



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Agreement for the supply of Reagents

Agreement for the supply of Reagents between the **Commonwealth of Australia** as represented by the Therapeutic Goods Administration of the Department of Health, existing under the laws of Australia ABN 40 939 406 804 (TGA) and the **Recipient**.

The **Recipient** is the organisation (i.e. Official Medicines Control Laboratory, National Regulatory Authority, influenza vaccine manufacturer, reference laboratory or research institution) entering into this Agreement and placing an Order for the supply of Reagents in accordance with this Agreement, or its nominated representative (e.g. nominated marketing and procurement body). The Third Party Contractor may also be a Recipient.

By clicking the "I Agree" button and submitting a completed Order Form, the Recipient:

1. acknowledges that it has read this Agreement;
 2. confirms its agreement with this Agreement; and
 3. confirms its compliance with the Applicable Requirements, including the sanctions regimes as at the date an Order is placed (see clause 6).
- A. As an Essential Regulatory Laboratory (ERL) the TGA standardises Reagents, in collaboration with other ERLs, for supply to vaccine manufacturers worldwide. The TGA undertakes testing in collaboration with the other ERLs.
- B. The TGA and the Recipient enter into this Agreement for the supply of Reagents which will be ordered under the Order Form.
- C. The Recipient acknowledges that the Third Party Contractor produces and supplies the Reagents, and provides the storage and transportation logistics for distribution of the Reagents to vaccine manufacturers for the TGA and that the TGA will also supply the Reagents to other vaccine manufacturers worldwide.

1. Interpretation

1.1 Definitions

Unless otherwise specified, the following definitions apply in this Agreement:

Agency means:

1. a government or government department or other body;
2. a governmental, semi-governmental or judicial person; or
3. a person (whether autonomous or not) who is charged with the administration of a Law,

and unless stated otherwise, includes Commonwealth, State and Territory Agencies in Australia.

Agreement means this agreement for the supply of Reagents, including the terms and conditions to this agreement, all schedules, appendices and plans and procedures referenced in any of those documents, as amended from time to time.

Agreement Material means Material created by the Recipient after the Commencement Date under or in connection with this Agreement, but excludes all Intellectual Property Rights in the Reagents.

Applicable Requirements means any applicable Law or government policy including those listed in **clause 6** or notified by the TGA to the Recipient and agreed in writing as an amendment to this Agreement in accordance with **clause 6**, which from time to time regulates, affects or concerns the provision of the Reagents under this Agreement.

Business Day means a day that is not a Saturday, Sunday or a national public holiday promulgated in the Commonwealth Government Gazette and any day of the week other than a Saturday, Sunday, local public holiday or national public holiday that falls within the jurisdiction in which the Third Party Contractor is located.

Claim means a claim, suit, proceedings, cause of action, demand of any kind, including those which are prospective or contingent and those the amount of which is not ascertained or ascertainable.

Commencement Date means the date 3 Business Days after the Recipient completes the Order Form and agrees to the terms of this Agreement by clicking the "I Agree" button, provided that the TGA has not, in accordance with **clause 2.1(b)**, or **clause 2.1 (e)** notified the Recipient that it does not accept the Agreement.

Completion Date means the date when all invoices are paid in full by the Recipient in accordance with this Agreement.

Confidential Information means information of the TGA or Recipient, as relevant, that:

1. is by its nature confidential;
2. is designated by the TGA or Recipient, as relevant, as confidential; and
3. is listed in the Order Form as being Confidential Information,

but does not include information which:

4. is or becomes public knowledge other than by breach of this Agreement or any other confidentiality obligation; or
5. has been independently developed or acquired by the receiving party as established by written evidence.

Day or day means a calendar day.

Delivery means the supply and delivery of Reagents in accordance with **clause 3.1** of this Agreement. **Deliver** and **Delivered** should be construed accordingly.

Delivery Point means the point where the Reagents are provided to the Recipient or the Recipient's nominated courier at the Third Party Contractor's premises as notified by the Third Party Contractor.

Essential Regulatory Laboratory or **ERL** means a laboratory that supplies and calibrates specific standards for each virus strain included in the vaccine. This enables manufacturers to formulate the vaccine correctly. The TGA is an ERL for influenza and may coordinate or participate in these studies.

Force Majeure means:

1. any occurrence or omission as a direct or indirect result of which the Party relying on it is prevented from or delayed in performing any of its obligations under this Agreement and that is beyond the reasonable control of that Party; or
2. an act of war (whether declared or not), terrorism, the mobilisation of armed forces, civil commotion or riot, natural disaster, lightning, fire, earthquake, storm, flood, drought, disease, explosion, industrial action or labour disturbance, currency restriction, embargo, action or inaction by an Agency, (except the TGA), or a failure of a supplier other than the TGA, public utility or common carrier.

GST has the same meaning as in the GST Law.

GST Law has the same meaning as in the *A New Tax System (Goods and Services Tax) Act 1999* (Cth) and any regulations made pursuant to that Act.

Handling Fee means the fee for the Reagents as specified in the Order Form, or as updated on the TGA website from time to time.

Indemnified Person means the TGA and TGA Personnel.

Insolvency Event means, for a person, being in liquidation or provisional liquidation or under administration, having a controller or analogous person appointed to it or any of its property, having failed to comply with a statutory demand, being unable to pay its debts or otherwise insolvent, dying, ceasing to be of full legal capacity or otherwise becoming incapable of managing its own affairs for any reason, taking any step that could result in the person becoming an insolvent under administration, entering into a compromise or arrangement with, or assignment for the benefit of, any of its members or creditors, or any analogous event.

Intellectual Property Rights or **IPR** means copyrights, and all rights in relation to inventions, patents, registered and unregistered trade marks (including service marks), registered designs, circuit layouts, and all other rights resulting from intellectual activity

in the industrial, scientific, literary or artistic fields and includes the right to apply for registration of any such rights.

Law means any applicable statute, regulation, by-law, ordinance or subordinate legislation in force from time to time anywhere including in Australia (whether made by a State, Territory, the Commonwealth, or a local government), the jurisdiction of the Recipient and overseas, and includes the common law and equity as applicable from time to time.

Loss or Losses means any loss, damage (whether direct or indirect), liability, cost or expense including legal costs and expenses on a solicitor and own client basis.

Material includes tangible property, documents, equipment, software, goods, information and data stored by any means.

Moral Rights means rights of integrity of authorship, rights of attribution of authorship, rights not to have authorship falsely attributed, and rights of a similar nature conferred by any law that exists, or may come to exist.

Order means an order submitted by the Recipient to the TGA for the supply of Reagents, pursuant to the Order Form and this Agreement.

Order Form means a form completed by the Recipient to place an Order for the supply of Reagents substantially in the form of **Schedule 1 - Influenza Reagent Order Form**, which may be updated from time to time.

Party means either the Recipient or the TGA, as the context requires.

Personal Information has the meaning given in the Privacy Act.

Privacy Act means the *Privacy Act 1988* (Cth).

Reagents means the influenza standardisation reagents that comprise of matched antigen and antisera produced by the Third Party Contractor as specified in the Order Form.

Recipient Personnel means the individuals who are the officers, employees, agents, subcontractors or advisers of the Recipient.

Recipient Representative means the person holding the position specified in the Order Form or any replacement person(s) appointed in accordance with **clause 7**.

Related Body Corporate has the meaning given in the *Corporations Act 2001* (Cth).

Single Radial Immunodiffusion or SRID means the immunodiffusion technique used in immunology to determine the quantity or concentration of haemagglutinin (HA) antigen in a sample (i.e. vaccine) using an immunological reaction between antibodies and the test antigen.

Taxes means any tax, levy, duty, charge, deduction or withholding, however it is described, imposed by an Agency, together with any related interest, penalty, fine or other charge.

Term means the term of this Agreement as described in **clause 2.1** and any reduction of that period under this Agreement.

TGA Material means any Material provided by the TGA to the Recipient for the purposes of this Agreement including any online forms completed by the Recipient, the Instructions for Use and any Material from the Third Party Contractor relevant to the Reagents, or which is copied or derived from Material so provided.

TGA Personnel means the individuals who are officers, employees, agents, advisers or subcontractors of the TGA.

TGA Representative means the person holding the position specified in the Order Form or any replacement person(s) appointed in accordance with **clause 7**.

Third Party Contractor means the contractor that manufacturers and/or supplies the Reagents to the TGA.

Wilful Misconduct means an act or omission that is taken:

1. intentionally to achieve a wrongful purpose;
2. without legal or factual justification; and
3. in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

1.2 Rules for interpreting this Agreement

1. Headings are for convenience only, and do not affect interpretation.
2. A reference to:
 - i) legislation (including subordinate legislation) is to that legislation as amended, re-enacted or replaced, and includes any subordinate legislation issued under it;
 - ii) a document or agreement, or a provision of a document or agreement, is to that document, agreement or provision as amended, supplemented, replaced or novated;
 - iii) a Party to this Agreement or to any other document or agreement includes a permitted substitute or a permitted assign of that Party;
 - iv) a person includes any type of entity or body or persons, whether or not it is incorporated or has a separate legal identity, and any executor, administrator or successor in Law of the person;
 - v) anything (including a right, obligation or concept) includes each part of it, provided that nothing in this **clause 1.2** implies that performance of part of an obligation constitutes performance of that obligation;
 - vi) writing includes any mode of representing or reproducing words in tangible and permanently visible form, and includes email transmissions;
 - vii) the background, a recital, clause, schedule or appendix is to the background, a recital, clause, schedule or appendix (as amended from time to time) of or to this Agreement;
 - viii) monetary units is to units of Australian currency;
 - ix) a matter being to the knowledge of a person means that the matter is to the best of the knowledge and belief of that person after proper inquiry, including inquiry which a reasonable person would be prompted to make by reason of knowledge of a fact; and

- x) words "includes" or "including" means without limitation.
- 3. A singular word includes the plural, and vice versa.
- 4. A word which suggests one gender includes the other gender.
- 5. If an example is given of anything (including a right, obligation or concept), such as by saying it includes something else, the example does not limit the scope of that thing.
- 6. The word "**agreement**" includes an undertaking or other binding arrangement or understanding, in writing.
- 7. A document will be incorporated into and form part of this Agreement if the Parties to this Agreement sign the document, and it is referred to in this Agreement, or the Parties expressly intend it to form part of this Agreement, and a reference to such a document is to that document as amended from time to time in accordance with the provisions of this Agreement.
- 8. Where a term is defined in this Agreement, another part of speech or grammatical form of that term has a corresponding meaning.
- 9. If the Day on or by which a person must do something under this Agreement is not a Business Day, the person must do it on or by the next Business Day.
- 10. If there is any inconsistency between:
 - i) the clauses of this Agreement and the schedules or any other document, the clauses of this Agreement will prevail to the extent of any inconsistency;
 - ii) a schedule to this Agreement and the content of a document incorporated as part of this Agreement, the content of the schedule to this Agreement will prevail to the extent of any inconsistency; and
 - iii) an obligation under this Agreement to comply with a Law and an obligation to comply with a standard that does not have force of law, the obligation to comply with the Law will prevail to the extent of any inconsistency.
- 11. In entering into this Agreement, the TGA is acting in its regulatory capacity as an ERL.
- 12. This Agreement applies to each Order Form that is lodged.
- 13. The terms of the Incoterms 2010 EXW only apply to this Agreement to the extent they are specifically referenced (with references to "the buyer" to be read as "the Recipient" and "the seller" to be read as "the TGA"). If there is any inconsistency between a term of the Incoterms 2010 EXW and a term of this Agreement, the term of this Agreement prevails to the extent of the inconsistency.

2. Scope of Agreement

2.1 Term of Agreement

1. Subject to this Agreement or Law, this Agreement commences on the Commencement Date and expires on the Completion Date.
2. Subject to **clauses 2.1(d)** and **2.1(e)**:
 - i) the TGA may, within 5 Business Days after the Recipient completes the Order Form and agrees to the terms of this Agreement by clicking the "I Agree" button, advise the Recipient that it does not accept the Agreement; and
 - ii) the TGA will also advise the Recipient what action is required by the Recipient to enable it to place an Order. The Recipient must then re-submit an Order and Agreement.
3. Subject to **clauses 2.1(d)** and **2.1(e)**, where the TGA does not advise the Recipient in accordance with **clause 2.1(b)** that it does not accept the Agreement, the TGA is deemed to have accepted the Agreement.
4. The Recipient acknowledges that during periods of high demand for the supply of the Reagents, the TGA may require more than 5 Business Days to advise the Recipient that it does not accept the Agreement under **clause 2.1(b)**. Where the TGA anticipates that it will require more than 5 Business Days, the TGA will promptly notify the Recipient in writing.
5. Where **clause 2.1(d)** applies:
 - i) the TGA will not be deemed to have accepted the Agreement in the manner contemplated in **clause 2.1(c)**. The TGA will notify the Recipient in writing to confirm whether or not the TGA accepts the Agreement. If the TGA it does not accept the Agreement, then **clause 2.1(b)(ii)** applies; and
 - ii) the delay in TGA accepting or not accepting the Agreement does not constitute an event of Force Majeure.

3. Supply, Delivery and Return of Reagents

3.1 Delivery of Reagents

1. Clauses A3(a) (Contracts of carriage and insurance) and A4 (Delivery) of the Incoterms 2010 EXW apply to this Agreement and set out delivery terms.
 2. The TGA must ensure that the Reagents are packaged in the manner appropriate for their transport.
 3. The Recipient must:
 - i) take Delivery of the Reagents when clauses A4 (Delivery) and A7 (Notice to the buyer) of the Incoterms 2010 EXW have been complied with by the TGA; and
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- ii) provide the TGA with confirmatory email of receipt of the Reagents.

Note: Appropriate evidence may include a receipt, for example a packing list or some other document.

- 4. Delivery of the Reagents to the Recipient will be deemed to be complete on the date the Recipient or its nominee takes physical possession of the Reagents.
- 5. The Recipient is responsible for loading the Reagents at the Delivery Point.
- 6. Where the Recipient requires assistance to load the Reagents at the Delivery Point, the TGA will facilitate the Recipient and the Third Party Contractor to agree to general arrangements for loading the Reagents. The Recipient will bear the costs, if any, in relation to such arrangements.
- 7. The TGA is not liable to meet or contribute to any costs or expenses reasonably incurred by the Recipient in storing, transporting or replacing the Reagents or otherwise incurred by the Recipient unless expressly provided for by this Agreement or other storage or distribution arrangement agreed with the TGA for the period after the Recipient owns the Reagents.

3.2 Ownership and risk

- 1. Ownership of the Reagents will pass to the Recipient upon Delivery in accordance with **clause 3.1(a)**.
- 2. Clause A5 (Transfer of risks) of the Incoterms 2010 EXW applies to this Agreement.
- 3. The Recipient bears all risk of Loss of or damage to the Reagents after the time the Reagents have been Delivered in accordance with **clause 3.1(a)**.

3.3 Delay

In the event that the TGA anticipates a delay to the Delivery of the Reagents, the TGA must notify the Recipient promptly in writing of the likely delay, the reasons for the delay, the proposed mitigation strategies.

3.4 Export licences, authorisations, security clearances, other formalities and information

- 1. Clauses B2 (Licences, authorizations, security clearances and other formalities), A10 (Assistance with information and related costs) and B10 (Assistance with information and related costs) of the Incoterms 2010 EXW apply to this Agreement.
- 2. The TGA must provide at the Recipient's request, risk and expense, any information in the possession of the TGA that is required for security clearance of the Reagents.

3.5 Returns and Refunds

1. Due to the nature of the Reagents, Reagents correctly supplied and Delivered in accordance with the Agreement will not be accepted for return and/or subject to refunds by the TGA.
2. Where the TGA accepts in writing that it has made an error in the Delivery of the Reagents to the Recipient (Affected Reagents) it will make arrangements with the Third Party Contractor to replace the Affected Reagents and notify the Recipient in writing. If replacement is not possible, then the TGA will credit any invoice issued and/or where relevant make arrangements to refund the Recipient any amount paid for those Affected Reagents.
3. The Recipient will not be entitled to a refund for Affected Reagents in the manner contemplated in **clause 3.5(b)** if the error is due to the act or omission of the Recipient.
4. Where the Recipient is entitled to a refund for Affected Reagents in the manner contemplated in **clause 3.5(b)**, the Recipient must dispose of the Reagents in accordance with all relevant Laws at its own cost.

4. Purpose and use of Reagents

1. The Recipient acknowledges that the Reagents are required for influenza vaccine formulation and to perform potency testing for influenza viruses by SRID assay. The purified antigen for use as a standardisation Reagent is produced for testing purposes.
2. The Recipient must only use the Reagents supplied under this Agreement in accordance with the relevant Instructions for Use available at: <https://www.tga.gov.au/influenza-reagents> and for the following purposes:
 - i) use as a standard or reference material in laboratory work in relation to biological research, manufacturing or quality control testing of biological products or in the field of in vitro diagnostics potency testing of influenza viruses by SRID; and
 - ii) Method Development (meaning finding more efficient and effective ways of testing) may be required.
3. For the avoidance of doubt, the Recipient is prohibited from using the Reagents for any other use or purpose other than in accordance with **clause 4(b)**. In particular, the Recipient:
 - i) must not sell or otherwise transfer its interest in the Reagents to any third party (except, for the avoidance of doubt, that provision of the Reagent to the Recipient organisation from its nominated representative (if any) is permitted);
 - ii) must not remove any copyright or proprietary notice in respect of Reagents;
 - iii) must use reasonable care and protection to prevent the unauthorised use, copying, publication or dissemination of information in respect of the Reagents;

- iv) must not use the Reagents for any purpose other than for the purposes of this Agreement; and
- v) must not sub-license any right granted to it by the TGA to any third party without the TGA's prior written consent.

5. Pricing Arrangements

5.1 Handling Fee for the Reagents

1. The Handling Fee for each of the Reagents is inclusive of all taxes (excluding GST). The Handling Fee may be updated by the TGA from time to time (see the TGA's website).
2. Except as expressly provided otherwise in this Agreement, the Handling Fee for the Reagents includes all packaging, transport, loading, unloading, storage and other costs and expenses of the TGA, up to the Delivery Point of the Reagents, including unloading of the Reagents at the Delivery Point.
3. The Handling Fee excludes GST and the costs payable by the Recipient under **clause 5.2**. Where GST is payable, it will be applied in accordance with **clause 5.5**.

5.2 Other costs

Clauses A6 (Allocation of costs), B6 (Allocation of costs) and B9 (Inspection of goods) of the Incoterms 2010 EXW apply to this Agreement.

5.3 Payments

1. All payments for Reagents under this Agreement are subject to:
 - i) Delivery of the Reagents in accordance with **clause 3.1(a)** (except for supply to Recipients in countries where evidence of payment is required to be provided with the Reagents for customs purposes); and
 - ii) receipt by the Recipient of an invoice for the Reagents in accordance with this Agreement.
2. Unless otherwise agreed:
 - i) any payments under this Agreement will be made by electronic transfer directly into a nominated bank account or by credit card, as specified at: <https://www.tga.gov.au/payment-options>;
 - ii) payments will be made in Australian dollars; and
 - iii) the Recipient is responsible for payment in Australian dollars of any bank charges charged in Australia or outside Australia that are applicable to any payments under this Agreement.

3. Payments are deemed to be made on the date they are received by the TGA's nominated bank.
4. Subject to the Delivery of the Reagents by the TGA and unless otherwise specified in this Agreement, amounts payable for the Reagents specified in an invoice must be paid within 28 Days after the date of receipt of the invoice.
5. Payment for Reagents under this Agreement is a fundamental term of this Agreement.

5.4 Invoices

1. Except for supply to Recipients in countries where payment documentation must be provided with the Reagents for customs purposes, the TGA must submit invoices to the Recipient for the Reagents as soon as practical after Delivery of the Recipients at the address specified in the Order Form or as otherwise agreed by the Parties in writing.
2. The TGA must provide all invoices in a soft copy format that is a PDF email of the invoice. An invoice is deemed to be received 1 Business Day after the date of sending, unless the TGA knows or reasonably ought to suspect that the email and the attached invoice were not delivered.
3. An invoice submitted for payment under **clause 5.4(a)** must contain each of the matters specified in the Order Form as well as all information required in an invoice for the purposes of the GST Act (where applicable).
4. If an invoice is found to have been rendered incorrectly, any underpayment or overpayment will be recoverable by or from the TGA, as the case may be, and, without limiting recourse to other available remedies, may be offset against any amount subsequently due to the TGA (including under another invoice).
5. Without limiting **clause 5.4(d)**, if the Recipient in good faith disputes the whole or any portion of the amount claimed in an invoice, the Recipient:
 - i) may withhold payments that are in dispute until the dispute is resolved; and
 - ii) must notify the TGA in writing (within 4 Days after receipt of the invoice) of the reasons for disputing the remainder of the invoice.
6. The TGA reserves the right to not fill any future orders of Reagents until any outstanding invoices have been paid by the Recipient or the invoice dispute is otherwise resolved.

5.5 Taxes

Note: Clause 5.5 only applies where supply of the Reagents is to a Recipient in Australia.

1. If a Party (**Supplying Party**) makes a supply under or in connection with this Agreement in respect of which GST is payable (**Taxable Supply**), the recipient of the Taxable Supply (**Taxable Supply Recipient**) must pay to the Supplying Party, an additional amount equal to the GST payable on the Taxable Supply (**GST Amount**).

2. If a Party must reimburse or indemnify another Party for a Loss, the amount to be reimbursed or indemnified is first reduced by any input tax credit the other Party is entitled to for the Loss, and then increased in accordance with **clause 5.5(a)**.
3. If a payment is calculated by reference to or as a specified percentage of another amount or revenue stream, that payment will be calculated by reference to or as a specified percentage of the amount or revenue stream exclusive of GST.
4. If the GST payable by a Supplying Party on any Taxable Supply made under or in connection with this Agreement varies from the GST Amount paid or payable by the Taxable Supply Recipient under **clause 5.5(a)** such that a further amount of GST is payable in relation to the Taxable Supply or a refund or credit of GST is obtained in relation to the Taxable Supply, then the Supplying Party will provide a corresponding refund or credit to, or will be entitled to receive the amount of that variation from, the Taxable Supply Recipient.
5. Any payment, credit or refund under this **clause 5.5** is deemed to be a payment, credit or refund of the GST Amount payable under **clause 5.5(a)**.
6. If an adjustment event occurs in relation to a Taxable Supply, the Supplying Party must issue an adjustment note to the Taxable Supply Recipient in relation to that Taxable Supply within 14 Days after becoming aware of the adjustment.
7. A Party need not make a payment for a Taxable Supply made under or in connection with this Agreement:
 - i) until it receives an invoice for the Taxable Supply to which the payment relates; and
 - ii) in the case of an invoice issued by the TGA, the invoice complies with **clause 5.4**, unless any requirement of that clause is inconsistent with the GST Act.
8. If the rate of GST varies, the Parties must, by amendment in writing to this Agreement in accordance with **clause 14.5**:
 - i) make a corresponding variation to the Handling Fee; and
 - ii) provide that the date on which any payment of the Handling Fee will vary as a result of the variation in the rate of GST will be the effective date of the variation of the rate of GST.
9. Except as provided in this **clause 5.5**, all Taxes imposed or levied in Australia or overseas in connection with this Agreement are to be borne by the TGA.

5.6 Costs and Stamp Duty

Each Party must bear and is responsible for its own costs in connection with the preparation, execution and carrying into effect of this Agreement.

6. Applicable Requirements

1. The Recipient must comply with, and use reasonable endeavours to ensure that Recipient Personnel comply with all the Applicable Requirements in using the Reagents including:
 - i) *Autonomous Sanctions Act 2011* (Cth);
 - ii) *Australian Autonomous Sanctions Regulations 2011*;
 - iii) Part 4 of the *Charter of United Nations Act 1945* (Cth);
 - iv) *Charter of United Nations (Dealing with Assets) Regulations 2008* (Cth);
 - v) all applicable Laws dealing with the supply and/or export of goods, services and information to foreign nationals or institutions, including under the *Customs Act 1901* (Cth); and
 - vi) Global Vaccine Action Plan 2011 - 2020.
2. The Recipient acknowledges that it is an offence to knowingly make any funds or assets available to a person or organisation on the list of persons and entities designated as terrorist, available at http://www.dfat.gov.au/icat/UNSC_financial_sanctions.html.
3. The Recipient must comply with the United Nations Security Council (**UNSC**) sanctions regimes under the *Charter of the United Nations Act 1945* (Cth) and the Australian autonomous sanctions regimes under the *Autonomous Sanctions Act 2011* (Cth).
4. In performing its obligations under this Agreement, the Recipient must not undertake an activity that is in breach of a UNSC sanction regime or Australian autonomous sanction regime in respect of a particular country, including:
 - i) making a sanctioned supply of export sanctioned goods;
 - ii) making a sanctioned import of import sanctioned goods;
 - iii) providing a sanctioned service;
 - iv) engaging in a sanctioned commercial activity;
 - v) dealing with a designated person or entity;
 - vi) using or dealing with a controlled asset; or
 - vii) the entry into or transit through Australia of a designated person or a declared person.

Further information regarding the sanctions regimes is available at <http://dfat.gov.au/international-relations/security/sanctions/sanctions-regimes/Pages/sanctions-regimes.aspx>.

7. Agreement Management

1. Each Party must at all times during the Term nominate a representative with authority to receive and sign notices and written communications for all matters arising under or in connection with this Agreement.
2. As at the Commencement Date, the Recipient Representative and the TGA Representative for each Party will be relevant person(s) specified in the Order Form. Replacement Representatives may be nominated by providing the other party with written notice.
3. The TGA Representative must liaise with the Recipient Representative as reasonably required by the TGA Representative during the Term.

8. Public Affairs Management

Without limiting the obligations of the Recipient in **clause 9**, but subject to any Law to the contrary, the Recipient must not make any public announcement in relation to the supply or use of the Reagents, this Agreement or to matters arising under or in connection with this Agreement to the general public or to a specific class of the general public without the prior written consent of the TGA.

9. Confidentiality and Privacy

9.1 Confidentiality

1. Subject to **clause 9.1(b)**, no Party to this Agreement (including any Personnel or subcontractor of the Party) may disclose any Confidential Information of the other Party to a third person without prior approval in writing from that Party.
2. No Party to this Agreement may disclose the other Party's Confidential Information except:
 - i) to the extent required by Law or by a lawful requirement of any Agency having authority over the first-mentioned Party;
 - ii) subject to any Law to the contrary, if required in connection with legal proceedings;
 - iii) in the case of the TGA, subject to any Law to the contrary and **clause 9.1(c)**, for governmental, reporting or public accountability reasons, including a request for information by the responsible Minister, a House of the Parliament of the Commonwealth of Australia or any State or Territory or a Parliamentary committee;
 - iv) to the extent necessary in order to obtain advice in relation to its rights under this Agreement;
 - v) to other regulatory authorities (if any);

- vi) to an Agency or to the Third Party Contractor for the purposes of the performance of this Agreement;
 - vii) to its officers or employees to the extent reasonably necessary to exercise its rights or to perform its obligations under this Agreement;
 - viii) in the case of the Recipient, to its external auditors where required for mandatory auditing requirements under the Laws of the jurisdiction in which it is incorporated or the rules of a stock exchange having authority in respect of the Recipient or its Related Body Corporates; and
 - ix) in the case of the Recipient, as part of its mandatory reporting requirements as a public company or under the rules of a stock exchange.
3. Except for disclosure under **clause 9.1(b)(iii)**, the party disclosing the information must ensure that the recipient of the information is made aware of the confidentiality of the Confidential Information.
4. It is acknowledged that where disclosure is made under **clauses 9.1(b)(i), 9.1(b)(ii) and 9.1(b)(iii)**, no guarantee can be given that the information may not be further disclosed by the recipient.

9.2 Protection of Personal Information

1. This **clause 9.2** applies only where the Recipient deals with Personal Information when, and for the purpose of, performing its obligations under this Agreement, and is restricted to Personal Information held or controlled by the Recipient in connection with this Agreement.
2. The Recipient agrees in respect of the supply of the Reagents under this Agreement:
- i) to use or disclose Personal Information obtained during the course of providing the Reagents under this Agreement only for the purposes of this Agreement;
 - ii) not to do any act or engage in any practice which, if done or engaged in by the TGA, would be a breach of the requirements of Division 2 of Part III of Privacy Act; and
 - iii) to otherwise comply with, and ensure all Recipient Personnel comply with, the Australian Privacy Principles (as defined in the Privacy Act).
3. Without limitation, in respect of eligible data breaches under the Privacy Act relevant to the Recipient and this Agreement, the Recipient must:
- i) ensure that the TGA is kept informed of any assessment (or requirement to make an assessment) of a suspected eligible data breach;
 - ii) take all reasonable measures, promptly and in accordance with the timeframes in the Privacy Act including assisting the TGA in any investigations, in order to determine:
 - i. whether an eligible data breach has occurred, or whether there are reasonable grounds to suspect an eligible data breach has occurred; and

- ii. the requirements to notify the Office of the Australian Information Commissioner (**OAIC**) and any third parties in respect of such eligible data breach; and
 - iii) work with the TGA to agree, who will issue notification of the eligible data breach to the OAIC and relevant third parties if the eligible data breach applies to both the Recipient and the TGA.
4. The Recipient agrees to ensure that any subcontract entered into for the purpose of fulfilling its obligations under this Agreement contains provisions to ensure that the subcontractor has the same awareness and obligations as the Recipient has under this **clause 9.2**, including the requirement in relation to subcontracts.

10. Freedom of Information

The Recipient must comply with, and must do such things as may be reasonably necessary to assist the TGA to comply with, the *Freedom of Information Act 1982* (Cth) and the *Freedom of Information Amendment (Reform) Act 2010* (Cth).

11. Intellectual Property Rights

11.1 Acknowledgement

This **clause 11** does not affect the ownership of the Intellectual Property Rights owned by either Party or the Third Party Contractor's Intellectual Property Rights in the Reagents and any Third Party Contractor Material.

11.2 Reagents

1. All Intellectual Property Rights in the Reagents remain at all times vested in the Third Party Contractor.
2. The Recipient must only use the Reagents in accordance with this Agreement.
3. The Recipient must not, and must ensure that its Recipient Personnel do not, modify the Reagents.

11.3 Agreement Material

1. All Intellectual Property Rights in any Agreement Material vests in, or, is hereby transferred or assigned to, the Recipient, immediately upon creation.
2. The Recipient grants the TGA a non-exclusive, perpetual, irrevocable, royalty free, transferable licence (including a right of sublicense) to use, copy, adapt, translate, reproduce and in any way exploit that Agreement Material (including any pre-existing Material embedded in that Agreement Material) for the TGA's purposes.

11.4 TGA Material

1. On and from the Commencement Date, the TGA grants the Recipient a non-exclusive, non-transferable, royalty-free licence for the Recipient and Recipient Personnel to use the TGA Material to the extent necessary for the Recipient to use the Reagents in accordance with this Agreement.
2. The Recipient must not (and must ensure that Recipient Personnel do not) modify the TGA Material.

11.5 Moral Rights

1. To the extent permitted by applicable Laws and for the benefit of the TGA, the Recipient must obtain from individuals as required genuine consent in writing to any act or omission that would otherwise infringe that individual's Moral Rights in any Agreement Material, and in particular consents to:
 - i) any use of that Agreement Material that does not identify that individual;
 - ii) any use of that Agreement Material that may falsely attribute authorship of that Material to any other person; and
 - iii) any variation to that Agreement Material.

12. Warranties and Indemnities

12.1 General warranties

1. Each Party warrants that:
 - i) it has full legal capacity and power:
 - i. to own its property and to carry on its business; and
 - ii. to enter into this Agreement;
 - ii) it holds each Authorisation that is necessary or desirable to:
 - i. execute this Agreement and to carry out the transactions that are contemplated by the same;
 - ii. ensure that this Agreement is legal, valid, binding and admissible in evidence; and
 - iii. enable it to properly carry on its business,and it is complying with any conditions to which any of these Authorisations is subject;
 - iii) is not affected by an Insolvency Event; and
 - iv) is not entering into this Agreement as trustee of any trust or settlement.
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2. Subject to any Law to the contrary, the Recipient agrees that the TGA's liability for failure to Deliver the Reagents will be limited to:
 - i) the replacement of the Reagents or supply of equivalent reagents; or
 - ii) the payment of the cost of replacing the Reagents or acquiring equivalent reagents.

12.2 Product liability

The Recipient should refer to the product liability provisions in the relevant Instructions for Use.

12.3 Recipient Indemnity

1. In respect of Reagents, the Recipient must at all times indemnify, and keep indemnified, the Indemnified Persons from and against any Loss incurred by any of the Indemnified Persons caused by or arising from any Claim by any person against any Indemnified Persons, to the extent that:
 - i) the Recipient has failed to use the Reagents in accordance with this Agreement, including any Intellectual Property Rights breach caused by the Recipient or Recipient Personnel;
 - ii) without limiting **clause 12.3(a)(i)**, the Loss was caused or contributed to in any way by any Wilful Misconduct, or any unlawful or negligent act or omission of the Recipient, or any Recipient Personnel, in the performance of this Agreement; or
 - iii) the Loss arises directly or indirectly from a breach of any of the obligations of the Recipient under **clause 9.2** or a subcontractor under the subcontract provisions referred to in **clause 9.2(d)**.
2. The Recipient's liability to any Indemnified Person under **clause 12.3(a)** will be reduced proportionally to the extent that any unlawful, or negligent act or omission or Wilful Misconduct of any Indemnified Person caused or contributed to the Loss.
3. It is not necessary for the Indemnified Person to have incurred any expense or made any payment before enforcing an indemnity under this Agreement.
4. Nothing in an indemnity contained in **clause 12.3(a)** shall in any way reduce or qualify an Indemnified Person's rights at Law in respect of the events which are the subject of the indemnity.

12.4 Indemnity requirements

1. The Recipient's obligation to indemnify an Indemnified Person is subject to the Indemnified Person:
 - i) giving prompt notice to the Recipient after becoming aware of any Claim giving rise to the indemnity; and

- ii) not making an admission or prejudicing the indemnifying Party's defence of any Claim or the indemnifying Party's ability to negotiate a satisfactory settlement;
 - iii) subject to **clause 12.4(b)**, allowing the indemnifying Party an opportunity to comment on, at the indemnifying Party's expense, the conduct of the defence and any negotiations for the settlement of any Claim giving rise to such indemnity; and
 - iv) taking reasonable steps to mitigate any Loss.
2. The Recipient acknowledges that the TGA is required to comply with government policy in the conduct of litigation (including, in the case of Health, the Legal Services Directions made under section 55ZF of the *Judiciary Act 1903* (Cth)). Where the Recipient conducts any litigation in relation to any indemnity under this Agreement, the Recipient must comply with the Legal Services Directions.

12.5 Disclaimer

1. The Recipient:
- i) agrees that it has sought appropriate professional advice about:
 - i. any information, statements, or representations relating to the Reagents, including those contained in the relevant Instructions for Use; and
 - ii. the regulatory regime applicable to the supply of the Reagents to the Recipient;
 - ii) acknowledges that, subject to any Law to the contrary, and to the maximum extent permitted by Law, the TGA (including TGA Personnel) disclaim all liability for any Loss (whether feasible or not) suffered by any other person acting in reliance on any part of the information, statements, or representations in **clause 12.5(a)(i)A**, whether or not the Loss arises in connection with any negligence, default or lack of care on the part of the TGA, TGA Personnel or any other person or any misrepresentation or any other cause;
 - iii) agrees that none of the TGA or TGA Personnel (to the extent permitted by Law):
 - i. profess any expertise, or represent any willingness to apply any expertise, for the benefit of the Recipient;
 - ii. make any express or implied representation or warranty that any estimate or forecast will be achieved or that any statements as to future matters will prove correct;
 - iii. (except so far as liability under any Law cannot be excluded) accept responsibility arising in any way for errors in, or omissions from, the information, statements, or representations in **clause 12.5(a)(i)A**, or in negligence in relation to the information, statements, or representations in **clause 12.5(a)(i)A**; or

- iv. assume any duty of disclosure or fiduciary duty to any interested person.

12.6 Insurance

1. Clause A3(b) (Contracts of carriage and insurance) of the Incoterms 2010 EXW applies to this Agreement.
2. The Recipient must hold all insurance relevant to the conduct of its business.

13. Termination

13.1 Mitigation

Each Party must seek to minimise its Losses in the event of the occurrence of a Force Majeure event, termination (in whole or part) or expiration of this Agreement.

13.2 Termination for default

1. Either Party may terminate this Agreement, by notice in writing to the other Party, with effect on and from the date specified in the notice if that other Party:
 - i) suffers an Insolvency Event;
 - ii) ceases, or threatens to cease, to carry on its business;
 - iii) fails to comply with a fundamental term of this Agreement and failure is not capable of remedy; and
 - iv) fails to comply with a fundamental term of this Agreement, and where that failure is capable of remedy, fails to commence to remedy the failure by 30 Business Days (or such other date agreed by the Parties) after receipt of a notice of default from the other Party.
2. The TGA may terminate this Agreement, by giving at least 10 Business Days' notice in writing, if:
 - i) the Recipient assigns or novates its rights otherwise than in accordance with the requirements of this Agreement; or
 - ii) the Recipient fails to use any of the Reagents in accordance with this Agreement.

13.3 Effect of termination

If this Agreement is terminated:

1. the Parties to this Agreement are relieved from future performance, without prejudice to any right of action that has accrued at the date of termination; and

2. the TGA will be paid (by the Recipient, as required in accordance with the terms of this Agreement) for any Reagents Delivered in accordance with this Agreement up to the date of termination.

13.4 Force Majeure

1. Neither Party will be considered to be in breach, or be liable to the other Party, in respect of any delay or failure to perform its obligations pursuant to this Agreement, if and to the extent such delay or failure is caused by an event of Force Majeure provided that the non-performing Party is without fault in causing the failure or delay, and the failure or delay could not have been prevented by reasonable precautions and cannot reasonably be circumvented by the non-performing Party at its reasonable expense through the use of alternate sources, work around plans or other means.
2. The TGA will not have the right to any payments from the Recipient as a result of any Force Majeure event except that the Recipient remains obliged to pay for Reagents that have been Delivered in accordance with this Agreement.

14. General obligations

14.1 Dispute resolution

1. The Parties to this Agreement agree that any dispute arising about this Agreement will be dealt with as follows:
 - i) first, the Party claiming that there is a dispute will send to the other a notice setting out the nature of the dispute;
 - ii) secondly, the Parties will try to resolve the dispute by direct negotiation, including by referring the matter to persons who have authority to intervene and direct some form of resolution;
 - iii) thirdly, the Parties have 10 Business Days from the receipt of the notice to reach a resolution or to agree that the dispute will be submitted to mediation or some other form of alternative dispute resolution procedure; and
 - iv) lastly, if:
 - i. there is no resolution or agreement; or
 - ii. there is a submission to mediation or some other form of alternative dispute resolution procedure, but there is no resolution within 15 Business Days after the submission, or such extended time as the Parties may agree in writing before the expiration of the 15 Business Days,then, either Party may commence legal proceedings.
2. Despite the existence of a dispute, the TGA will (unless requested not to do so by the Recipient in writing) continue to provide the Reagents.

3. Without limiting a Party's right to commence legal proceedings in relation to a dispute, this **clause 14.1**:
 - i) does not apply to action by a Party under or purportedly under but subject to **clause 13**; and
 - ii) does not preclude either Party from commencing legal proceedings for urgent interlocutory relief.

14.2 Audit

The TGA or its representative may conduct monitoring, inspections, investigations or audits (**audits**) relevant to the Recipient's performance under this Agreement, including its use of the Reagents, and any other matters reasonably determined by the TGA to be relevant to the Recipient's performance under this Agreement. The Recipient must provide the TGA or its representative with any information available to the Recipient to assist with an audit.

14.3 Disclosure of proceedings

The Recipient must disclose any litigation, arbitration, mediation, conciliation, proceedings (administrative or otherwise) or any investigations (**Proceedings**) that are taking place, are pending, or to the best of any of the Recipient Personnel's knowledge after due inquiry, are threatened against it or a Related Body Corporate which, if adversely decided, would in all the circumstances be reasonably likely to have a material adverse effect on the Recipient's ability to perform its obligations under this Agreement, and/or the Recipient's reputation.

14.4 Assignment and novation

Neither Party may assign or transfer any of its rights or obligations under this Agreement without the prior consent in writing of the other Party, such consent not to be unreasonably delayed and not to be unreasonably withheld.

14.5 Variation

This Agreement (including all Schedules) cannot be varied, except with the agreement of the Parties effected by formal amendment in writing and signed by an authorised representative on behalf of each Party to this Agreement.

14.6 Notices

1. Subject to this **clause 14.6(a)**, a notice or consent, report or other communication (**Notice**) under this Agreement is only effective if it is in writing, signed by or on behalf of the person giving it and addressed to the person to whom it is to be given, and either:

- i) hand delivered (received on delivery) or sent by pre-paid mail (by airmail, if the addressee is overseas) (received 3 Business Days after the date of posting or 7 Business Days after the date of posting if posted to or from outside Australia) to that person's address; or
 - ii) sent by email to that person's email address (received 1 Business Day after the date of sending, unless the party sending the email knows or reasonably ought to suspect that the email and the attached notice were not delivered), where the documents attached will be in pdf or a scanned image of the original communication, including a handwritten signature, and attached to an email stating that the attachment is a notice under this Agreement.
- 2. The TGA and the Recipient's respective addresses and email addresses for receiving Notices are specified in the Order Form (subject to either of them notifying the other of a change of address or email address in writing).

14.7 Waiver of rights

A right may only be waived in writing and signed by the Party giving the waiver.

14.8 Entire agreement

This Agreement including the completed Order Form constitutes the entire agreement between the Parties to this Agreement and supersede all communications, negotiations, arrangements and agreements, either oral or written, between the Parties with respect to the subject matter of this Agreement.

14.9 Severance

If any provision of this Agreement is invalid or not enforceable in accordance with its terms, other provisions which are self-sustaining and capable of separate enforcement with regard to the invalid or unenforceable provision are, and continue to be, valid and enforceable in accordance with their terms.

14.10 Survival of provisions and preservation of rights

Termination or expiry of this Agreement for any reason does not extinguish or otherwise affect:

- 1. any rights of either Party to this Agreement against the other Party which:
 - i) accrued prior to the time of termination or expiry; or
 - ii) otherwise relate to or may arise at any future time from any breach or non-observance of obligations under this Agreement which arose prior to the time of termination or expiry; and

2. the provisions of this Agreement which by their nature survive expiry or termination, including without limitation clauses in relation to Intellectual Property Rights, confidentiality, privacy, indemnity, insurance, warranties, dispute resolution, Applicable Requirements and this **clause 14.10** and all clauses required to give effect to these clauses; and
3. the rights and obligations in **clause 4** and the relevant Instructions for Use in respect of any Reagents still in the Recipient's possession after termination or expiry of this Agreement.

14.11 Further Assurance

Each Party must do, sign, execute and deliver and must procure that each of its Personnel do, sign, execute and deliver all deeds, documents, instruments and acts reasonably required of it or them by notice from another Party effectively to carry out and give full effect to this Agreement and the rights and obligations of the Party under this Agreement.

14.12 Applicable Law

1. This Agreement will be governed by the Laws for the time being in force in the Australian Capital Territory and the Parties to this Agreement agree to submit to the non-exclusive jurisdiction of the courts of the Australian Capital Territory.
2. The United Nations Convention on Contracts for the International Sale of Reassortants and Reagents will not apply to this Agreement.

14.13 Representations and inducements

Each Party to this Agreement acknowledges that the other Party has not (nor has any person acting on its behalf) made any representation or other inducement to it to enter into this Agreement, except for representations or inducements expressly referred to or set out in this Agreement.

14.14 Remedies are cumulative

The rights, powers and remedies provided in this Agreement are cumulative and are not exclusive of the rights, powers or remedies provided by Law independently of this Agreement.

14.15 Contra Proferentum

No rule of construction will apply in the interpretation of this Agreement to the disadvantage of one Party on the basis that that Party put forward or drafted this Agreement or any part of this Agreement.

14.16 Compliance with Law

Each Party to this Agreement must comply with all relevant Laws in performing this Agreement.

Schedule 1 – Influenza Reagent Order Form

<https://forms.business.gov.au/smartforms/servlet/SmartForm.html?formCode=influenza-reagent-or>