

SUPPLY AGREEMENT

Between

MINISTERIO DE SALUD DE CHILE

And

SINOVAC LIFE SCIENCES CO., LTD.
(北京科兴中维生物技术有限公司)

December 2020



Supply Agreement

This **Supply Agreement** (this "**Agreement**") is made as of 10 December 2020 ("**Effective Date**") by and between:

Ministerio de Salud, a public entity of the Republic of Chile, having its principal office at 541 Mac Iver Street, Santiago, Chile, hereinafter referred to as "**Buyer**"

And

Sinovac Life Sciences Co., Ltd. (北京科兴中维生物技术有限公司), a company organized and existing under the laws of the People's Republic of China, having its principal office at No.21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P.R. China, hereinafter referred to as "**SINOVAC**".

Buyer and SINOVAC shall collectively be referred to as "**Parties**" and individually as a "**Party**".

WHEREAS

1. SINOVAC is a wholly owned subsidiary of Sinovac Biotech Ltd., a world leading biopharmaceutical research, development, production and marketing company.
2. SINOVAC has developed a SARS-CoV-2 Vaccine (Vero Cell) ("**Vaccine**"). SINOVAC has completed the phase I and II clinical trials for the Vaccine in the People's Republic of China ("**China**") and has launched and is currently conducting the phase III clinical trials for the Vaccine in multi-locations, including Chile, Brazil, Indonesia and Turkey.
3. Buyer intends to purchase from SINOVAC and SINOVAC agrees to supply and sell to Buyer the Vaccine in the form of finished product ("**Product**").

THEREFORE, the Parties have agreed the terms and conditions hereunder as follows:

Article 1 Purchase and Supply, Regulatory Approvals

- 1.1 Before 31 March 2021, Buyer shall purchase from SINOVAC and SINOVAC shall supply to Buyer, in total, ten million ninety-eight thousand (10,098,000) doses of the Product in the specifications which meet the requirements set out in Appendix A ("**Product Specifications**"), subject to the necessary emergency use approval or authorization, market authorization, and/or product registration for the Vaccine granted ("**Regulatory Approvals**") by the Instituto de Salud Pública de Chile ("**ISP**") ("**Phase I Purchase**").
- 1.2 Within ten (10) business days of the signing of this Agreement, Buyer shall place the purchase order of ten million ninety-eight thousand (10,098,000) doses for the Phase I Purchases pursuant to Article 2.1.
- 1.3 Based on the reasonable estimate by the Parties that the Regulatory Approvals are likely to be issued before 10 January 2021, the Phase I Purchase shall be delivered in [REDACTED] as set forth in the following schedule:

[REDACTED]

- [REDACTED]
- 1.4. Notwithstanding the above, if the Regulatory Approvals are issued after 10 January 2021 but still before 31 March 2021, [REDACTED] from the date of the issuance of such Regulatory Approvals. [REDACTED]

[REDACTED] The deliveries may be made all together or in combination, subject to the agreement of the Parties in writing.

- 1.5. Buyer, at any time prior to the issuance of the Regulatory Approvals, shall be entitled to complete the schedule contained in Articles 1.3 and 1.4. In that case, the different dispositions in this contract will consider as if the Regulatory Approvals would have been issued the date that the Buyer exerted the right in this clause.
- 1.6. In addition to the confirmed supply of the Product in the Phase I Purchase, in ten million ninety-eight thousand (10,098,000) doses as described in Article 1.1 above, subject to the Regulatory Approvals granted by the ISP before 30 March 2021 [REDACTED]

All the purchases made from April 2021 as described in this Article are collectively "Phase II Purchases", except for those set in Phase I Purchase that might be delayed due to the delay in issuance of the Regulatory Approvals as described in Article 1.4.

For such supply of the Product in the Phase II Purchases, the schedule of the delivery shall be agreed by the Parties thirty (30) days in advance to the expected delivery date in a supplemental agreement or amendment to this Agreement.

Article 2 Purchase Orders

- 2.1 Buyer shall place the purchase order for the purchase and supply of the Product made under this Agreement in the form set forth in Appendix B ("Purchase Order") via facsimile transmission or any other non-verbal electronic means (including email transmission).
- 2.2 Buyer shall specify in the Purchase Order the date of delivery for each delivery under the Purchase Order ("Date of Delivery").

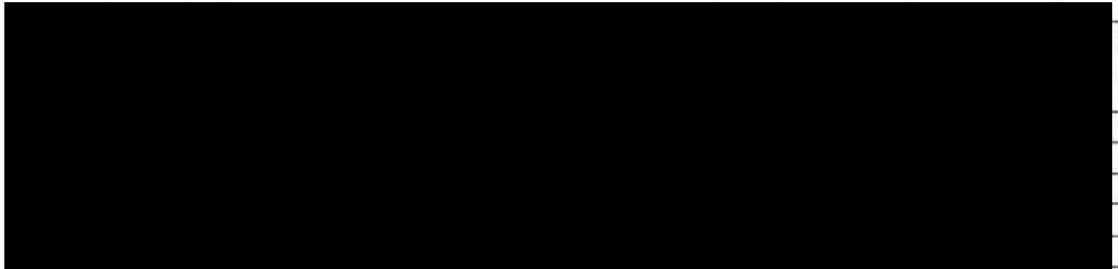
Except the Purchase Order for the Phase I Purchase, all the other Purchase Orders made under this Agreement must be placed and sent to SINOVAC at least [REDACTED] in advance of the estimated date of delivery required by Buyer in the Purchase Orders ("Date of Delivery").

- 2.3 SINOVAC shall confirm the Purchase Order by issuing the Pro Forma Invoices within five (5) business days of the issuance date of the Regulatory Approvals.

- 2.4 The Purchase Order shall not become effective and binding on both Parties until they are confirmed by SINOVAC pursuant to Article 2.2. If Buyer receives no response from SINOVAC within the said five business days of receipt of the Purchase Order, the Purchase Order shall be deemed as having been confirmed by SINOVAC.
- 2.5 The terms and conditions of this Agreement shall prevail if the terms and conditions stated in the Purchase Orders are inconsistent with the terms and conditions of this Agreement.
- 2.6 An confirmed Purchase Order shall not be cancelled either by SINOVAC or by Buyer without due cause.
- 2.7 Buyer shall provide SINOVAC a forecast report of the Product it will require for the next year before the end of every calendar year from 2021 onwards.

Article 3 Purchase Price and Trade Term

- 3.1 SINOVAC will charge and Buyer will pay for the Product purchased and supplied in the Phase I Purchase under this Agreement, at the unit prices set forth below ("Unit Prices").

A large rectangular area of the document is completely redacted with a solid black box, obscuring the unit prices mentioned in the preceding text.

The Unit Prices set forth above are agreed with the condition that the Regulatory Approvals can be granted and issued before 31 March 2021.

3.2

A rectangular area of the document is redacted with a solid black box, obscuring the content of clause 3.2.

- 3.3 If the Regulatory Approval from ISP or any other agency member of the Pharmaceutical Inspection Co-operation Scheme has not been issued before 31 March 2021, Buyer may, at its sole discretion, cancel the Phase I Purchase, in whole or in part, and even terminate this Agreement with a prior written notice to SINOVAC.

Notwithstanding the above provisions, if Buyer does not cancel the Phase I Purchase in whole or terminate this Agreement and still choose to place the Purchase Order for Phase I Purchase, in whole or in part, in the quantity agreed in Article 1.1, the Unit Price of the Product will be [redacted] and the delivery schedule set on in Article 1.4 above shall be followed or the Parties may agree upon a new schedule.

If Buyer cancels the Phase I Purchase in whole or in part or even terminates this Agreement according to the provisions stipulated above, SINOVAC will reimburse the payments that Buyer has made for the supplies of the Product that has been cancelled.

3.4 Buyer and SINOVAC agree that the Unit Prices of the Product in the Phase II Purchases to be supplied by SINOVAC from May 2021 to December 2023 shall be agreed by the Parties in a separate contract. [REDACTED]

Article 4 Payment

4.1 SINOVAC shall, within five (5) business days of the receipt of the Purchase Order, issue to Buyer a Pro Forma Invoice, in the format as set forth on Appendix C, to confirm the Purchase Order.

4.2 The Parties agree to settle the payment of the purchase price of the Product under each Purchase Order made under the Phase I Purchase according to the following schedule:

[REDACTED]

4.3 The payment schedule for the supply of the Product in the Phase II Purchases from May 2021 onwards set out in Articles 1.2, 1.3 and 1.4 shall be agreed by the Parties [REDACTED] of the expected delivery date of the purchase in writing with a supplemental agreement to this Agreement.

4.4 [REDACTED]

4.5 [REDACTED]

4.6 All the payments under this Agreement shall be paid [REDACTED]

[REDACTED]

Article 5 Delivery of the Product

5.1



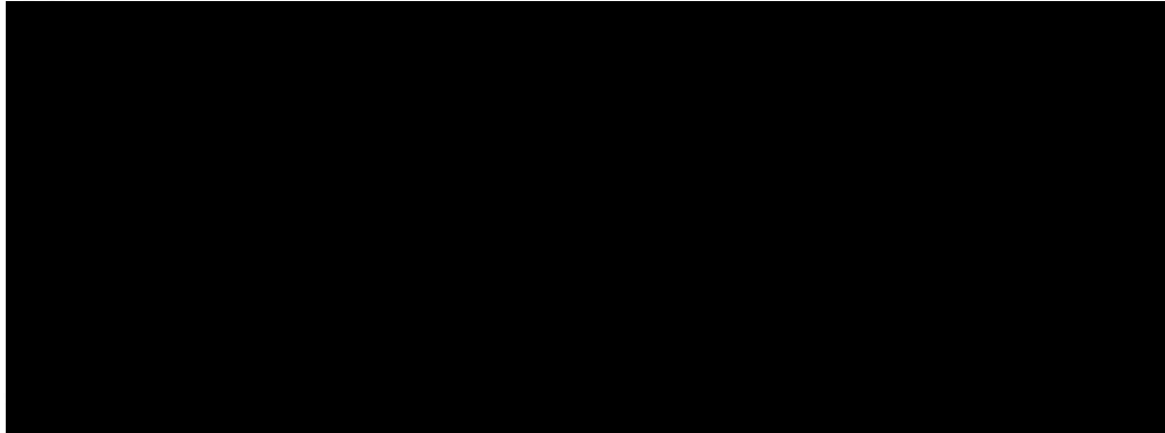
5.2



5.3 If Buyer wishes to change the Date of Delivery, it shall notify SINOVAC at least three (3) business days in advance in writing.

Buyer shall bear and pay the additional costs incurred by SINOVAC due to the change of the Delivery Date, including but not limited to storage fees, warehouse costs, and penalties charged by warehouses.

5.4



5.5

5.6

5.7

5.8

5.9 Buyer must obtain, at its own costs, all the import licenses, permits or other official authorizations and carry out and complete all the customs formalities necessary for the import of the Product into Chile.

5.10



5.11

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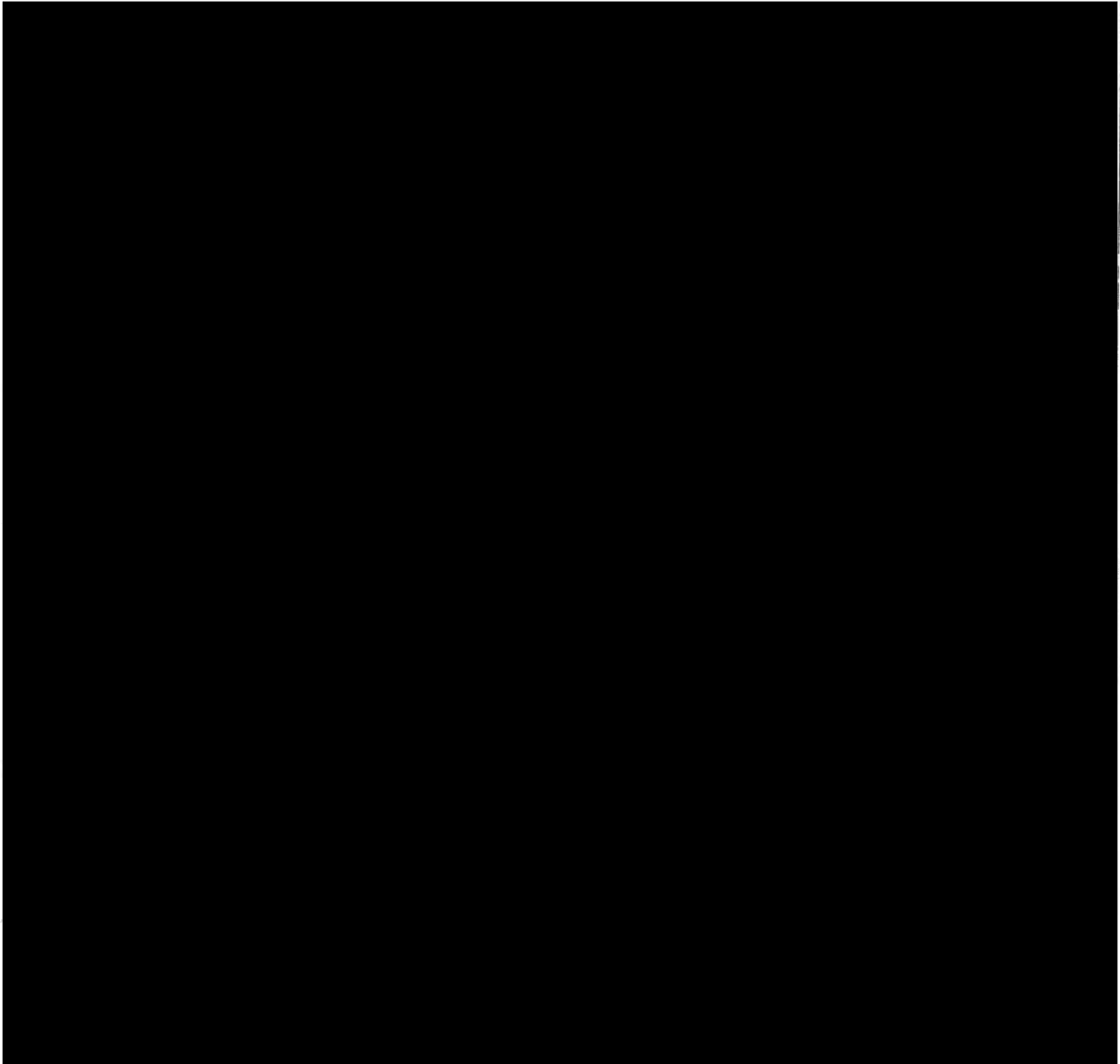
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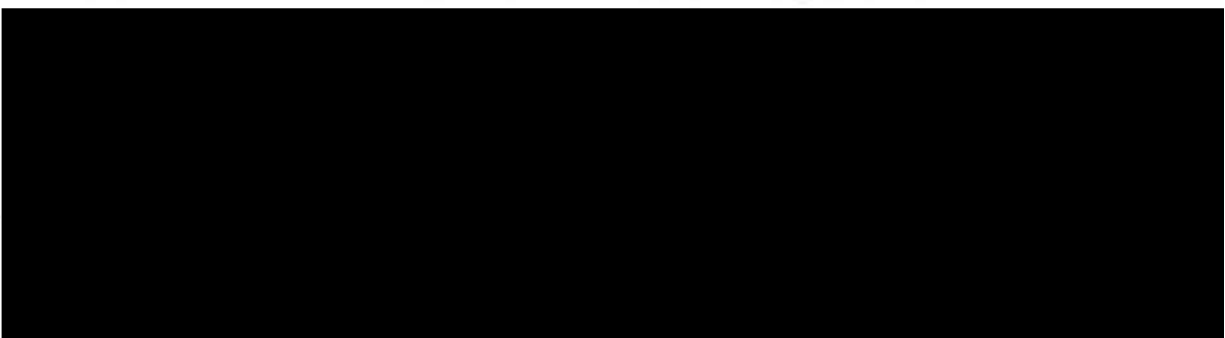
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Article 6 Final Acceptance

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- 6.1 Upon the arrival of the Product at the site of Buyer, Buyer shall conduct the external visual examination and inspection of the Product, which shall be the shipment inspection ("**Final Inspection**"), within ten (10) business days thereof. The Final Inspection shall be conducted to check the external visual of Product in respect of the batch production information and the COA, wrapping and packaging, exterior conditions and number of packages, the cold-chain transportation conditions, and further inspect the quantity, the Product.
- 6.2 If the Product does not have any damage, defect, shortage in quantity or the other non-compliance, and after the examination and inspection of the documents and information shared by SINOVAC to Buyer, as described above in Article 6.1, Buyer shall sign the shipment acceptance document. Upon the signing of the shipment acceptance document, the Product shall be deemed as having passed the Final Inspection and Buyer shall be deemed as having finally accepted the Product ("**Final Acceptance**").



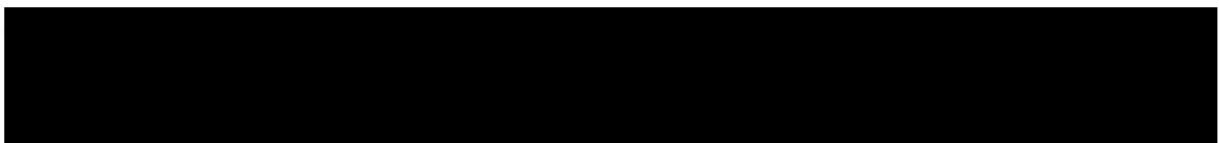


Article 8 Adverse Event and Serious Adverse Event Reporting

- 8.1 Buyer shall guarantee that the Product shall be only provided to and administered on the person permitted by the laws of Chile and Buyer shall notify SINOVAC about all Serious Adverse Events (“SAEs”) and Adverse Events (“AEs”) reported with the Product, if there is any, so that SINOVAC can comprehensively assess the product quality as well as controlling potential risks and improving management levels of pharmacovigilance (PV).
- 8.2 Buyer shall follow the requirements and instructions set out in Appendix D, to provide SINOVAC with all reporting documents about SAEs and AEs, reported with the Product, according to the following timelines:
- All Death cases and Cluster cases, within twenty-four (24) hours, and
 - All SAEs on a case by case basis, within five (5) business days, and
 - All AEs, on a quarterly basis, no later than one hundred (100) calendar days, of “date of first receipt”
- 8.3 Buyer shall notify SINOVAC immediately in writing of any decision of Suspension of Sales/Use or Withdrawal from Market made by the relevant authorities in Chile once such decision firstly comes to the knowledge of Buyer.
- 8.4 Before the date of 31 January of each year, Buyer shall provide SINOVAC with all documents which have not been transmitted for the previous year, including “Reporting form for adverse events following immunization (AEFI)”, “Reporting form for adverse events following immunization (AEFI) cluster” and “Summary of reports for adverse events following immunization in 20XX”.
- 8.5 All the AEs and SAEs, as well as compensations for damages caused by the AEs and SAEs in connection with the Product, shall be handled according to the laws and regulations of Chile, taking into consideration both the specific and general laws and regulations regarding damages. If the laws and regulations of Chile are silent on this, all the AEs and SAEs shall be handled according to the laws and regulations of China.

Article 9 Product Complaint by End Customer

- 9.1 In the event that Buyer receives any complaint regarding the Product, it shall notify SINOVAC immediately within five (5) business days.
- 9.2 Buyer and SINOVAC shall jointly conduct an investigation on the complaint.



Article 10 Product Recalls

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- 10.1 Whenever a recall of the Product in Chile is being contemplated for any reason ("Recalls") by the relevant health regulatory authorities, the Parties shall without prejudice to their obligations under any governmental regulation in Chile and prior to any notification to the authorities or prior to any unilateral action and/or communication, promptly consult with each other with the view to decide on the appropriate action to take with respect thereto.
- 10.2 Buyer shall bear all the expenses of any Recall resulting from damages or defects in the Product occurring after Final Acceptance of the Product by Buyer, not related to the manufacturing and delivery of the Product by SINOVAC.
- 10.3 SINOVAC shall bear all the expenses for the Recalls resulting from SINOVAC's fault, actions or inactions or for mandatory Recalls imposed by the relevant regulatory authority in Chile for reasons related to quality and/or safety of the Product.
- 10.4 Buyer and SINOVAC shall equally share and bear all the expenses of any Recall other than those resulting from the situations described in Article 10.2 and 10.3 provided always that such Recall is due to the fault of neither Party.
- 10.5 The expenses of Recalls shall include, without limitation, the value of the recalled Product and the expense of notification and destruction or return of the recalled Product.

Article 11 Anti-Corruption

- 11.1 Buyer fully understands that SINOVAC, as a company listed in Nasdaq, US, shall be subject to and comply with the Foreign Corrupt Practices Act ("FCPA") and as the business partner of SINOVAC, Buyer shall also be subject to compliance with the requirements of FCPA.
- 11.2 Buyer hereby represents and warrants that:
- (a) Buyer will fully comply with the requirements of FCPA.
 - (b) Buyer, its Affiliates or their respective employees, officers, directors, advisors, consultants and attorneys will not and shall not, in any form, directly or indirectly, offer or agree to offer any personal benefits or interests (including but not limited to cash, cash equivalent, securities, gifts, gift cards or vouchers, meals, accommodations, hospitalities, entertainment, sightseeing activities, travel expenses, services, employment offers, loans, donations or contributions, any transfer of value, or other personal benefits or interests) ("**Illegitimate Benefits**") to any government officials, staff of public healthcare institutions, healthcare professionals or business partners to influence any act or decision of those persons with respect of or in relation to the business contemplated under this Agreement in order to gain business opportunities, advantageous position in the market or other commercial or business benefits for Buyer or SINOVAC.
 - (c) Buyer, its Affiliates or their respective employees, officers, directors, advisors, consultants, attorneys have never, in any form, directly or indirectly, offered or agreed to offer and will not offer or agree to offer any Illegitimate Benefits to any personnel of SINOVAC or his/her relatives, which may have inappropriately influenced the selection of Buyer by SINOVAC to perform this Agreement.

"indirectly" in this Article 11.2 includes offering the Illegitimate Benefits to the family members or relatives of the said person or persons otherwise closely related to the person or persons.

- 11.3 If Buyer violates any of the above-mentioned statements, representations and warranties, it shall be deemed as material breach of this Agreement, in which case, SINOVAC shall have the right to terminate this Agreement with a written notice and Buyer shall pay to SINOVAC a punitive penalty equivalent to 30% of the total Purchase Price under this Agreement.

Article 12 Force Majeure

- 12.1 Neither Party to this Agreement shall be liable for any delay or failure in the performance of any of its obligations hereunder, if such delay in whole or in part is due to any unexpected and/or unavoidable events that are out of its reasonable control, including, without limitation, acts of God, fires, storms, floods, earthquakes, riot, strikes, acts of war, civil unrest or intervention of any governmental authority ("**Force Majeure Event**") provided that such exemption of liability shall be limited to the extent of the influence of the Force Majeure Event.
- 12.2 The Party which has been affected by the Force Majeure Event ("**Affected Party**") shall immediately inform the other Party of the occurrence of the Force Majeure Event and, within fourteen (14) days thereafter, the Affected Party shall send by commercially available means to the other Party the evidence of the occurrence of the Force Majeure Event, demonstrating the details of the event and the performance of this Agreement that has been affected. When the Force Majeure Event subsides, the Affected Party shall immediately notify the other Party of the same by commercially available means.
- 12.3 Notwithstanding this, in the case of the Force Majeure Event, the Affected Party still has the obligation to take all necessary measures to hasten the performance of this Agreement and minimize the damages and losses to the other Party caused by the Force Majeure Event.
- 12.4 In the event that the Force Majeure Event lasts for more than two (2) months, any Party shall have the right to immediately terminate this Agreement by sending a written notice to the other Party.

Article 13 Term and Termination

- 13.1 This Agreement shall commence on the Effective Date.
- 13.2 At any time prior to the expiration of the Agreement, one Party ("**Notifying Party**") may terminate this Agreement through written notice to the other party in writing if:
- (i) the other Party breaches this Agreement and fails to take any remedy measures within the period stated in the written notice sent by the Notifying Party;
 - (ii) the other Party materially and substantially breaches this Agreement and as a result, this Agreement cannot be performed or the objectives of this Agreement cannot be realized;
 - (iii) the other Party becomes or is threatened to become bankrupt, or is the subject of proceedings for liquidation or dissolution, or ceases to carry on business or becomes unable to pay its debts as they come due.

13.3





Article 14 Dispute Resolution

- 14.1 This Agreement shall be governed by the laws of the Republic of Chile.
- 14.2 All disputes in connection with this Agreement or the execution thereof shall be settled friendly through negotiations. In the case that no settlement or no agreement in respect of the extension of the negotiation period can be reached within two (2) months of the arising of the dispute, the dispute shall be submitted to the court of Chile which has the due jurisdiction.

Article 15 General Provisions

- 15.1 The headings of the Articles of this Agreement have been inserted for convenience of reference only and do not constitute a part of interpretation of this Agreement.
- 15.2 No Party shall assign, whether entirely or in part, the rights and/or obligations under this Agreement to any third party without first having obtained the other Party's written consent.
- 15.3 No omission or delay on the part of any Party hereto to enforce at any time any of the provisions of this Agreement shall be deemed or construed to be a waiver by the omitting Party of any such provision or of its rights hereunder nor shall any single or partial exercise of any right or remedy preclude any further or other exercise of such right or remedy.
- 15.4 SINOVAC and Buyer may agree to and make amendment and/or supplement to this Agreement according to the progress of the performance of this Agreement.
- Any amendments and supplements to this Agreement agreed upon by both Parties shall be made and signed in writing by both Parties in the format of written amendments or supplemental agreement.
- 15.5 Any data, information, including the commercial arrangements, exchanged between the Parties, contained in this Agreement shall be kept confidential at all times and neither Party shall disclose or cause to disclose, or use or cause the use of, such Confidential Information without the express written consent of the other Party or when it is required to be disclosed by the relevant laws to which either Party is subject.
- 15.6 This Agreement and the schedules attached thereto constitute and incorporate the complete and exclusive understanding of the terms of this Agreement between the Parties hereto with respect to the subject matter hereof, and no statements or agreements, oral or written, made prior to or at the signing hereof shall vary or modify the written terms hereof, and neither Party shall claim any modification or rescission from any provision hereof unless such modification or rescission is in writing, signed by both Parties.
- 15.7 In the event that any agreement or covenant in this Agreement is held to be invalid by a court having competent jurisdiction, the Parties shall use their best efforts to include a new valid Article that restores the interests of both Parties.
- 15.8 This Agreement is written and made in English and Spanish. Both language versions shall have equal legal force and significance. In case of discrepancy between the two language versions, the English language version shall prevail.
- 15.9 This Agreement will take effect on the Effective Date upon signing by the representatives of both Parties.
- 15.10 This Agreement shall be made and signed in four (4) originals which each Party holding two (2) originals.

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[MINISTERIO DE SALUD] (Signature and Stamp here)	SINOVAC LIFE SCIENCES CO., LTD. (Signature and stamp here)
Name: Paula Daza Narbón Title: Subsecretaria Salud Pública Date: _____	
In presence of:	
Designation:	
Sign: 	Sign:

~~Stamp~~

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Appendix A Product Specifications

Product	Packaging	Specifications
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Appendix B PURCHASE ORDER

Buyer's Order Number: INSERT BUYER'S ORDER NUMBER

Order Number: INSERT SELLER'S ORDER NUMBER

DATE: INSERT THE DATE OF THIS ORDER

Buyer: INSERT FULL ENTITY NAME

Address: INSERT ENTITY ADDRESS

Contact Person: INSERT FULL NAME

Contact Number: INSERT CELL NUMBER

Tel: INSERT TELEPHONE NUMBER

Email: INSERT EMAIL ADDRESS

Seller:

Product Name	Description	Specification Quantity	Unit Price (Per Liter)	Amount
		<u>INSERT QUANTITY</u>	<u>USD PRICE</u>	<u>USD INSERT TOTAL AMOUNT</u>
TOTAL: <u>INSERT TOTAL AMOUNT IN WORDS</u>				<u>USD INSERT TOTAL AMOUNT</u>

Shipment Method

Place of Delivery

Expecting Delivery Date

INSERT CITY, COUNTRY

INSERT DATE

SIGNATURE & SEAL

Legal Representative: INSERT FULL NAME

Signature:

Date:

Company Stamp

SAMPLE

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Appendix C PRO FORMA INVOICE

SAMPLE

Date: <u>INSERT DATE</u>	
Pro Forma Invoice Number:	<u>INSERT SELLER'S PEI NUMBER</u>
Order Number:	<u>INSERT SELLER'S ORDER NUMBER</u>
Sales Contract Number:	<u>INSERT SELLER'S SALES CONTRACT ORDER NUMBER</u>
Consignee's Name and Address: <u>INSERT BUYER'S FULL ENTITY NAME</u> <u>INSERT BUYER'S ENTITY POST ADDRESS</u>	
Exporter's Name and Address:	

PRICE AND SHIPMENT

Means of Transport and Route:	By air transportation from Supply location (City Name) to Receiving location (City Name)		
Price Term:	[REDACTED]		
Product	Description	Quantity	Unit Price
		<u>INSERT QUANTITY</u>	<u>USD PRICE</u>
			<u>Total Amount</u>
			<u>USD INSERT TOTAL AMOUNT</u>
TOTAL: <u>INSERT TOTAL AMOUNT IN WORDS</u>			<u>USD INSERT TOTAL AMOUNT</u>

PACKING AND MEASUREMENT

 	Packing (Pieces)	Volume (m ³)	Gross Weight(kg)	Net Weight (kg)
Unit Specification				
In Total	<u>Number</u>	<u>Number</u>	<u>Number</u>	<u>Number</u>
Marks	<u>INSERT THE SHIPPING MARKS</u>			

Exporter's Bank Details:

DECLARATION

The Product of the Vaccine must be stored between +2°C and +8°C. DO NOT FREEZE.

We declare that:

- [1] This Pro Forma Invoice shows the actual price of goods described.
- [2] All particulars provided herein are true and correct to best of our knowledge

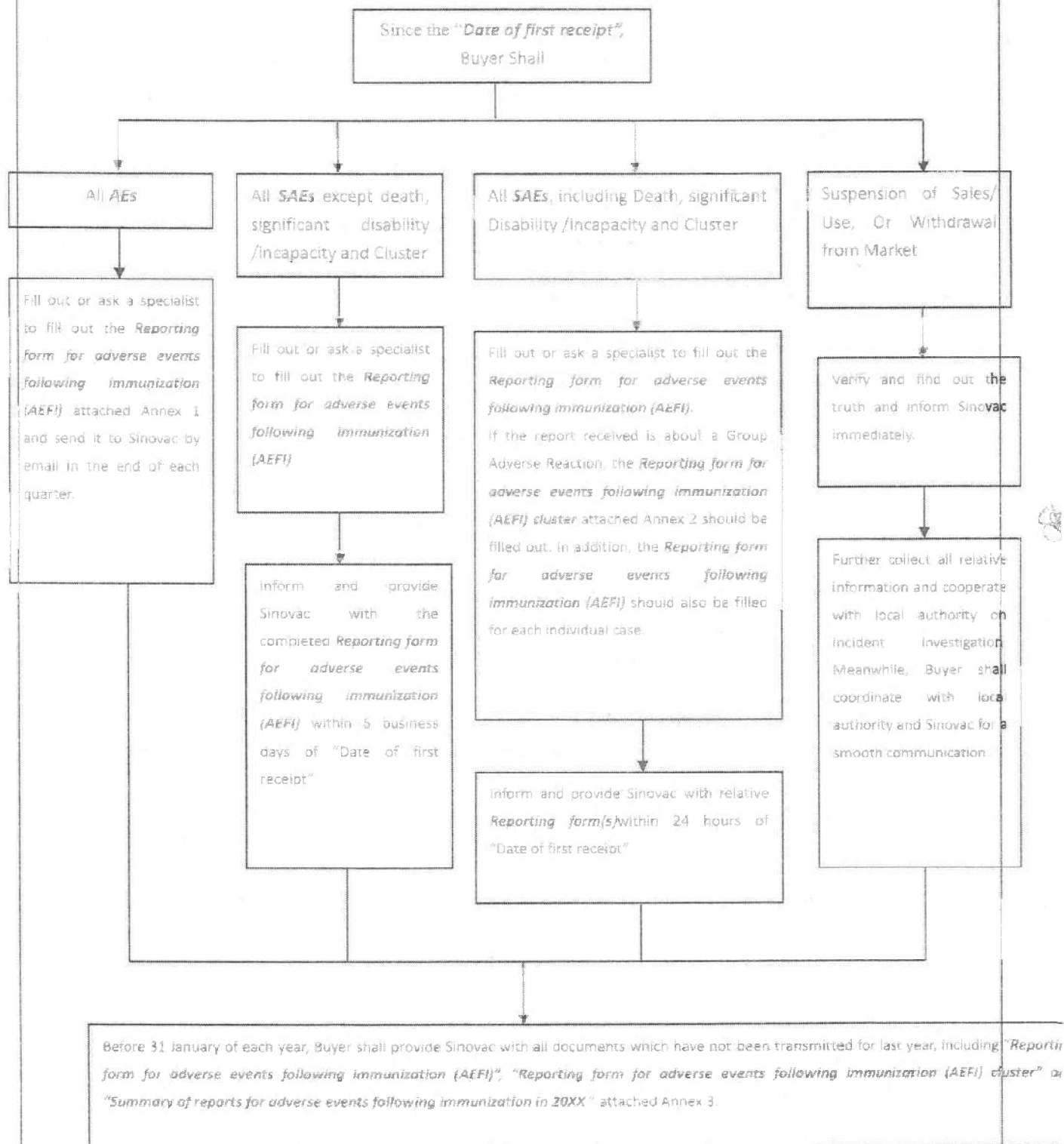
Pro Forma Invoice Maker:

Date:

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Appendix D AĒ and SAE Reporting

Working Procedure of Safety Data Exchange



Definitions:

- **"Date of first receipt"**: The date of first receipt of adverse event information (i.e. "clock date") should be considered as the date of first receipt by any employee of Buyer or a third party such as a partner or a CRO appointed by Buyer. The date of first receipt will be considered as Day 0 for the calculation of transmission and submission timeframes.
- **"Adverse Event" (AE)**: Any untoward medical occurrence in a patient or clinical investigation subject administered a medicinal or pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a product whether or not considered related to the product.
- **"Serious Adverse Event" (SAE)**: Any untoward medical occurrence that at any dose:
 - ✓ results in death,
 - ✓ is life-threatening,
 - ✓ requires in-patient hospitalization or prolongation of existing hospitalization,
 - ✓ results in persistent or significant disability /incapacity,
 - ✓ is a congenital anomaly / birth defect
 - ✓ medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalization, but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These cases should also usually be considered as SAEs.

The term "life threatening" refers to an event in which the patient was at risk of death at the time of the event, and it does not refer to an event which hypothetically might have caused death if it were more severe.

- **"Cluster"**: Two or more cases of the same event or similar events related in time, geography, and/or the vaccine administered. National programme managers may decide upon a more precise definition.

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Annex 1

Reporting form for adverse events following immunization (AEFI)

Initial Follow-up report AEFI Reporting ID Number :

Type of report: new serious common

Reporting organization: Medical institutions Business enterprise

Manufacturing enterprise Individual Other

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Patient name: Telephone : Sex : <input type="checkbox"/> M <input type="checkbox"/> F Weight (kg) : Race : Date of birth : (DD/MM/YYYY) // Or age:	Reporter's Name: Occupation: <input type="checkbox"/> doctor <input type="checkbox"/> nurse <input type="checkbox"/> pharmacists <input type="checkbox"/> other Institution, Department & address: Telephone: E-mail: Signature:
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Relevant important information : History of smoking History of drinking pregnancy History of liver disease
History of kidney disease History of allergy Other

Name of vaccines received & concomitant medication (if exist)	Date of vaccination/ medication	Dose (e.g. 1st, 0.5ml)	Batch/Lot number	Expiry date	Manufacturer	License number

Adverse event(s): Date & Time AEFI started (DD/MM/YYYY): <u> / / </u> <input type="checkbox"/> Hr <input type="checkbox"/> Min Was the patient hospitalized? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, Hospital departments: Case ID: Date patient notified event to health system (DD/MM/YYYY) <u> / / </u>	Describe AEFI (signs, symptoms and time course) and treatment e.g. relevant diagnostic tests/laboratory data, if any. Use one additional sheet if necessary :
--	--

Outcome : Recovering Recovered Not recovered Unknown Recovered with sequelae it is :

Died if died, direct cause of death: date of death:(DD/MM/YYYY) : ___/___/___

Autopsy done: Yes No Unknown

Past disease history and medication history (including history of similar reaction or other adverse reaction and family history of adverse reaction e.g. Allergic reaction) Yes No Unknown If Yes, what they were. Use additional sheet if needed:

Influence on past disease of patient: Not clear Duration extended Sicker Sequelae Died

AEFIs are grouped into five categories.

Assessment of reporter : Vaccine product-related reaction Vaccine quality defect-related reaction
Immunization error-related reaction Immunization anxiety-related reaction Coincidental event

Signature:

Notes/comments

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Annex 2 :

Reporting form for adverse events following immunization (AEFI) cluster

Vaccinated at:		Used by (place) :		Number of people :	
Number of people with adverse event :		Number of people with serious adverse event :		Death toll :	
Date of first vaccination (DD/MM/YYYY) :			Date of first adverse event : (DD/MM/YYYY) :		
Name of vaccine		Manufacturer	Dose (e.g. 1st, 0.5ml)	Batch/Lot number	License number
Name of medical device or concomitant medication(if exist)		Manufacturer	Batch/Lot number		License number
<p><i>The medical devices here refer to syringe, infusion, and other medical devices which were used with vaccine received at the same time and were related with AEFI cluster.</i></p>					
Name of adverse event :					
Describe AEFI cluster (signs, symptoms and time course) and treatment e.g. relevant diagnostic tests/laboratory data, if any. Use one additional sheet if necessary :					
Evaluation of Reporter or Reporting Institution					
Reporter information		Telephone:	E-mail:	Signature :	
Reporting Institution: contact person:			Telephone:		

Reporting date(DD/MM/YYYY) : / /

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Annex 3 :

Summary of reports for adverse events following immunization in 20XX

Country or Region:		Year of Reporting:		
	Number of AE	Number of SAE (including Unexpected Adverse Reaction)	Number of Death Cases	Number of Cluster Cases
January				
February				
March				
April				
May				
June				
July				
August				
September				
October				
November				
December				
TOTAL				
Reporter information	Reporting Institution:		contact person:	
	Address:		E-mail & Telephone:	
	Signature:			

Reporting date (DD/MM/YYYY): / /