

Undertaking to the Australian Competition and Consumer Commission

Given under section 87B of the Trade Practices Act by Novartis AG

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1. Person giving the Undertaking

This Undertaking is given to the Australian Competition and Consumer Commission (ACCC) by Novartis AG together with its subsidiaries, including Novartis Pharmaceuticals Australia Pty Limited ACN 004 244 160 (Novartis), on behalf of itself and its subsidiaries.

Novartis AG is the ultimate holding company of the multinational group of pharmaceutical companies that comprise the Novartis Group, including six wholly owned subsidiaries in Australia.

2. Background

- (a) On 4 January 2010, Novartis exercised a call option to purchase the shares held by Nestlé SA (Nestlé) in Alcon, Inc (Alcon) (the **Proposed Acquisition**). Novartis would become the majority shareholder in Alcon as a result of the Proposed Acquisition.
- (b) In Australia, Novartis offers a wide range of healthcare products including branded and generic prescription medicines, over-the-counter medicines, contact lenses and lens care products, injectable miotic products and animal health products.
- (c) Alcon focuses primarily on the vision sector, and is active in Australia in the areas of ophthalmic and miotic pharmaceuticals; ophthalmic surgical products, including surgical and diagnostic equipment, injectable miotic products, as well as contact lens care products.

The ACCC's review

- (d) On 8 April 2010, the ACCC commenced its informal review of the Proposed Acquisition.
- (e) The ACCC undertook market inquiries and considered information provided by the parties, industry participants and others. The ACCC's inquiries were aimed at assessing whether or not the Proposed Acquisition would have the effect or be likely to have the effect of substantially lessening competition in a market in contravention of section 50 of the *Trade Practices Act 1974* (the Act).

The ACCC's competition concerns

- (f) Novartis and Alcon are the only suppliers of injectable miotic products in Australia. The ACCC is concerned that, in the absence of this Undertaking, the Proposed Acquisition would remove the only significant competitor to Novartis in Australia in the supply of injectable miotic products. The Proposed Acquisition would result in Novartis being the sole supplier of injectable miotics products in Australia.
- (g) The ACCC considered that in the absence of this Undertaking, the Proposed Acquisition would have the effect or be likely to have the effect of substantially lessening competition in relation to the market for the supply of injectable miotics products.

The Federal Trade Commission

- (h) The Federal Trade Commission (FTC) in the United States of America (US) initiated an investigation of the Proposed Acquisition.
- (i) In order to avoid delay in securing clearance from the FTC, Novartis has committed to divest certain assets related to the Injectable Miotics Product, and pursuant to this commitment, Novartis has entered into the Miotics Divestiture Agreement to sell its Injectable Miotics Assets to Bausch & Lomb. This global divestment is evidenced by its inclusion as an Exhibit to a Consent Decree that will be issued by the FTC.
- (j) The Consent Decree will manage the process of the sale of the Injectable Miotics Assets, including handling of confidential information and regulatory approvals for those assets.
- (k) The Consent Decree contains provisions including: an Interim Monitor Provision (Order III), which provides for the appointment of an Interim Monitor to ensure Novartis expeditiously complies with all of its obligations and perform all of its responsibilities under the Consent Decree; a preservation of the business associated with the Injectable Miotics Product provision (Order II, J); and a Divestiture Trustee provision (Order IV), which provides for the appointment of a Divestiture Trustee in the event that Novartis has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Injectable Miotics Assets as required by the Consent Decree.

Proposed divestiture of Injectable Miotics Australian Assets

- (l) Novartis does not consider that the Proposed Acquisition would be likely to substantially lessen competition in relation to the supply of injectable miotics products. However, in order to avoid delay and to address the ACCC's competition concerns, Novartis has, without admission, provided this Undertaking pursuant to section 87B of the Act.
- (m) The objective of this Undertaking is to address the ACCC's competition concerns which would otherwise arise as a consequence of the Proposed Acquisition.
- (n) The manufacturing of the Injectable Miotics Product involves steps of production in Germany, Switzerland and Belgium, with the Injectable Miotics Product being imported into Australia. The Injectable Miotics Product is then supplied in Australia using the Injectable Miotics Australian Assets.
- (o) As part of the global divestments, the Injectable Miotics Assets, which includes the Intellectual Property used to manufacture Injectable Miotics Product, are being divested to a single global purchaser. Novartis is seeking approval to divest the Injectable Miotics Assets to Bausch & Lomb.
- (p) Consistent with the global divestments, the ACCC requires the Injectable Miotics Australian Assets to be divested to the same purchaser as the Injectable Miotics Assets are being divested to globally, provided this purchaser does not raise competition concerns in Australia.
- (q) Given that the manufacturing of the Injectable Miotics Product occurs globally, the Injectable Miotic Australian Assets that are to be divested consist of the Intellectual Property and inventory detailed in Schedule 1. These assets are used only to supply the Injectable Miotics Product in Australia.

- (r) This Undertaking addresses the ACCC's competition concerns by:
- (i) ensuring that the Injectable Miotics Australian Assets are sold to an ACCC Approved Purchaser who will supply the Injectable Miotics Product in Australia effectively;
 - (ii) creating or strengthening a viable, effective, stand-alone, independent and long term competitor for the supply of injectable miotics products in Australia;
 - (iii) ensuring that the purchaser of the Injectable Miotics Australian Assets has the necessary assets (including Intellectual Property and Product Approvals) to compete effectively with Novartis in the supply of injectable miotics products in Australia; and
 - (iv) enabling the purchaser of the Injectable Miotics Australian Assets to constrain Novartis in the supply of injectable miotics products including by increasing the price of products, or decreasing the quality of its service.

3. Defined terms and interpretation

3.1 Definitions in the Dictionary

A term or expression starting with a capital letter:

- (a) which is defined in the Dictionary in Schedule 2 (Dictionary), has the meaning given to it in the Dictionary; and
- (b) which is defined in the Corporations Act, but is not defined in the Dictionary, has the meaning given to it in the Corporations Act,

3.2 Interpretation

The interpretation clause in Schedule 2 sets out rules of interpretation for this Undertaking.

4. Commencement and termination of Undertaking

4.1 Commencement

This Undertaking comes into effect when:

- (a) the Undertaking is executed by Novartis; and
- (b) the Undertaking so executed is accepted by the ACCC.

4.2 Termination

- (a) Subject to clause 4.2(b) this Undertaking terminates on the Final Date.
- (b) Notwithstanding clause 4.2(a), this Undertaking terminates on the date the ACCC consents in writing to the withdrawal of this Undertaking in accordance with section 87B of the Act.

5. Sale of Injectable Miotics Australian Assets

- (a) Subject to clause 6(c) below, Novartis will comply with the Consent Decree in relation to the Injectable Miotics Assets.
- (b) No later than the Initial Divestiture Date, Novartis must, in accordance with this Undertaking, divest, or cause the divestiture of, the Injectable Miotics Australian Assets to the Approved Purchaser in accordance with the Miotics Divestiture Agreement.
- (c) Nothing in the Miotics Divestiture Agreement will be taken to limit or contradict the terms of this Undertaking.
- (d) The ACCC has approved, as a condition precedent to accepting this Undertaking, Bausch & Lomb as an Approved Purchaser of the Injectable Miotics Australian Assets on the basis of the following:
 - (i) Bausch & Lomb will complete the transaction contemplated by the Miotics Divestiture Agreement with Novartis (as amended and restated) by which Bausch & Lomb will acquire the Injectable Miotics Assets;
 - (ii) Bausch & Lomb is and will remain independent of, and has no direct or indirect interest in, Novartis;
 - (iii) Bausch & Lomb is of good financial standing and has an intention to maintain and use the Injectable Miotics Australian Assets and sell the Injectable Miotics Product in Australia;
 - (iv) Bausch & Lomb is able to supply the Injectable Miotics Product in Australia effectively; and
 - (v) the sale of the Injectable Miotics Australian Assets to Bausch & Lomb will address any competition concerns of the ACCC, including the likely long-term viability and competitiveness of the Injectable Miotics Australian Assets under the ownership of Bausch & Lomb.
- (e) The ACCC may revoke its:
 - (i) acceptance of an Approved Purchaser; and/or
 - (ii) acceptance of this Undertaking,
 if the ACCC becomes aware that the information provided to it was incorrect, inaccurate or misleading.
- (f) Novartis must:
 - (i) enforce the terms of the Miotics Divestiture Agreement and any contract, arrangement or understanding with an Approved Purchaser under which an Approved Purchaser is obliged to acquire the Injectable Miotics Australian Assets; and
 - (ii) ensure that the Injectable Miotics Australian Assets are sold to an Approved Purchaser simultaneously with an Approved Purchaser's acquisition of the Injectable Miotics Assets.

6. Licences, permits, regulatory approvals and Third Party Consents

- (a) Novartis must effect or obtain the transfer, subject to law, of all licences, permits and/or other regulatory approvals to an Approved Purchaser that are required by the Approved Purchaser in order to:
 - (i) maintain and use the Injectable Miotics Australian Assets; and
 - (ii) import into Australia, and supply in Australia, the Injectable Miotics Product.
- (b) Novartis must:
 - (i) obtain or assist an Approved Purchaser to obtain all Third Party Consents before, or as soon as practicable after the Initial Divestiture Date;
 - (ii) comply with all requirements necessary to obtain any Third Party Consents, including by promptly providing information to the third party; and
 - (iii) act in good faith in its negotiations with an Approved Purchaser in relation to gaining any Third Party Consents.
- (c) If, before the Initial Divestiture Date:
 - (i) the Approved Purchaser fails to obtain or is unable to obtain any licence, permit or other regulatory approval referred to in clause 6(a) above, then Novartis must continue to do everything in its power to satisfy clause 6(a) above as soon as possible after the Initial Divestiture Date (and until such time as clause 6(a) is satisfied); or
 - (ii) Novartis fails to obtain or is unable to obtain any Third Party Consents, then Novartis must provide the ACCC, at least 7 Business Days prior to the Initial Divestiture Date, with details of those licences, permits, approvals or third Party Consents (including reasons why approval, consent or transfer could not be given prior to that date, and what is required to obtain the approval, consent or transfer).
- (d) Subject to clause 6(e), notwithstanding that Novartis has complied with clauses 6(b) and 6(c) of this Undertaking it remains a breach of this Undertaking if Novartis is unable to effect the divestiture of the Injectable Miotics Australian Assets by reason of a failure to obtain any Third Party Consents.
- (e) Nothing in this Undertaking shall be construed as an attempt or agreement to assign any Injectable Miotics Australian Asset, including any Product Approvals, or other right, which by its terms or by law is non-assignable without the consent, authorisation, qualification or similar approval of a third party or a governmental authority or is cancellable by a third party in the event of an assignment unless and until such consents, authorisations, qualifications or approvals have been obtained.

7. Preservation of the Injectable Miotics Australian Assets

7.1 Maintenance of the Injectable Miotics Australian Assets

- (a) From the Control Date, Novartis must not sell or transfer its interest, or any assets comprising part of, or used in, the business associated with the Injectable Miotics Australian Assets or make any Material Change, except in accordance with this Undertaking.
- (b) Until the Divestiture Date, Novartis must take such actions as are necessary to:
 - (i) maintain the full economic viability, marketability and competitiveness of the business associated with the Injectable Miotics Product;
 - (ii) minimize any risk of loss of competitive potential for the business associated with the Injectable Miotics Product; and
 - (iii) prevent the destruction, removal, wasting, deterioration, or impairment of any of the Injectable Miotics Product except for ordinary wear and tear.

7.2 Direction to personnel

As soon as practicable after the Control Date, Novartis must in writing direct its personnel in Australia, including directors, contractors, managers, officers, employees and agents, not to do anything inconsistent with Novartis's obligations under this Undertaking.

7.3 Confidential Information

- (a) Subject to clauses 7.3(b), 7.3(c) and 7.3(d), Novartis must not, at any time from the Control Date and for a period of 12 months after the end of the term of this Undertaking, use or disclose any confidential information about the Injectable Miotics Australian Assets gained through:
 - (i) the ownership and/or management of the Injectable Miotics Australian Assets; or
 - (ii) the provision of any services or Technical Assistance to, or through any interim supply or toll manufacturing arrangement with, the Approved Buyer of the Injectable Miotics Australian Assets.
- (b) Clause 7.3(a) does not apply to information that Novartis requires to comply with legal and regulatory obligations, including obligations relating to:
 - (i) taxation;
 - (ii) accounting;
 - (iii) ASIC, Securities & Exchange Commission and stock exchange disclosure obligations; and
 - (iv) pharmacovigilance.
- (c) Clause 7.3(a) does not apply to information that Novartis requires to carry out its obligations under this Undertaking, including its obligations to sell the Injectable Miotics Australian Assets, or to comply with legal and regulatory obligations, provided such information:

- (i) is only made available to those officers, employees, contractors and advisers of Novartis who need to know the information for the purpose of ensuring compliance with the Undertaking or with legal and regulatory obligations; and
- (ii) is not used for any other purpose.
- (d) Clause 7.3(a) does not apply to information that relates to both the Injectable Miotics Australian Assets and to products or businesses retained by Novartis which cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Injectable Miotics Australian Assets. To the extent that this information exists, Novartis is permitted to use such information in connection with its retained products and businesses only.

7.4 Novartis's obligations in relation to the Injectable Miotics Australian Assets

Without limiting this clause 7.4 Novartis must, from the Control Date until the Divestiture Date (or other period specified) take all steps having regard to the nature of the Injectable Miotics Australian Assets to ensure that:

- (a) existing arrangements, agreements, or contracts with customers, suppliers or other third parties that were in place at the Control Date relating to the Injectable Miotics Australian Assets continue, subject to any Material Changes made by Novartis to improve the operational efficiency of the Injectable Miotics Australian Assets and which are notified to the ACCC;
- (b) Novartis does not directly or indirectly procure, promote or encourage the redeployment of personnel necessary for the operation of the Injectable Miotics Australian Assets as at the Control Date to any other business operated by Novartis;

8. Confidential clause 8

The details of clause 8 are confidential.

9. Independent audit

9.1 Proposed Auditor

- (a) By no later than 10 Business Days before the Control Date, Novartis must identify a prospective independent auditor (**Proposed Auditor**) and provide the ACCC with written notice of the identity of the Proposed Auditor, together with such information and documents as the ACCC requires to assess whether to object to the appointment of the Proposed Auditor, including a copy of the proposed terms of appointment.
- (b) The Proposed Auditor must be a person who has the qualifications and experience necessary to carry out the functions of the Approved Independent Auditor and is independent of Novartis and Alcon. The criteria by which the independence of the Proposed Auditor will be determined include whether the person is:
 - (i) a current employee or officer of Novartis or Alcon;

- (ii) a person who has been an employee or officer of Novartis or Alcon in the past 3 years;
- (iii) a person who, in the opinion of the ACCC, holds a material interest in Novartis or Alcon;
- (iv) a professional adviser of Novartis or Alcon, whether current or in the past 3 years;
- (v) a person who has a contractual relationship, or is an employee or contractor of a firm or company that has a contractual relationship with Novartis or Alcon, but for the terms of any Approved Independent Auditor agreement with Novartis;
- (vi) a supplier, or a person who is an employee or contractor of a firm or company that is a supplier of Novartis or Alcon; or
- (vii) a material customer of, or a person who is an employee or contractor of a firm or company that is a material customer of Novartis or Alcon.

9.2 Appointment of Approved Independent Auditor

If:

- (a) within 5 Business Days of receipt by the ACCC of the written notice referred to in clause 9.1(a); or
- (b) such further period as is required by the ACCC and notified to Novartis in writing prior to the expiration of the 5 Business Day period,

the ACCC informs Novartis that it:

- (c) does not object to the Proposed Auditor, Novartis will:
 - (i) appoint the Proposed Auditor as the Approved Independent Auditor as soon as practicable, and by no later than the Control Date, on terms approved by the ACCC and consistent with the performance by the Approved Independent Auditor of his or her functions under this Undertaking, and
 - (ii) forward to the ACCC a copy of the executed terms of appointment; or
- (d) does object to the Proposed Auditor, Novartis will:
 - (i) appoint a person identified by the ACCC at its absolute discretion as the Approved Independent Auditor on terms approved by the ACCC and consistent with the performance by the Approved Independent Auditor of his or her functions under this Undertaking; and
 - (ii) forward to the ACCC a copy of the executed terms of appointment.

9.3 Obligations relating to the Approved Independent Auditor

- (a) Novartis must procure that the terms of appointment of the Approved Independent Auditor include obligations on the Approved Independent Auditor to:
 - (i) continue to satisfy the independence criteria in clause 9.1(b) for the period of his or her appointment;

- (ii) provide any information or documents requested by the ACCC about Novartis's compliance with this Undertaking directly to the ACCC;
 - (iii) report or otherwise inform the ACCC directly of any issues that arise in the performance of his or her functions as Approved Independent Auditor or in relation to any matter that may arise in connection with this Undertaking; and
 - (iv) follow any direction given to him or her by the ACCC in relation to the performance of his or her functions as Approved Independent Auditor under this Undertaking.
- (b) Without limiting the obligations in this Undertaking, Novartis must:
- (i) provide a copy of the executed terms of appointment for the Approved Independent Auditor to the ACCC within 1 Business Day of their execution;
 - (ii) comply with and enforce the terms of appointment for the Approved Independent Auditor;
 - (iii) maintain and fund the Approved Independent Auditor to carry out his or her functions;
 - (iv) indemnify the Approved Independent Auditor for any expenses, loss, claim or damage arising directly or indirectly from the performance by the Approved Independent Auditor of his or her functions as the Approved Independent Auditor except where such expenses, loss, claim or damage arises out of the gross negligence, fraud, misconduct or breach of duty by the Approved Independent Auditor;
 - (v) not interfere with, or otherwise hinder, the Approved Independent Auditor's ability to carry out his or her functions as the Approved Independent Auditor;
 - (vi) provide and pay for any external expertise, assistance or advice required by the Approved Independent Auditor to perform his or her functions as the Approved Independent Auditor;
 - (vii) provide to the Approved Independent Auditor any information or documents requested by the Approved Independent Auditor that he or she considers necessary for carrying his or her functions as the Approved Independent Auditor or for reporting to or otherwise advising the ACCC;
 - (viii) not request any information relating to the compliance audit from the Approved Independent Auditor without such a request having been approved by the ACCC;
 - (ix) ensure that the Approved Independent Auditor will provide information or documents requested by the ACCC directly to the ACCC;
 - (x) ensure that the Approved Independent Auditor reports or otherwise informs the ACCC directly of any issues that arise in the performance of his or her functions as Approved Independent Auditor or in relation to any matter that may arise in connection with this Undertaking;

- (xi) direct its personnel, including directors, contractors, managers, officers, employees and agents, to act in accordance with this clause 9.3;
- (xii) from the Control Date, ensure that all relevant personnel are aware of the Approved Independent Auditor and the obligations in clause 9.3; and
- (xiii) not appoint the Approved Independent Auditor, or have any agreements, understandings or arrangements with the Approved Independent Auditor, to utilise the Approved Independent Auditor's services for anything other than compliance with this Undertaking.

9.4 Compliance Audit

- (a) Novartis will procure that the Approved Independent Auditor prepares the audit report set out in clause 9.4(b) below. The first audit report is to be provided within 30 Business Days after the Initial Divestiture Date and thereafter every 12 months until the termination of this Undertaking.
- (b) The Approved Independent Auditor is to prepare a detailed report (**Auditor's Report**) on:
 - (i) Novartis's compliance with this Undertaking;
 - (ii) full reasons for the conclusions reached in the audit;
 - (iii) any qualifications made by the Approved Independent Auditor in forming his or her views; and
 - (iv) any recommendations by the Approved Independent Auditor to improve the integrity of the auditing process and any reasonable recommendations to improve Novartis's processes or reporting systems in relation to compliance with this Undertaking.
- (c) Novartis must provide the ACCC with copies of the Auditor's Report within two Business Days of the Auditor's Report being received by Novartis.
- (d) Novartis must require the Approved Independent Auditor to provide to the ACCC details of any possible failure to comply by Novartis with the obligations in this Undertaking immediately upon such a possible failure to comply coming to the attention of the Approved Independent Auditor.
- (e) Novartis must implement any recommendations of the Approved Independent Auditor made pursuant to clause 9.4(b)(iv), and notify the ACCC of the implementation of the recommendations, within 10 Business Days of receiving the Auditor's Report or after a period agreed with the ACCC.
- (f) Novartis must comply with any direction of the ACCC in relation to matters arising from the Approved Independent Auditor's report within 10 Business Days of being so directed (or such longer period as agreed with the ACCC).
- (g) Notwithstanding this clause 9.4, the Approved Independent Auditor may report or otherwise inform the ACCC directly and immediately of any issues that arise in the performance of his or her engagement and functions as Approved Independent Auditor or in relation to compliance by Novartis with this Undertaking.

9.5 Resignation or termination of the Approved Independent Auditor

- (a) Novartis must immediately notify the ACCC in the event that an Approved Independent Auditor resigns or otherwise stops acting as an Approved Independent Auditor before the termination of this Undertaking.
- (b) The ACCC may approve any proposal by, or alternatively may direct, Novartis to terminate an Approved Independent Auditor if in the ACCC's view the Approved Independent Auditor acts inconsistently with the provisions of this Undertaking or the terms of his or her appointment.
- (c) If either clauses 9.5(a) or 9.5(b) applies, the ACCC may nominate alternative auditor to be the Approved Independent Auditor.
- (d) Novartis must, within 5 Business Days of the ACCC nominating an alternative Approved Independent Auditor:
 - (i) appoint an Approved Independent Auditor nominated by the ACCC on terms approved by the ACCC and consistent with the performance by the Approved Independent Auditor of his or her functions under this Undertaking; and
 - (ii) forward to the ACCC a copy of the executed terms of appointment.

10. Information

- (a) Novartis must notify the ACCC in writing of the date of the proposed Control Date at least one week before the proposed Control Date.
- (b) Novartis must notify the ACCC in writing of the occurrence of:
 - (i) the completion of the Proposed Acquisition within one Business Day of the Control Date; and
 - (ii) the divestiture of the Injectable Miotics Australian Assets within one Business Day of the Injectable Miotics Divestiture Date.
- (c) Novartis must provide the ACCC with a copy of the executed Asset Purchase Agreement, and any other agreements between Novartis and the Approved Purchaser relating to the sale of the Injectable Miotics Australian Assets within one Business Day of any such agreement being executed.
- (d) In respect of Novartis' compliance with this Undertaking, the ACCC may request the Interim Monitor and/or Divestiture Trustee to produce information, documents and materials to the ACCC that may be within the Interim Monitor's and/or Divestiture Trustee's (as the case may be) custody, power or control in the time and in the form requested by the ACCC.
- (e) Novartis must respond in a timely manner to any queries or requests for information or documents made by the ACCC (including by a person authorised by the ACCC under Schedule 2, paragraph 2(o)) about this Undertaking.
- (f) The ACCC may direct Novartis in respect of its compliance with this Undertaking to, and Novartis must:
 - (i) furnish information, documents and materials to the ACCC in the time and in the form requested by the ACCC;

- (ii) produce information, documents and materials to the ACCC within Novartis's custody, power or control in the time and in the form requested by the ACCC; and/or
 - (iii) direct its personnel, including its directors, contractors, managers, officers, employees and agents, to attend the ACCC at a reasonable time and place appointed by the ACCC to answer any questions the ACCC (including its Commissioners, its staff or its agents) may have.
- (g) In respect to Novartis's compliance with this Undertaking, the ACCC may request the Approved Independent Auditor or Divestiture Agent to:
- (i) furnish information, documents and materials to the ACCC in the time and in the form requested by the ACCC;
 - (ii) produce information, documents and materials to the ACCC within the Approved Independent Auditor's or Divestiture Agent's custody, power or control in the time and in the form requested by the ACCC; and/or
 - (iii) attend the ACCC at a time and place appointed by the ACCC to answer any questions the ACCC (including its Commissioners, its staff or its agents) may have.
- (h) Novartis will use its best endeavours to ensure that the Approved Independent Auditor or Divestiture Agent complies with any request from the ACCC in accordance with clause 10(g).
- (i) Information furnished, documents and material produced or information given in response to any request or direction from the ACCC under this clause 10 may be used by the ACCC for any purpose consistent with the exercise of its statutory duties.
- (j) Any direction made by the ACCC under clause 10(e) will be notified to Novartis, in accordance with clause 15.1.
- (k) The ACCC may, in its discretion, to be exercised in good faith:
- (i) advise the Approved Independent Auditor or Divestiture Agent of any request made by it under this clause 10; and/or
 - (ii) provide copies to the Approved Independent Auditor or Divestiture Agent of any information furnished, documents and material produced or information given to it under this clause 10.
- (l) Nothing in this clause 10 requires the provision of information or documents in respect of which Novartis has a claim of legal professional or other privilege.

11. Disclosure of Undertaking

- (a) Novartis and the ACCC agree that:
- (i) Confidential Annexure 1 will remain confidential at all times;
 - (ii) Clause 8 will remain confidential until after the Initial Divestiture Date; and
 - (iii) Schedule 3 will remain confidential until after the Divestiture Date.

- (b) Novartis acknowledges that the ACCC may, subject to clause 11(a):
 - (i) make this Undertaking publicly available;
 - (ii) publish this Undertaking on its Public Section 87B Undertakings Register; and
 - (iii) from time to time publicly refer to this Undertaking.
- (c) Nothing in the confidential parts of this Undertaking referred to in clause 11(a) prevents the ACCC from disclosing such information as:
 - (i) is required by law;
 - (ii) is permitted by s 155AAA of the Act;
 - (iii) is necessary for the purpose of enforcement action under section 87B of the Act; or
 - (iv) is necessary for the purpose of making such market inquiries as the ACCC thinks fit to assess the impact on competition arising in connection with this Undertaking.
- (d) Nothing in the confidential parts of this Undertaking prevents the ACCC from using the information contained in this Undertaking for any purpose consistent with its statutory functions and powers.

12. Related Bodies Corporate

Where the performance of an obligation under this Undertaking requires a Related Body Corporate of Novartis to take or refrain from taking some action, Novartis will procure that Related Body Corporate to take or refrain from taking that action, as the case may be.

13. No Derogation

- (a) This Undertaking does not prevent the ACCC from taking enforcement action at any time whether during or after the period of this Undertaking in respect of any breach by Novartis of any term of the Undertaking.
- (b) Nothing in this Undertaking is intended to restrict the right of the ACCC to take action under the Act for penalties or other remedies in the event that Novartis does not fully implement and/or perform its obligations under this Undertaking or in any other event where the ACCC decides to take action under the Act for penalties or other remedies.

14. Costs

Novartis must pay all of its own costs incurred in relation to this Undertaking.

15. Notices

15.1 Giving Notices

- (a) Any notice or communication to the ACCC pursuant to this Undertaking must be sent to:

Name: Australian Competition and Consumer Commission
Address: 23 Marcus Clarke Street
CANBERRA ACT 2601
Fax number: (02) 6243 1212
Attention: Executive General Manager - Mergers and Acquisitions Group

(b) Any notice or communication to Novartis pursuant to this Undertaking must be sent to;

Name: Novartis International AG
Address: Novartis Campus, Lichtstrasse 35, CH-4056
Basel, Switzerland
Fax no: +41 61 324 4300
Attention: Susan Jones, Head Corporate Legal Antitrust

With a copy to:

Name: Novartis Pharmaceuticals Australia Pty Limited
Address: 54 Waterloo Road, North Ryde, NSW 2113
Fax number: (02) 9805 3751
Attention: Ray Steinwall, General Counsel

15.2 Change of address or fax number

If Novartis or the ACCC gives the other 3 Business Days' notice of a change to its address or fax number, any notice or communication is only given to the relevant entity if it is delivered, posted or faxed to the most recently advised address or fax number.

Signed by Novartis AG by its authorised signatory:


Signature of officer

Felix Senn
Authorized Signature

Full name of officer and office held

26.07.10
Date: July 2010



Signature of officer

Dr. Martin Henrich
Authorized Signatory

Full name of officer and office held

26.07.10
Date: July 2010

Accepted by The Australian Competition
and Consumer Commission pursuant to
section 87B of the Trade Practices Act 1974
(Cth):



Signature of officer

GRAEME SAMUEL

Full name of officer and office held

29 July 2010

Date:

Signature of officer

Full name of officer and office held

Date:

Schedule 1 - Injectable Miotics Australian Assets

The Injectable Miotics Australian Assets in Australia includes:

- (a) the following trade mark registrations in Australia

Trade Mark	Country	Registration No.	Owner
Miochol	Australia	429211 (Australian registration)	Novartis AG
Miochol	Australia	890162 (Australian registration) 690308 (International registration)	Novartis AG

- (b) Australia Patent No. 745124 - Methods and compositions for stabilizing acetylcholine compositions

- (c) domain registration:

Domain name	Country	Owner	Expiry date
miochol.com.au	Australia	Novartis Pharmaceuticals Australia Pty Ltd	17 July 2012

- (d) the Australian Register of Therapeutic Goods certification being Registration No. 118510 issued by the TGA to Novartis for the approval to supply the Injectable Miotics Product in Australia;
- (e) the inventory of the Injectable Miotics Product as at the date of the transfer of the Australian Register of Therapeutic Goods certificate to Bausch & Lomb; and
- (f) the product specification and associated artwork relating solely to the Injectable Miochol Product.

Schedule 2 - Dictionary

1. Dictionary

In this Undertaking:

ACCC means the Australian Competition and Consumer Commission.

Act means the *Trade Practices Act 1974* (Cth).

Alcon means Alcon, Inc, together with its Australian subsidiary, Alcon Laboratories Pty Ltd.

Approval Notice means a notice from the ACCC in accordance with clause 8.8(a).

Approved Purchaser means a buyer of the Injectable Miotics Australian Assets approved by the ACCC:

- (a) as set out in clause 5(d) (Bausch & Lomb); or
- (b) in the event that Bausch & Lomb's approval as the Approved Purchaser is revoked under clause 5(c), as set out in clauses 8.7-8.8.

Bausch & Lomb means Bausch & Lomb Incorporated, together with its subsidiaries including Bausch & Lomb (Australia) Pty Limited.

Business Day means a day other than a Saturday or Sunday on which banks are open for business generally in New South Wales.

Commencement Date means the date on which the Undertaking comes into effect under clause 4.1.

Control Date means the date on which the Proposed Acquisition is completed.

Consent Decree means that decree issued by the FTC requiring the divestiture of the Injectable Miotics Assets by Novartis pursuant to the Miotics Divestiture Agreement.

Corporations Act means *Corporations Act 2001* (Cth).

Day means the period of time prescribed under this Undertaking that is calculated by the following method: the calculation of the relevant time period begins with the first Business Day following that on which the act, event, or development initiating such period of time occurred. When the last day of the period is not a Business Day, the period shall run until the end of the next following Business Day.

When such period of time is seven days or less, and includes some days which are not Business Days, each non-Business Day shall be excluded from the calculation. When such period of time exceeds seven days, and includes some days which are not Business Days, each of the non-Business Days shall be included in the calculation.

Divestiture Agent is defined in clause 8.2.

Divestiture Date means the date on which the sale of the Injectable Miotics Australian Assets to an Approved Purchaser is completed.

Divestiture Trustee is defined in clause 8.4(a)(iv).

Final Date means the date that the ACCC approves the termination of this Undertaking, being the date that:

- (a) all licences, agreements or obligations imposed by this Undertaking have been transferred, granted, provided or fulfilled; and
- (b) all transitional services provided by Novartis to the Approved Purchaser under the Miotics Divestiture Agreement are concluded.

Initial Divestiture Date means 10 Days after the Control Date.

Injectable Miotics Assets has the meaning set out in Section 2.1 of the Miotics Divestiture Agreement.

Injectable Miotics Australian Assets comprises the Injectable Miotics Assets associated with the supply and sale of the Injectable Miotics Product in Australia (including the assets described in Schedule 1).

Injectable Miotics Divestiture Date means the date on which Novartis no longer has ownership or control of the Injectable Miotics Australian Assets.

Injectable Miotics Product means the pharmaceutical product, Miochol®-E, (acetylcholine chloride powder and solvent for intraocular solution) offered by Novartis for sale in Australia as at the date of this Undertaking pursuant to applicable Product Approvals.

Intellectual Property includes all rights in Australia in relation to copyright, trade marks, inventions (including patents, innovation patents and utility models), confidential information, trade secrets, technical data, information, know-how, formulae, specifications, drawings, data, manuals and instructions which are owned by Novartis and used exclusively for the supply and sale of the Injectable Miotics Product in Australia except for the corporate name or corporate get up of any other bodies corporate owned or controlled by Novartis.

Interim Monitor has the meaning contained in Order 1 of the Consent Decree.

Material Change means any change to the structure, attributes, extent or operations of the Injectable Miotics Australian Assets that may affect, or impact on, the Injectable Miotics Australian Assets' competitiveness, independence from Novartis and its viability.

Miotics Divestiture Agreement means the Asset Purchase Agreement and the Supply Agreement between Novartis and Bausch & Lomb Incorporated, each dated 21 July 2010 and all related amendments, exhibits, attachments, agreements, and schedules, between Novartis and Bausch & Lomb. The Miotics Divestiture Agreement is attached to this Undertaking as Confidential Annexure 1.

Novartis means Novartis AG, together with its subsidiaries including Novartis Pharmaceuticals Australia Pty Limited.

Product Approvals means any approvals, registrations, permits, licences, consents, authorizations, and other approvals, and pending applications and requests therefore, required exclusively for the importation, supply and sale of the Injectable Miotics Product in Australia.

Product Marketing Materials means all marketing materials owned or controlled by Novartis and used specifically in the marketing or sale of the Injectable Miotics Product in Australia as at the Control Date.

Proposed Auditor is defined in clause 9.1

Proposed Acquisition is defined in clause 2(a).

Proposed Purchaser means a person who proposes to acquire the Injectable Miotics Australian Assets.

Proposed Purchaser Notice means a notice given under clause 8.7.

Public Section 87B Undertakings Register means the ACCC's public register of s 87B undertakings, available at www.accc.gov.au.

Related Body Corporate has the meaning set out in section 50 of the Corporations Act.

Sale and Purchase Agreement means an agreement in respect of the sale and purchase of the Injectable Miotics Australian Assets.

Third Party Consents means any consents (excluding by a governmental agency or authority) required for the assignment, novation, sale, sub-licensing or transfer of any assets, licences, material contracts, permits or approvals used in the supply of Injectable Miotics Product within Australia.

TGA means the Therapeutic Goods Administration.

Undertaking is a reference to all the provisions of this document including its schedules.

Unsold Business has the meaning in Clause 8.1

2. Interpretation

In the interpretation of this Undertaking, the following provisions apply unless the context otherwise requires:

- (a) a reference to this Undertaking includes all of the provisions of this document including its schedules;
- (b) headings are inserted for convenience only and do not affect the interpretation of this Undertaking;
- (c) if the day on which any act, matter or thing is to be done under this Undertaking is not a Business Day, the act, matter or thing must be done on the next Business Day;
- (d) a reference in this Undertaking to any law, legislation or legislative provision includes any statutory modification, amendment or re-enactment, and any subordinate legislation or regulations issued under that legislation or legislative provision;
- (e) a reference in this Undertaking to any company includes its Related Bodies Corporate;
- (f) a reference in this Undertaking to any agreement or document is to that agreement or document as amended, novated, supplemented or replaced;
- (g) a reference to a clause, part, schedule or attachment is a reference to a clause, part, schedule or attachment of or to this Undertaking;
- (h) an expression importing a natural person includes any company, trust, partnership, joint venture, association, body corporate or governmental agency;
- (i) where a word or phrase is given a defined meaning, another part of speech or other grammatical form in respect of that word or phrase has a corresponding meaning;
- (j) a word which denotes the singular also denotes the plural, a word which denotes the plural also denotes the singular, and a reference to any gender also denotes the other genders;

- (k) a reference to the words 'such as', 'including', 'particularly' and similar expressions is to be construed without limitation;
- (l) a construction that would promote the purpose - or object - underlying the Undertaking (whether expressly stated or not) will be preferred to a construction that would not promote that purpose or object;
- (m) material not forming part of this Undertaking may be considered to:
 - (i) confirm the meaning of a clause is the ordinary meaning conveyed by the text of the clause, taking into account its context in the Undertaking and the competition concerns intended to be addressed by the Undertaking and the clause in question; or
 - (ii) determine the meaning of the clause when the ordinary meaning conveyed by the text of the clause, taking into account its context in the Undertaking and the purpose or object underlying the Undertaking, leads to a result that does not promote the purpose or object underlying the Undertaking;
- (n) in determining whether consideration should be given to any material in accordance with paragraph (m), or in considering any weight to be given to any such material, regard must be had, in addition to any other relevant matters, to:
 - (i) the effect that reliance on the ordinary meaning conveyed by the text of the clause would, have (taking into account its context in the Undertaking and whether that meaning promotes the purpose or object of the Undertaking); and
 - (ii) the need to ensure that the result of the Undertaking is to completely address any ACCC competition concerns;
- (o) the ACCC may authorise the Mergers Review Committee, a member of the ACCC or a member of the ACCC staff, to exercise a decision making function under this Undertaking on its behalf and that authorisation may be subject to any conditions which the ACCC may impose;
- (p) in performing its obligations under this Undertaking, Novartis will do everything reasonably within its power to ensure that its performance of those obligations is done in a manner which is consistent with promoting the purpose and object of this Undertaking.
- (q) a reference to:
 - (i) a thing (including, but not limited to, a chose in action or other right) includes a part of that thing;
 - (ii) a party includes its successors and permitted assigns; and
 - (iii) a monetary amount is in Australian dollars.

Schedule 3 – Confidential

The details of Schedule 3 are confidential.

Annexure 1 - Confidential

The details of Annexure 1 are confidential.