales are for its hydrogen peroxide cleaning system product, rather than its MPS product. Alcon does not have a hydrogen peroxide cleaning system product. On this basis, aggregation as a result of the acquisition will be limited.

- 18. To what extent do you consider that the merged entity would be constrained in its actions by the conduct of existing competitors in the markets affected? Where relevant please include a full discussion and examples of:**
- 18.1 the ease with which customers may switch between suppliers, and, if so, how readily;**
- 18.2 any local or overseas firms that are not currently producing the product, or providing the service in the market, but could enter the market quickly (using essentially their existing productive capacity) in a response to an attempt by suppliers to raise prices or reduce output or quality (near competitors and importers); and**
- 18.3 the extent to which existing competitors, near competitors and importers could expand in the market, and any difficulties that they might face in doing so.**

**18.1** The pharmaceutical industry is characterized by rapid technological changes. Such rapid innovation ensures the market positions are volatile, and that the incumbents must compete vigorously in order to maintain their business.

**18.2** The majority of the products in the relevant categories for this transaction are OTC products which, given the nature of the categories, are price-sensitive. The price of prescription products (including products in the S1E and S1G categories) is tightly controlled by Pharmac. Pharmac has significant power as a buyer in the market for prescription products (as expanded on below).

**18.3** The extent to which competitors can expand into the various categories depends on the products involved, but it would be easy for existing competitors to increase their productive capacity and/or imports to New Zealand.

**18.4** The categories we are discussing contain a large number of multi-national pharmaceutical companies, which place competitive constraints on both Novartis and Alcon, and will continue to do so post-acquisition.

**18.5** Dealing with each category in turn we note the following:

**S1E (Miotics and anti-glaucoma preparation)**

- 18.6** In the wider S1E category, there will remain a number of significant competitors post acquisition including Pfizer ([ ]%), Allergan ([ ]%) and Merck & Co ([ ]%);
- 18.7** In the potential sub-category for miotics for use in cataract surgery, post acquisition Novartis/Alcon will have [ ]% share. Sigma Pharmaceuticals will continue to actively compete against the merged firm in this category post acquisition with [ ]% share.
- 18.8** There are at least two global companies who supply products into the sub-category for miotics for use in cataract surgery in Australia but do not participate in this category in New Zealand. They are Allergan and Bausch & Lomb. It would not be difficult for these companies to enter New Zealand with products already approved and sold by them in Australia, as they already have a presence in relation to other pharmaceutical categories in New Zealand. If a product is already approved in certain jurisdictions (generally the United States, Europe or Australia) Medsafe has an abridged approval process. It would therefore be cheaper and quicker to obtain approval for a product already approved in Australia.

#### **S1G (Ocular anti-allergics, decongestants and antiseptics)**

- 18.9** Novartis considers that the proposed acquisition is unlikely to have a significant impact on the extent and variety of product offerings available to customers in this category, especially in light of the high number of competitors and broadly substitutable products currently available for sale in this category.
- 18.10** Post acquisition, there will continue to be a number of substantial competitors in this category who compete actively with the merged firm, including Aspen (who will remain the category leader with [ ]% share), Bausch & Lomb ([ ]%) and Johnson & Johnson ([ ]%).
- 18.11** Barriers to entry in this category have also proven to be lower than for other pharmaceutical products due to the absence of registration requirements in this category.
- 18.12** There was recently new entry into the S1G category in Australia from Inova-Pharma, which introduced a product that competes with Alcon's Patanol product.

It would be relatively easy for Inova-Pharma to introduce its product into New Zealand.

### **S1K (Artificial tears and ocular lubricants)**

- 18.13** The products in this category are all OTC and generally price-sensitive. Post-acquisition Allergan, who currently has a [ ]% share, will remain the category leader. There will also remain a large number of other competitors, including Aft Pharmaceuticals and the international supplier Bausch & Lomb.
- 18.14** Barriers to entry in this category are lower than for other pharmaceutical product categories as artificial tear/dry eye products are considered to be a medical device, rather than a medical substance, and therefore subject to significantly lower registration barriers with Medsafe.
- 18.15** There are at least two global companies who supply products into the S1K category in Australia but do not participate in this category in New Zealand. They are Aspen and Johnson & Johnson. It would not be difficult for these companies to enter New Zealand with products already approved and sold in Australia.

### **S1L (Preparations for use with contact lenses)**

- 18.16** The products in this category are all sold OTC and purchased by customers through the pharmaceutical, grocery or optometry channels. This product category is considered by the parties to be price sensitive, with lower levels of customer brand loyalty present, particularly in relation to MPS due to the high substitutability of MPS products.
- 18.17** At the ATC3 level, based on the IMS data set out above, post-acquisition Novartis/Alcon at around [ ]% of the category will continue to face significant competition from Bausch & Lomb with [ ]%, Abbott with [ ]%, and multiple other smaller players.
- 18.18** These competitors will continue to actively compete with the merged firm in this category post acquisition and constrain the merged firm on price. Furthermore, we note that Johnson & Johnson's public documents refer to it having a "major program underway" in contact lens solutions. Its future entry into this category (as a well established company already in the business of manufacturing and

supplying contact lenses) would serve to further constrain Novartis and Alcon post acquisition (refer to paragraph 12.39 above for details).

**18.19** Based on the data available, Novartis has a limited presence in this category, with its small lens care range (currently consisting of only two products), with no plans to introduce any new products into this category. Bausch & Lomb and Abbott will both remain as major competitors post-transaction.

**18.20** The proposed acquisition will ultimately result in combining the parties' largely complementary product portfolios (with Novartis' focus on its hydrogen peroxide cleaning system product and Alcon's focus principally on its MPS product) to enable them to compete more effectively in a market environment currently characterised by effective rivalry between multiple competitors.

## POTENTIAL COMPETITION

### CONDITIONS OF ENTRY

- 19. Please explain the requirements for new entry and/or importers in the relevant market(s), including:**
- **a breakdown of the estimated costs; anticipated timeframes;**
  - **regulatory requirements;**
  - **frontier requirements (e.g. tariffs, import licensing, quarantine requirements); and**
  - **business requirements involved.**
- 20. Include a full discussion on:**
- 20.1 any factors that could impede entry; and**
- 20.2 what might prompt new entry post-merger.**

**20.1** In general, the pharmaceutical industry is characterized by the presence of both a large number of players competing in the many therapeutic classes and a large number of generic drugs. The companies in these markets use similar technology, distribution channels and marketing techniques to those employed by Novartis and Alcon.

**20.2** Competition in human healthcare is intensified by the low barriers to entry or expansion that characterise the industry. As noted above, there are a number of fringe competitors already in most of the categories identified, and such competitors could expand production. Numerous paths are available for new entrants, including, at the highest level, the choice between developing new branded originator pharmaceuticals or focusing on manufacturing and selling generic versions of existing off-patent branded pharmaceuticals.

**20.3** In the branded pharmaceuticals business, if existing originating products have patent protection, entering a new product area requires a significant investment for an originating product, particularly the cost of R&D and the cost of developing clinical trial information to obtain marketing authorisations. These costs can be reduced in several ways, however, including licensing-in products from other firms and focusing on the final development stages. Pharmaceutical companies can reduce entry costs related to manufacturing through contract manufacturing, which is common in the pharmaceutical industry.

- 20.4** Entry into generic products is easier, since entrants need only replicate well-established products and generally are not required to submit extensive clinical trial information to obtain a marketing authorisation. Entry costs related to manufacturing and distribution are low. Generic reproduction decreases the need for significant investment in research and development, significantly expediting the registration process.
- 20.5** The research and development of active pharmaceutical ingredients and manufacturing of products is made at a worldwide level. This means that local branches of multinational companies will not have to bear elevated sunk costs owed to research and development for pharmaceutical products.
- 20.6** In New Zealand, the majority of competitors are multinational companies, which may offer certain products abroad that are not offered in the categories in New Zealand. There would not be significant barriers to entry for those companies to introduce products sold overseas into New Zealand.
- 20.7** Once a company has a presence in New Zealand, and has established distribution networks, the main barrier to expansion is regulatory approval of the product. As mentioned above at paragraph 18.8, an abridged approval process is available where a product has already been approved in the United States by the FDA, in Europe by the EMEA or in Australia by the TGA.
- 20.8** In *Johnson & Johnson/Pfizer* (Decision 594), the Commission considered potential competition in the market for OTC human worm treatments. The Commission considered four factors that might impede market entry (at paragraphs 116-123):
- (a) ability to source the product;
  - (b) access to distribution channels;
  - (c) marketing and advertising; and
  - (d) regulatory approval through Medsafe.
- 20.9** As the majority of the categories in the present application are markets for OTC products, these considerations apply equally here. Looking at each factor in turn we note:

#### **Ability to source product**



**20.10** New prescription pharmaceuticals in the four categories affected by the proposed transaction could be introduced into New Zealand by, or sourced from, one of the many multinational pharmaceutical companies with their own manufacturing facilities offshore. They may also be made in New Zealand by a manufacturer of generics such as Douglas Pharmaceuticals.

**20.11** A new entrant would be likely to distribute its product through independent distributors or wholesalers.

#### **Access to distribution channels**

**20.12** Distribution services are widely available. Novartis uses a freight forwarder, DHL, to transport its products and also for warehousing and logistics. Novartis understands that DHL also provides these services to a number of other pharmaceutical companies. The freight forwarding market is highly competitive and access to these distribution services is widely available.

**20.13** Alcon in New Zealand use Pharmaco NZ Ltd to provide distribution and other services. Pharmaco also provides distribution and other services to a number of other pharmaceutical companies.

#### **Marketing and advertising**

**20.14** To support a prescription pharmaceutical, a new entrant would need to invest in a level of sales support in order to make the product known to buying agencies, physicians, pharmacists and other referrers.

#### **Regulatory approval through Medsafe**

**20.15** A company wishing to market a medicine that has not previously been marketed in New Zealand must obtain the consent of the Minister of Health (or the Minister's delegate) to distribute a "new medicine". Such medicines fall into three categories:

- (a) *Innovator medicines that contain new active substances or are administered in a novel way.* To obtain consent, the company must submit an application dossier containing detailed information about the safety, quality and efficacy of the medicine. The application is considered by the Medicines Assessment Advisory Committee, which is a committee of experts set up to advise the Minister of Health. As stated above in

paragraphs 18.8 and 20.7, an abridged process is available if the product has already been approved in the United States, Europe or Australia.

- (b) *Multi-source or generic medicines that do not have new active substances or novel dose forms, but are a different brand from the previously approved product.* To obtain consent to market the new brand, the company must submit an abridged application dossier that contains information about the safety, quality and efficacy of the new medicine for assessment by Medsafe evaluators.
- (c) *Over-the-counter medicines that contain active ingredients with a well established record of use.* These may be new products containing active ingredients in different combinations, or new brands of previously approved over-the-counter medicines. To obtain consent to market a new over-the-counter medicine, the company must submit an abridged application dossier for assessment by Medsafe evaluators.

**20.16** If an application for consent to market a new medicine is acceptable, the Minister of Health or their delegate approves the medicine. Notification of the consent is published in the New Zealand Gazette, and the medicine can then be marketed. The consent applies only to a single brand of the medicine made by a particular manufacturer.

**20.17** There are a number of factors that will affect how quickly Medsafe can grant regulatory approval - but if the requisite clinical programme for a prescription pharmaceutical had been completed off-shore then this could be done within 12 – 18 months.

**20.18** Registration costs range from \$8,000 for a low risk type therapy (non-prescription) to \$90,000 for a high risk product.

## LIKELIHOOD, EXTENT AND TIMELINES OF ENTRY (THE LET TEST)

**21. Please name any likely businesses (including overseas businesses) you are aware of that do not currently supply the market but which you consider could supply each of the relevant market(s). Discuss the likelihood of such entry.**

**21.1** Novartis New Zealand is not currently aware of any specific intention from potential competitors to enter New Zealand, but advises that this is certainly possible, and there may well be a number of players in overseas markets that could potentially enter New Zealand.

**21.2** As noted above, a number of global companies supply products into one or more of the relevant categories in Australia but do not do so in New Zealand. These include Allergan and Bausch & Lomb (in the S1E sub-category for miotics – see para. 18.8 above) and Aspen and Johnson & Johnson (in the S1K category – see para. 18.15 above). These competitors could enter the relevant categories in New Zealand with relative ease, given that their products are already approved and sold in Australia and both already have a strong presence in other ophthalmic categories in New Zealand.

**21.3** Another example of possible entry is the Johnson & Johnson pipeline products for contact lens solutions in the S1L category (mentioned at paragraph 12.39 above).

**22. To what extent do you consider that potential entry would be sufficient to constrain the merged entity in the markets affected?**

**22.1** Potential entry into the category will be a significant constraint on Novartis/Alcon post-acquisition.

**23. How long would you expect it to take for entry to occur, and for market supply to increase, in respect of each of the potential entrants named in question 21 above? Provide reasons for your estimates.**

**23.1** The major time constraint for entry of a new product is the time to obtain registration from Medsafe. This will depend on the product, but the minimum time for registration would be 3 months (for example, if a product was already approved in Australia). If it is a high risk product, obtaining registration could take over a

year. In general, OTC products can be introduced into the categories quicker than prescription products.

**23.2** If funding from Pharmac is required, this will also impact the time for entry, as negotiations with Pharmac could take two to three years.

**23.3** For Novartis, there is also a [ ] lead time for supply, but this process can be undertaken concurrently with obtaining registration.

**23.4** Some examples of timeframes for the introduction of new products by Novartis are as follows:

(a) Miochol-E powder (sold in the S1E category) was first submitted for registration on 4 May 2005 and was approved by Medsafe on 9 August 2005, taking a total of 97 days;

(b) Lucentis Solution for injection (sold in the S1P category) was first submitted for registration on 15 March 2006 and it was approved by Medsafe on 21 June 2007, a total of 436 days; and

(c) Nyogel Eye Gel (previously sold in the S1E category) was first submitted for registration on 17 December 2001 and was approved by Medsafe on 22 August 2002, a total of 248 days.

## **COUNTERVAILING POWER OF BUYERS**

**24. To what extent do you consider that the merged entity would be constrained in its actions by the conduct of buyers in the markets affected? Where relevant, please include:**

**24.1 a full discussion on the ability of buyers to self supply or import, and the alternative sources of supply available to buyers; and**

**24.2 evidence of buyers seeking alternative supply and/or switching suppliers.**

**24.1** The market power of pharmaceutical companies, regardless of market share and regardless of whether they focus on branded or generic products, is constrained by the high degree of regulation that characterizes this industry and the role of Pharmac in pricing decisions.

**24.2** For these reasons, prices are not set independently by pharmaceutical companies but negotiated with Pharmac and other health authorities, who take into account policy considerations such as patients' access to products and the control of healthcare budgets. We expand on this below.

## **Pharmac**

**24.3** The purchasers of pharmaceuticals are public and private hospitals and retail pharmacies. Although Pharmac is not a purchaser of pharmaceuticals, the competitive landscape is extensively shaped by Pharmac's role as agent of the Crown in managing government expenditure on pharmaceuticals. Through its ability to influence prices and set subsidy levels, Pharmac can substantially alter market shares in pharmaceutical markets.

**24.4** The role of Pharmac as a monopsonist is well recognised, including by the Court of Appeal in *Astrazeneca Limited v Commerce Commission* [2008] NZCA 479 (paragraph 19):

*"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".*

**24.5** The high degree of power held by Pharmac is acknowledged by a statutory exemption to prevent Pharmac's buying practices from breaching the Commerce Act.

**24.6** In relation to the relevant categories identified in this application, Pharmac is a constraint in the S1E category (particularly the anti-glaucoma sub-category) and S1G category. In the S1E category, a significant number of anti-glaucoma products are funded and doctors will prescribe the funded glaucoma treatments. In the S1G category, Pharmac is less of a constraint than in the S1E category, as only a few of the products are funded. Novartis' Zaditen product in this category is not funded.

## District Health Boards

- 24.7** Where products used by public hospitals are not subsidised by Pharmac, the hospitals will either purchase these at the supplier's list price or at prices negotiated by Pharmac. Section H of the Pharmaceutical Schedule includes pharmaceuticals that can be purchased at a national price by DHBs for use in their hospitals. These are referred to as National Contract Pharmaceuticals.
- 24.8** This constraint is more significant in the S1E miotics for use in cataract surgery category.

## Other Buyers

- 24.9** As stated above, [ ]% of Novartis' sales are to wholesalers. These wholesalers do not purchase exclusively from Novartis, but purchase from a large number of different pharmaceutical companies, in order to supply product to pharmacies and DHBs. If Novartis were to increase its price, Novartis' sales would decrease as purchasers from wholesalers would switch to other products.
- 24.10** Novartis generally supplies products from its price list, but the targeted pharmacy distribution centres (for example Life Pharmacies) will negotiate discounts and "co-op". "Co-op" relates to the purchasing of marketing. The discount on product prices is on average approximately [ ]% If no discount was offered, or if the "co-op" was not paid, then the pharmacies may not make shelf space available for Novartis' products, which would have a detrimental effect on Novartis' sales.

**25. If you consider that there is a constraint from buyers, identify the top five buyers by sales and/or volume (including overseas companies/importers) in the relevant market(s). Where there are significant differences in the size of the buyers please provide details for five medium and five small buyers.**

**25.1** The top five customers for Novartis New Zealand (based on 2009 sales) are:

- (a) Pharmacy Retailing Ltd;
- (b) CDC Pharmaceuticals Ltd;
- (c) Health Support Services Ltd;
- (d) Pharmacy Wholesalers (BOP) Ltd; and
- (e) Pharmacy Wholesalers (Central) Ltd.

**25.2** These are all wholesalers who sell the product to retail pharmacies or hospitals (DHB's). They account for [ ]% of Novartis' sales.

**COORDINATED MARKET POWER**

**26. Identify and discuss the various characteristics of the market that, post-merger, you consider would either facilitate or impede coordination.**

**26.1** The Applicant believes that factors conducive to collusion do not currently exist and that this is unlikely to change post the proposed transaction. This renders market co-ordination unlikely.

**26.2** The factors conducive to collusion, and whether Novartis considers they are present in the relevant categories identified, are set out in the following table:

Factors conducive to collusion	Presence of factors post the Proposed Transaction
<b>High seller concentration</b>	Not present – there would still be a number of strong competitors in each relevant category (except S1E miotics, where there will still be one strong competitor)
<b>Undifferentiated product</b>	Generally not present, as products are differentiated (the exception being S1T, but Novartis is no longer selling into this category)
<b>Static production technology</b>	Not present – development is an ongoing process for all competitors and large sums are spent in research and development.
<b>Slow speed of new entry</b>	Not present for an overseas supplier with a prominent brand, could occur quickly (dependent on Medsafe registration)
<b>Lack of fringe competitors</b>	Not present – numerous fringe competitors.
<b>Acquisition of a maverick business</b>	Not present – Alcon is unlikely to be classified as a maverick (a competitor who 'punches above its weight')
<b>Price inelastic market demand</b>	Demand is relatively elastic – Retailers will change suppliers if prices increase above competitive levels

<b>History of anti-competitive behaviour</b>	Not present
<b>No countervailing buying power</b>	Not present – buyers have countervailing buying power, as well as Pharmac and District Health Boards

## EFFICIENCIES

<b>27.</b>	<b>If applicable, provide a description of any efficiencies that you believe the acquisition could bring. Would such efficiencies enhance rivalry, or offset the impact of a lessening of competition? Please include a full discussion on:</b>
<b>27.1</b>	<b>how the merger would facilitate the realisation of efficiency improvements. Specify the steps the combined entity anticipates it would take, and the timeframe needed, to achieve the efficiencies. Where relevant, include a discussion of the risks and costs involved;</b>
<b>27.2</b>	<b>the magnitude of the efficiencies, whether the impact would be on fixed, variable or other costs, and generally how the cost structure of the merged entity would change;</b>
<b>27.3</b>	<b>whether such efficiencies could be realised without the merger, or over a longer timeframe; and</b>
<b>27.4</b>	<b>whether, and the extent to which, such efficiencies would be passed on to the customers of the merged entity.</b>

**27.1** Novartis and Alcon's eye care businesses are highly complementary with only minimal overlaps, and as a consequence, the acquisition will enable them to achieve large efficiencies. For instance, Novartis produces contact lenses, which Alcon does not, Alcon produces intra-ocular lenses, which Novartis does not and Alcon produces ophthalmic surgical devices, which Novartis does not. Novartis views eye care as a growth segment in health care because of changing demographics and increasing demand for eye care in emerging markets. Novartis



expects that the transaction will enhance its global presence thanks to the complementary product portfolios offered by Novartis and Alcon.

- 27.2** Novartis expects that synergies can be realized within three years of closing. In combining the best of the parties' respective capabilities and eliminating duplicative operations, the proposed transaction will enable Novartis to enhance its capabilities to meet demand relating to increasing vision care needs of an aging population. The existence of vigorous competition ensures that end consumers clearly will benefit from the operating and cost savings generated by the acquisition.
- 27.3** In addition, by means of this acquisition, Alcon's ownership structure will be simplified and its eye care division will benefit from access to the Novartis Group's global operations, expertise, and resources. This will also enable the companies to move faster to achieve the full potential of the combined business.
- 27.4** From a financial benefit perspective, Novartis estimates approximately US\$[ ] million of annual pre-tax cost synergies could be generated world-wide within three years after completing the proposed acquisition through shared service agreements, collaborations, joint ventures and other business arrangements.

#### **OTHER FACTORS**

**28. Where relevant, provide a description of any other features of the market(s) that should be taken into account in considering the effect of the proposed merger.**

Not Applicable.

## PART 6: FURTHER INFORMATION AND SUPPORTING DOCUMENTATION

29. Provide the contact details of relevant competitors, buyers and suppliers and any other relevant market participants in the form of the example table shown below.

	NAME OF COMPANY	CONTACT DETAILS	RELEVANT CONTACT PERSON
	BOTH LEGAL AND TRADING NAMES	POSTAL AND PHYSICAL ADDRESS, TELEPHONE AND FAX, WEBSITE	NAME, POSITION AND CONTACT DETAILS INCLUDING TELEPHONE PHONE, FAX, EMAIL
<b>COMPETITORS</b>	Abbott Laboratories NZ Limited	Ground Floor, Building D 4 Pacific Rise Mount Wellington PO Box 22-801 Otahuhu Auckland New Zealand Phone: +64 9 573 6030 Fax: +64 9 573 6040 www.abbott.com	Nick Leach, New Zealand Commercial Director Phone: +64 4 586 4975 Fax: +64 4 586 2417
	AFT Pharmaceuticals Limited	Level 2, 9 Anzac Street, Takapuna PO Box 33-203 Takapuna Auckland Phone +64 9 488 0232 Fax +64 9 488 0234 www.aftpharm.com	
	Allergan New Zealand Limited	Cnr Manu Tapu Drive & Joseph Hammond Place Mangere Auckland International Airport PO Box 1873 Auckland 1 New Zealand Phone: 0800-659-912 Fax: 0800-659-913 www.allergan.com	
	Apotex NZ Limited	32 Hillside Road Glenfield Private Bag 102995 North Shore Auckland New Zealand Phone: +64 9 444 2073 Fax: +64 9 444 2951 www.apotexnz.co.nz	
	Aspen Pharmacare	c/o Healthcare Logistics P.O Box 62-027 Mt Wellington	

		Auckland New Zealand Phone: +64 9 570 1080 Fax: +64 9 915 9581 www.aspenpharma.co.nz	
	Bausch & Lomb (New Zealand) Limited	2a Fisher Crescent, Mt Wellington Auckland New Zealand. P.O.Box 24 138 Royal Oak, Auckland 1003 Phone: +64 9 634 1138 Fax: +64 9 259 4067 www.basch.com	
	Corneal Lens Corporation New Zealand Limited	58 Armargh Street Christchurch P.O.Box 2344 Christchurch New Zealand Phone: +64 3 366 6247 Fax: +64 3 366 8351 www.corneal-lens.co.nz	
	Haag-Streit International	Gartenstadtstrasse 10 3098 Koeniz Switzerland Phone: +41319780111  www.haag-streit.com	
	Johnson & Johnson (New Zealand) Limited	13a Gabador Place Mt Wellington Auckland 1641 New Zealand Phone: +64 9 574 1783 Fax: +64 9 573 6234 www.jnjnz.co.nz	
	Merck Sharp & Dohme (New Zealand) Limited	Level 2 109 Carlton Gore Road Newmarket Auckland New Zealand  Phone: +64 9 375 9210 Fax: +64 9 375 9212 www.msd.com/nm/nz	
	Pfizer New Zealand Limited	Level 3 Pfizer House 14 Normanby Road Mt Eden Auckland New Zealand Phone: +64 9 638 0000 Fax: +64 9 638 001 www.pfizer.co.nz	Frances Benge, Managing Director Phone: +64 9 638 0000 Fax: +64 9 638 0021
	Reckitt Benckiser (New Zealand) Limited	Lincoln Manor 289 Lincoln Road Henderson Auckland New Zealand	

		Phone: +64 9 839 0200 Fax: +64 9 839 0202 www.rb.com/home	
	Sanofi-Aventis New Zealand Limited	James & Wells Tower Part Level 8 56 Cawley Street Ellerslie PO Box 12851 Penrose Auckland New Zealand Phone: +64 9 580 1810 www.sanofi-aventis.com.au	Alan Carter, Country Manager  Phone: +64 9 580 1829  Fax: +64 9 580 1811
	Sigma Pharmaceuticals Pty Limited	1408 Centre Road Clayton Victoria 3168 Locked Bag 268 96 Merrindale Drive Croydon Vic 3136 Australia Phone: +61 3 9839 2800 Fax: +61 3 9839 2801 www.sigmaco.com.au	
	Smith & Nephew Limited	PO Box 442 Shortland Street Auckland 1140 New Zealand Unit 1A, Charann Place, Avondale Auckland 1026 New Zealand Phone: +64 9 828 4059 Fax: +64 9 820 2866 www.global.smith-nephew.com	
	Toomac Holdings Limited	32C Poland Road Glenfield 0627 PO Box 36-190 Northcote North Shore City 0748 New Zealand Phone: +64 9 443 5347 Fax: +64 9 443 5345 www.toomac.co.nz	
<b>CUSTOMERS</b>	Pharmacy Retailing Ltd	54 Carbine Road Mt Wellington, Auckland, 1006 p: 09 5701080	
	CDC Pharmaceuticals Ltd	226 Cambridge Terrace Naenae Lower Hutt City Wellington 5045 P O Box 39280 Wellington mail Centre Lower Hutt Phone (04) 5670038 Fax:(04) 5670037 www.cdc.co.nz	
	Health Support Services Ltd	PO Box 44 027, Pt Chevalier, Auckland,	

		Phone: (09) 815 2600 Fax: 0800 266 960 or 09 815 1911 www.healthsupport.co.nz	
	Pharmacy Wholesalers (BOP) Ltd	7 Tangmere Place, Greerton, Tauranga 3112 P O Box 104, Seventh Avenue, Tauranga 3140 Phone +64-7-541 3756 www.pwl.co.nz	
	Pharmacy Wholesalers (Central) Ltd	207 Courtney Street New Plymouth Telephone:(06) 757 3061 Facsimile: (06) 757 9963 www.pwlcentral.co.nz	
<b>TRADE ASSOCIATIONS</b>	Researched Medicines Industry Association (RMI)	Level 8 86-90 Lambton Quay Wellington PO Box 10-447 Wellington New Zealand Phone: (04) 494 1153 www.rmianz.co.nz	
<b>ANY OTHER RELEVANT MARKET PARTICIPANTS OR INTERESTED PARTIES</b>	Pharmac	PO Box 10-254 Wellington New Zealand Phone: +64 4 460 4990 Fax: +64 4 460 4995 www.pharmac.govt.nz	
	Medsafe  New Zealand Medicines and Medical Devices Safety Authority	Level 6 Deloitte House 10 Brandon Street Wellington New Zealand P O Box 5013 Wellington Phone: +64 4 819 6800 Fax: +64 4 819 6806 www.medsafe.govt.nz	
	New Zealand Medical Association	26 The Terrace PO Box 156 Wellington New Zealand Phone: +64 4 472 4741 Fax: +64 4 471 0838 www.nzma.org.nz	
	Pharmacy Guild of NZ Inc	P O Box 27139, Marion Square Wellington 6141 Ph. 04 802 8200 Fax. 04 384 8085	
	Royal Australian and New Zealand College of Ophthalmologists	Registered Office: 94-98 Chalmers Street Surry Hills NSW 2010 AUSTRALIA	

	<b>(RANZCO)</b>	Phone : +61 2 9690 1001 Fax : +61 2 9690 1321 Email : ranzco@ranzco.edu  NEW ZEALAND BRANCH OFFICE Level 2, 26 The Terrace, P O Box 156, Wellington. Telephone: 64 4 4941029 Fax: 64 4 4710838 Email: nz.br.ranzco@nzma.org.n z Branch Officer: Alison Robertson	
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**30. Please provide a copy of the most recent annual report for each of the merger parties. If an annual report is not available, please provide a copy of the audited financial statements of the merger parties (profit and loss account, showing total turnover and profit before tax, and balance sheet). If the merger only relates to a segment of the business of the merger parties, please also provide a copy of any management accounts for the relevant business segment.**

**30.1** Please find **attached** copies of:

- (a) The 2009 annual report for Novartis;
- (b) The 2009 annual report for Alcon Inc.; and
- (c) The 2008 annual report for Alcon Pharmaceuticals Limited.

## PART 7: CONFIDENTIALITY

**31. 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.**

**31.1** Confidentiality is sought in respect of the information in this application that is contained in bold square brackets and green shading. Confidentiality is sought for the purposes of section 9(2)(b) of the Official Information Act on the grounds that:

- (a) the information is commercially sensitive and contains valuable information which is confidential to the merger parties, Novartis and Alcon; and
- (b) disclosure of it is likely to give an unfair advantage to competitors of the merger parties and/or unreasonably prejudice the commercial position of the merger parties.

**31.2** Novartis and Alcon request that they be notified of any request made to the Commission under the Official Information Act for release of their own confidential information, and that the Commission seeks their views as to whether the information remains confidential and commercially sensitive at the time responses to those requests are being considered.

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

**32. Provide a separate schedule of all confidential information claimed in the application. The Commission requires applicants to provide a separate schedule listing all the confidential information so the Commission can process confidentiality requests quickly.**

**32.1** Please refer to the **attached** schedule of all confidential information (which is the same as the information in this application contained in square brackets).

**33. Provide two copies of the application. One copy must be a confidential version and the other a public version.**

**33.1** In the confidential version of the application any information for which confidentiality is sought must be highlighted in bold and contained in [square brackets].

**33.2** In the public version the confidential information should be removed from within the square brackets, with the brackets remaining, thus [ ].

**33.1** A confidential version and a public version have been provided.

**33.2** In the confidential version of the application confidential information is highlighted in bold, contained in square brackets and shaded in green.



**THIS NOTICE** is given by **Novartis AG (The Company)**.

The Company hereby confirms that:

- all information specified by the Commission has been supplied;
- if information has not been supplied, reasons have been included as to why the information has not been supplied;
- all information known to the applicant(s) which is relevant to the consideration of this application/notice has been supplied; and
- all information supplied is correct as at the date of this application/notice.

The Company undertakes to advise the Commission immediately of any material change in circumstances relating to the application/notice.

Dated this     day of March 2010

I am the General Manager of Novartis New Zealand Limited and am duly authorised to make this application on behalf of The Company

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Signed by Sean Evans, General Manager, Novartis New Zealand Limited.