Your Obligations

Principles and Policies

- You are aware of Novartis' obligations under the current version of the Medicines Australia Code of Conduct (and equivalent Codes in Your country of origin and the country in which the Activity is undertaken) and You will not do anything that would result in Novartis being in breach of any such Code. In particular, You will not engage in off-label promotion of a Novartis product
- You agree that any payment to You under this Agreement is not intended to influence any decision You make as a health care professional, including Your decision on the prescribing of products
- You confirm that You have not offered, promised or paid, either directly or indirectly, any benefit to a Government official (including, but not limited to, a healthcare professional employed by a government-owned healthcare facility) to induce such Government official to act in any way in connection with his or her official duties with respect to the Activity performed under this Agreement or to otherwise obtain an improper advantage for You or Novartis
- You must disclose to relevant audiences and in relevant publications or presentations relating to the Activity, any financial support or assistance You have received from Novartis or any relationship You have with Novartis, as required by law or which a reasonable and ethical person would expect to be disclosed in the circumstances
- You confirm You have not been debarred or disqualified from the practice of medicine under applicable law or regulation and You will immediately inform Novartis if this happens at any time after this Agreement is signed
- You are aware of Novartis' obligations for adverse event reporting in accordance with all local laws and regulations including the guidelines titled the *Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines*

Undertaking the Activity

- You are undertaking the Activity for or on behalf of Novartis independently and not as an agent or employee of Novartis
- You will undertake the Activity personally and will not sub-contract performance of it (or part of it) to someone else, without Novartis' prior approval
- You agree that there is no conflict of interest in You undertaking the Activity
- In the event Novartis has disclosed any confidential information to You, You agree to keep that information confidential
- You will undertake the Activity diligently, with all necessary skill and care, and within the timeframe specified in this Agreement or otherwise notified to You by Novartis
- You agree to comply with all relevant laws that apply to You in the performance of the Activity
- If required, You must seek Your employer's approval in accordance with the conditions of Your employment. You must immediately inform Novartis if Your employer refuses to grant approval. The Agreement will not commence until Your employer has granted approval to You.

Privacy and Disclosure Laws

- You consent to Novartis (and entities engaged by Novartis within and outside Australia including: Switzerland, Ireland, India, France and others) collecting, storing and using (including disclosing) Your personal information, for the purpose of the Activity, for the administration of this Agreement, to verify your status as a healthcare professional, and to ask you about the types of information You would like to receive in the future
- You acknowledge that Novartis (and entities engaged by Novartis within and outside Australia)

will collect, store and use (including disclose) Your personal information, to comply with any reporting and disclosure obligations of Novartis under the current version of the *Medicines Australia Code of Conduct* and equivalent codes or laws where the Activity may be undertaken or this Agreement is performed (collectively the **Disclosure Laws**). In particular, You acknowledge that Novartis will publish personal information about You on its website (or on websites where it is required to be published under the Disclosure Laws) including but not limited to the following information:

- Your name and profession
- Your business/practice address
- A description of the Activity You undertook under this Agreement
- The amount of air travel, accommodation costs (room rate), registration fee and any other amount required to be disclosed under the Code paid by Novartis and/or reimbursed to You for You to undertake the Activity

- In accordance with the Disclosure Laws, if You are an HCP registered to practice under a law of Australia, You will be entitled to review and confirm or correct Your personal information prior to publication by Novartis
- Subject to the other privacy obligations mentioned, Your personal information will be handled in accordance with Novartis' Privacy Policy (available at: http://www.novartis.com.au/privacy-policy)

Administrative arrangements

- To the extent that the Activity involves travel for or on behalf of Novartis, such travel will be covered under Novartis' global travel insurance policy. If You travel for personal reasons either before, during or after the Activity, You agree to arrange appropriate travel insurance and/or other coverage in relation to any such personal travel
- You agree not to vary any arrangements relating to the Activity without Novartis' prior approval
- Subject to the below, this Agreement will end when You have completed the Activity and complied with all other obligations under this Agreement. Obligations which are capable of applying after the end of the Agreement will continue to apply, including: Your obligation of confidentiality, Novartis' right to store and use Your personal information for the administration of future Activities, and permission to reproduce Your presentation material and recordings without charge
- If Novartis decides to cancel the Activity (without cause) or the Activity is cancelled by a third party:
  - Novartis will pay for expenses You have reasonably incurred (or for which You are contractually liable) as at the date of cancellation;
  - You must not use any airfares, accommodation, transfers or other entitlements, even though those amounts may have been paid by Novartis;
- Novartis may terminate this Agreement and cancel the Activity without any liability to You, if You are in breach or threatened breach of this Agreement, including the privacy obligations set out above

Pharmacovigilance Principle

Novartis is responsible for monitoring the safety of Novartis Products, in Australia New Zealand.

Both Novartis and You as a service provider are responsible for reporting spontaneous adverse events in accordance with the requirements of local regulatory authorities and international requirements.

In order to fulfill these requirements the parties will comply with the following reporting obligations.

1. All adverse events (AE) that You become aware of during the term of your agreement with Novartis in relation to the use of a Novartis Product, regardless of your causality assessment, must be reported to Novartis Patient Safety (PS) **within twenty-four hours (24 hrs)** of awareness by You. You will notify Novartis Patient Safety by using the Novartis online AE reporting tool, email/fax/phone or verbally, using the Novartis Patient Safety contact details specified below.
2. Novartis Patient Safety will confirm receipt. You must immediately re-send the AE report or contact Novartis Patient Safety if a confirmation of receipt by Novartis is not received within 24 hours or next business day of the initial transmission of the report.
3. Novartis Patient Safety has the responsibility of forwarding the AE to the Global Patient Safety Group of Novartis in accordance with Novartis' internal procedures.
4. Novartis Patient Safety will report the AE to the relevant Health Authority if required. This does not preclude You from also reporting the AE to the health authority in your capacity as a healthcare provider.
5. Novartis Patient Safety may require further details on the reported AE. You agree that Novartis Patient Safety may follow-up with You in order to collect further information on the AE report.
6. The information You provide to Novartis Patient Safety will be treated in accordance with local privacy laws, and the Novartis Privacy Policy, and may be processed and stored on servers located in jurisdictions outside of the country in which it was collected. This information may be shared with health authorities, or other pharmaceutical companies with whom Novartis has a license agreement, and third parties we work with for the purpose of meeting the regulatory requirements for reporting safety information on Novartis products.
7. This Schedule shall be reviewed regularly by both Parties, at least every 3 years or if any of the following Criteria are met: Significant change in the agreement, significant change in the pharmacovigilance regulations or significant change in the status of either Party.

Novartis reserves the right to amend this Agreement at any time if a requirement is imposed upon by an authority or, in its sole clinical discretion, such amendment is necessary for medical safety. Upon written notice from Novartis of any such amendment, You will comply immediately and any failure to comply shall be deemed as a breach of this Agreement.

All procedures are in accordance with the current local Australian Guidelines for Pharmacovigilance titled, Pharmacovigilance responsibilities of medicine sponsors, Australian recommendations and requirements

All procedures are in accordance with the current local New Zealand Regulations, section 41 of the Medicines Act 1981 and Guideline on the Regulation of Therapeutic Products in New Zealand, Part 8: Pharmacovigilance.

Definitions

Adverse event or AE
Any untoward medical occurrence in a patient or clinical-trial subject administered a medicinal product / medical device (MD), and which does not necessarily have to have a causal relationship with this treatment.

An adverse event can therefore be any unfavorable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product/medical device, whether or not considered related to the medicinal product/medical device.
The special scenarios current as at the date of this agreement, includes, all cases of

- Laboratory findings outside a published reference range (without symptom)
- Drug-drug, drug-food interactions (with or without clinical symptoms)
- Kinetic interactions in which the only effect is a change in drug plasma concentrations
- Transmission of infectious disease via medication
- Lack of efficacy, or lack of expected therapeutic effect (as defined in the product label)
- Death without known cause
- Pregnancy exposure (with or without outcome) and drug use during lactation
- Overdose, drug abuse and misuse (with or without symptoms)
- Drug dependence/addiction
- Medication errors such as accidental exposure, occupational exposure, dispensing/prescribing errors, drug maladministration (with or without clinical symptoms)
- Disease progression and aggravation (with or without symptoms)
- Withdrawal reaction/syndrome and rebound effects
- Treatment non-compliance with clinical symptoms
- Unexpected beneficial effect (i.e. beneficial effect that is not related to the indications for which the product was given)
- Off-label use

Hereafter adverse events, special scenarios and other reportable situations are collectively referred as “AEs” in this agreement.

Healthcare Professional (HCP)
A person who is a member of the medical, dental, pharmacy or nursing professions and entitled to provide health care under the laws of jurisdiction or any other person who in the course of their professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product.

Novartis
Novartis Group Companies, including Novartis Pharmaceuticals Australia Pty Limited and Sandoz Pty Ltd shall be referred to as Novartis for the purposes of this Schedule.

Patient Safety
Name of pharmacovigilance department at Novartis.

Products
Any products where Novartis Patient Safety Country Office AU has pharmacovigilance (PV) responsibilities. This includes products managed by the Novartis divisions of Innovative Medicines (comprised of the divisions of Pharmaceuticals and Oncology) and Sandoz. Product primarily refers to

medicinal products. In some cases it may be inclusive of a product registered with the national territory Health Authority as a device or a biological product.

Contact Details for Pharmacovigilance Responsibilities

Novartis Patient Safety
Novartis Pharmaceuticals Australia Pty Ltd
54 Waterloo Road
Macquarie Park NSW 2113

e-mail: patientsafety.aunz@novartis.com
Ph: 1800 814 677 (Australia) 0800 650 555 (New Zealand) / +612 9805 3439
Fax: 1800 650 493 (Australia) 0800 650 493 (New Zealand) /+612 8874 2306
Online: Pharmacovigilance Intake (PVI) website: www.report.novartis.com