

Moot Proposition

Facts & Events:

1. The Ministry of Health and Family Welfare, Government of Bigland, (Ministry, henceforth) invited bids for development of a vaccine to counter a virus transmitted through avian vectors. The vaccine was available abroad and Bigland had been importing the vaccine as there are no indigenous producers.
2. The Ministry offered an Advance Marketing Commitment (AMC) in order to assuage the fears of the bidders that there would be no market for sale if the virus wanes and accordingly the Ministry offered an advance sum of Rs. 10 crore to 5 successful bidders.
3. As a consequence, AMC was executed between the Ministry and individual suppliers. **Annexure-1** Salient features were as follows: -
 - 3.1. Purpose was to encourage the bidders to create and invest in the infrastructure to manufacture the vaccine and to defray a part of the costs.
 - 3.2. The Bidders represented that they had all the necessary infrastructure for development, manufacture, storage and supply of the Product and the same has already been created by them.
4. Ministry advanced Rs.10 crore to each of the five indigenous vaccine manufacturers vide letter dated 01.02.2020 in the form of Demand Draft dated 29.01.2020 for developing the vaccine indigenously.
5. Department for Control of Drugs (DCG, henceforth) gave the required permission vide letter dated 08.03.2020. By another letter dated 11.05.2020, DCG granted permission for conducting Phase II / III clinical trial of the vaccine as well.
6. Ministry sent letter dated 16.06.2020 and conveyed the Ministry's impression that the claimant and other manufacturers were running behind the schedule and they were asked to intimate the progress made and further time required for manufacturing and marketing of Influenza vaccine. After 14 days, the same officer sent another letter dated 30.06.2020 and asked the claimant to intimate the progress made and further time required for manufacturing and marketing of Influenza vaccine. Director, Bigland Council of Medical Research (BCMR,

henceforth) also sent letter dated 12.10.2020 to vaccine manufacturers requiring them to convey the current status of the vaccine production in terms of completion of clinical trial, submission of data to DCG, obtaining market approval and production of vaccine etc.

7. After completion of Phase – I, II and III of clinical trials of the vaccine, DCG granted approval vide letter dated 11.10.2020.
8. By an email dated 13.10.2020, the indigenous manufacturers informed the Ministry about the grant of license for manufacturing vaccine. **Annexure-2**
9. However, the Ministry sent letter dated 28.01.2021 to the claimant and blamed it for not informing the progress of manufacturing and marketing of the vaccine and also threatened that as per Clause 4.2 of Article IV of the AMC, MoH&FW is entitled to claim refund with interest @ 12%. **Annexure-3**
10. The indigenous manufacturers immediately sent response dated 08.02.2021 and denied the receipt of communications dated 16.06.2020, 30.06.2020 and 12.10.2020 referred to in letter dated 10.01.2021. They also pointed out that it had been informing BCMR and DCG about the progress of vaccine development and also to the officials of Ministry through e-mail and telephonic conversation. Along with the reply, the manufacturers enclosed the approval granted by DCG vide letter dated 11.10.2020 and other accompanying documents. **Annexure-4**
11. Ministry issued notice dated 29.04.2021, which was accompanied by tender document and invited bids for supply of Influenza Vaccine and for entering into price agreement. Relevant extracts are **Annexure-5**.
12. After considering the bids submitted by indigenous vaccine manufacturers, Ministry determined the price at Rs.250/- for each set of complete doses. By letter dated 04.08.2021, the indigenous manufacturers were directed to convey acceptance of price, which the latter did on 08.08.2021.
13. As a sequel to the acceptance of price, Ministry sent letter dated 24.08.2021 and conveyed the Government's decision to place an order for supply of 1 Crore doses of vaccine at a total cost of Rs. 250,00,00,000/- and directed the manufactures to get in touch with the Medical Store Organisation to obtain instructions as to where the consignment is to be delivered subject to rider that the consignment should be delivered during the period October – December, 2021. **Annexure-6**.

14. On receipt of the aforesaid letter, the Indigenous Manufacturer submitted representation dated 28.09.2021 to and informed him that it will be able to supply the vaccine after 150 days from the date of order because that much time is required for testing any batch after manufacturing. The claimant also requested that supply order be issued at the earliest giving at least 150 days' time for the first supply. **Annexure-7.**
15. Ministry issued Formal Supply Order on 05.10.2021 and called upon the claimant to supply 1 Crore doses during the period October – December 2021. **Annexure-8.**
16. On receipt of Formal Supply Order, the claimant made representation dated 25.10.2021 and reiterated its request that minimum 150 days may be granted for first supply because vaccine was a non-routine vaccine for which process is initiated only after receipt of order, which includes procurement of raw-material, sourcing of major inputs and other processes and certification which is followed by dispatch under cold chain system. The claimant emphasised that due to various steps required to be taken for production of the vaccine, it will not be possible to supply 1 Crore doses between October – December, 2021. The claimant finally requested that the supply order be amended with the terms and conditions of the lead period and minimum 140 days be given from the date of amendment for the first supply, after which 20 Lakh doses per month. **Annexure-9.**
17. By letter dated 28.11.2021, Ministry informed the claimant that the delivery schedule cannot be changed. **Annexure-10.**
18. Thereafter, the indigenous manufacturers made representation dated 29.12.2021 and conveyed its readiness to supply 60 lakh vials by the end of January, 2022 and another 20 lakh vials before 31.03.2022. It was also mentioned in the representation that the remaining 20 lakh vials will be supplied after delivery of the second consignment.
19. The ministry issued notice dated 09.01.2022 and called upon the claimant to refund the advance of Rs.10 crore with 12% interest on the premise that it failed to supply the vaccine in accordance with letter dated 24.08.2021 and Formal Supply Order dated 05.10.2021. **Annexure-11.**

Issues:

1. Whether the claimant (Vaccine Manufacturer) is entitled to Rs. 14.50 crore from the respondent as price of Influenza vaccine manufactured at the instance of the respondent with 12% interest.
2. Whether the claimant (Ministry) is liable to refund of Rs.10 crore given by the respondent as Advance Marketing Commitment for developing Influenza vaccine and also pay to the respondent interest 12% from the date of payment till the date of realisation.

Legal Points:

1. Whether proper information was delivered by each side to opposite party.
2. Whether time was the essence of the contract.
3. Whether the damages sought by the both the parties are justified.

ADVANCE MARKET COMMITMENT AGREEMENT FOR THE INFLUENZA VACCINE

This Agreement is made on this 1st day of January, 2020 by and between

Ministry of Health & Family Welfare, Government of Bigland;

And

“Indigenous Vaccine Manufacturers”

Whereas, the Indigenous Vaccine Manufacturers confirm that all necessary infrastructure for development, manufacture, storage and supply of the Product, has already been created by them at their own cost. The Indigenous Vaccine Manufacturers have agreed to develop, manufacture and supply the Product to Ministry on such terms as may be mutually agreed upon from time to time.

Whereas, the Ministry has offered to pay an amount of Rs.1 crore (Rupees One Crore) to each of the Indigenous Vaccine Manufacturers as advance payment in the form of Advance Market Commitment (AMC), to be adjusted against the consideration of supplies of the Product in future, on the terms, covenants and conditions of this Agreement.

Now, therefore, in consideration of the mutual benefits to be arrived and the covenants and the conditions contained herein, the Parties to this Agreement agree as follows:

1. Definitions: In this Agreement, in addition to the terms defined above, the following terms have the meaning as described below, unless otherwise specified:
 - 1.1. “Advance Market Commitment” or “AMC” shall mean the upfront legally binding financial commitment by Ministry to support purchase of the Product as and when the Product is developed.
 - 1.2. “Interim Licensing” shall mean the approval for the use of the Product post-face I/II human clinical trials under Emergency Use Authorization.
 - 1.3. “Product” shall mean inactivated influenza vaccine to be developed and provided by the indigenous vaccine manufacturers to Ministry from time to time pursuant to the contract for supply of Product as may be entered into between the parties from time to time (“supply Agreement”).
2. SCOPE OF AGREEMENT
 - 2.1. Ministry agrees to provide an AMC of Rs. 1 Crore (Rupees One Crore Only) to each Indigenous Vaccine Manufacturer as advance payment upon signing of this Agreement, to be adjusted against the consideration of supplies of the Product in future.

- 2.2. The Parties have agreed that the above said amount of Rs.1 Crore with interest accruing thereon shall be adjusted against the consideration amount in respect of supplies of the Product to be made in terms of this Agreement.
 - 2.3. Indigenous Vaccine Manufacturers agree to take all reasonable steps and make their best efforts to develop the Product, at their own cost and supply the mutually agreed quantities of the Product to Ministry post interim licensing after completion of Phase I/II human clinical trials, by April, 2020, subject to grant of license from National Regulatory Authority and confirmation of required quantities by Ministry.
 - 2.4. Indigenous Vaccine Manufacturers (IVM) agree that they shall obtain, at their own cost, all the licenses, permits and other regulatory approvals necessary for the development and/or manufacture of the Product in the Territory and shall ensure that all such licenses, permits and other regulatory approvals are, and shall at all times during the term of this Agreement, be in full force and effect.
 - 2.5. Ministry agrees to accept the Product upon Indigenous Vaccine Manufacturers providing such safety, immunogenicity, stability, manufacturing and other data and information as determined by the National Regulatory Authority in the Territory and post interim licensing after completion of Phase I/II human clinical trials.
 - 2.6. In case of change of strain of the current pandemic influenza vaccine due to a drift on or before the commencement of supplies of the Product, the timelines for supply as mentioned in Clause 2.3 above, shall be further extended by a period of four (4) months on the basis of the mock dossier from the date of receipt of new strain from WHO designated Essential Reference Laboratories.
 - 2.7. The Parties have agreed that in the event of Ministry accepting the Product as agreed in clause 2.5 above, Ministry will have the first claim over all quantities of the product that may be produced by the Indigenous Vaccine Manufacturers till the amount paid as AMC is entirely set off against the supplies of the Product.
3. DETERMINATION OF PRICE OF THE PRODUCT
- 3.1. The Parties agree that after the development of the Product as explained in clause 2.5 above, Ministry would ask each of the Indigenous Vaccine Manufacturers to quote their price for the Product following the standard tender process. Ministry would evaluate the price so quoted by each of the eligible Indigenous Vaccine Manufacturer and then announce the lowest price (L1) so determined and ask the other two qualifying Indigenous Vaccine Manufacturers (L2 & L3) to match the price of L1 to supply the Product at the price so determined.
 - 3.2. The Indigenous Vaccine Manufacturers agree to supply and Ministry agrees to purchase such quantities of Product, post interim licensing, at the price so

determined under clause 3.1 and on such other terms & conditions as may be mutually agreed between the Parties from time to time by entering into the Supply Agreement or other suitable agreement in this regard.

4. REFUND OF AMC AMOUNT

- 4.1. The Parties agree that in case all or any of the Indigenous Vaccine Manufacturers fail to supply the Product as stipulated in Clause 2.3 or 2.6 above, as the case may be, due to unavoidable circumstances / uncertainties and causes beyond their control, such Indigenous Vaccine Manufacturer(s) shall make a request in writing for extension of the said time limit before the expiry of the said period giving detailed reasons for such delay. Ministry shall carefully examine and consider such a request for extension of the delivery period, which shall not be unreasonably withheld or delayed.
- 4.2. The Parties agree that in case all or any of the Indigenous Vaccine Manufacturers fail to supply the Product as above, due to failure to take all reasonable steps in a timely manner or on account of its gross negligence, Ministry shall be entitled to claim refund of the entire amount of the AMC provided by Ministry in terms of this Agreement from such defaulting Indigenous Vaccine Manufacturer(s) with interest at the rate of twelve per cent (12%) per annum from the date of release of advance till the date of adjustment/reimbursement of the advance.
- 4.3. The Parties agree that in terms of clause 4.2 above, the Indigenous Vaccine Manufacturers shall be liable to refund the AMC amount within a period of thirty (30) days from the date of receipt of such claim with interest at the rate of twelve per cent (12%) per annum from the date of release of advance till the date of adjustment/reimbursement of the advance or alternatively, such Indigenous vaccine Manufacturer/s will have the option to get the amount of Rs. 10 Crore with interest at the rate of twelve per cent (12%), per annum from the date of release of advance till the date of adjustment/reimbursement of the advance adjusted against future supplies to Ministry.
- 4.4. The parties agree that in case due to commercial viability reasons, it is not feasible for any of the Indigenous Vaccine Manufacturers to match the prices of L1, such Indigenous Vaccine Manufacturer/s will have the option to withdraw from supply agreement of pandemic Influenza vaccine and would refund the advance payment of Rs. 10 crore to Ministry within 30 days from the date Ministry asks the Indigenous Vaccine Manufacturer/s under Article 3.1 of the agreement to match the L-1 price with interest at the rate of twelve per cent(12%) per annum from the date of release of advance till the date of adjustment / reimbursement of the advance to Ministry on this advance payment or alternatively such Indigenous Vaccine Manufacturer/s will have the option to get the amount of Rs. 10 crore with interest at the rate of twelve per cent (12%) from the date of release of advance till the date of adjustment / reimbursement of the advance, adjusted against future supplies to Ministry. In case, any of the Indigenous Vaccine Manufacturer fails to refund the AMC

amount of Rs.10 Crore with interest cited or exercise the option within 30 days from the date of receipt of such claim, the Ministry shall recover the amount with interest at the rate of twelve per cent (12%) per annum from the date of release of advance till the date of adjustment / reimbursement of the advance, from the supply / supplies of other vaccines to the Ministry of Health & Family Welfare or other Ministries / Departments of the Government of Bigland.

- 4.5. The Parties agree that in case Ministry does not purchase the mutually agreed quantities of Product within a period of six (6) months from the date on which the Indigenous Vaccine Manufacturers offer the Product to Ministry, the AMC amount limited to the extent of the cost of the offered quantities, will neither be refundable nor adjustable against any consideration for future supplies.

5. FORCE MAJEURE

- 5.1. Neither Party shall be liable to the other for any failure to perform its obligations under the Contract where such performance is rendered impossible by circumstances beyond its control including without limitation strike, riot and civil commotion, natural disasters and government action & change of strain, but nothing in this condition shall limit the obligations of the Indigenous Vaccine Manufacturers to use their reasonable commercial endeavours to fulfil their obligations under this Agreement.

- 5.2. The Parties agree that since none of the Parties have experience of strains involved, therefore, in case due to change of strain, which is beyond the control of indigenous Vaccine Manufacturers, Ministry will compensate the Indigenous Vaccine Manufacturer's for stocks of bulk and or finished product produced with existing strain upto & not exceeding the amount of Rs.10 Crore paid under AMC but limited to the cost of such bulk or finished product (which shall be the property of the Ministry) & therefore, Ministry will neither seek refund nor adjust this amount against future supplies by the Indigenous Vaccine Manufacturer/s. However, the parties agree that this would be a onetime adjustment and shall not become a basis of any future supply agreement for the Product."

6. MISCELLANEOUS PROVISIONS

- 6.1. Jurisdiction & Dispute Resolution: In the event of any dispute the same shall at the request of either Party be referred to and settled by arbitration in accordance with the Arbitration & Conciliation Act, 1996.

7. DISPUTE RESOLUTION, APPLICABLE LAW AND JURISDICTION

- 7.1. Mediation Settlement- If any dispute or difference or claims of any kind arise between the parties under this Agreement, then the Parties shall meet together promptly, at the request of any Party, in an effort to resolve such dispute, difference or claim by mediation between them.

7.2. Arbitration- Failing amicable settlement, the dispute or differences or claims as the case may be, shall be finally settled by binding arbitration under the Arbitration and Conciliation Act, 1996.

Annexure-2

Date : 13.10.2020

Dear Sir,

I am happy to inform you that we have received our DCG license for commercial manufacturing and marketing of our vaccine, in Bigland.

We sincerely thank you for all the support from you and BCMR, Seasonal influenza :

We are interested in developing and commercializing a seasonal influenza vaccine for Bigland and the developing world. We are evaluating our options for product development, manufacturing and strain selection to address the influenza strains of our regions. On the technical and manufacturing aspects, we are well equipped to manufacture and supply seasonal influenza vaccines using our MDCK platform technology.

Ps: I tried to call you to inform our Influenza licensure, but you were not reachable.

Thank you

XXXXX"

**Government of Bigland
Ministry of Health & Family Welfare**

By Registered Post

Dated: 28th January, 2021

To

President,
Indigenous Vaccine Manufacturers

Subject: Advance Market Commitment Agreement (AMC) for Influenza Vaccine - reg.

Sir,

1. In order to encourage the development and manufacturing of vaccine indigenously, Ministry has entered into an Advance Market Commitment (AMC) Agreement with five indigenous vaccine manufacturers.
2. As per the provision contained in clause no. 2.1 of the above cited Agreement, a fund of Rs.10.00 crore has been placed at the disposal of indigenous manufacturers as advance payment. As per the condition stipulated in the same clause, this fund is to be adjusted against the consideration of supplies of the product in future.
3. In accordance with the provision stipulated in clause no. 2.3 of the aforementioned Agreement, the indigenous vaccine manufactures were required to develop and supply the mutually agreed quantity of the product by April 2020. It has also been laid down in clause 4.1 of the said Agreement that in case the indigenous vaccine manufacturers fail to supply the product within the prescribed time limit on account of reasons for which they cannot be held responsible, they would make a request in writing for extending the stipulated time-limit, before the expiry of that period, giving justification for such a request.
4. Vide letters of even number dated 16th June 2020 and 30th June, 2020, it was requested to intimate the progress made in the development of the vaccine as well as whether further time was required by them for manufacturing and marketing the vaccine (copies enclosed). No reply has been received.
5. Vide letter of even no. dated 12th October 2020 (copy enclosed) the indigenous vaccine manufacturers were asked to intimate the following:
 - i) Current status of vaccine production;

- ii) Installed capacity, if the marketing approval has already been obtained;
- iii) Time limit by which the vaccine alongwith the quantity can be supplied

No reply even to this letter has been received

6. As per the provision contained in clause no. 4.2 of the said Agreement, Ministry is entitled to claim refund of the entire amount of the AMC from the indigenous vaccine manufacturers with interest at the rate of 12% per annum from the date of release of the advance amount till the date of adjustment/reimbursement of the advance, if the manufacturers fail to supply the product due to failure/negligence on their part.
7. Since, in spite of the three letters as referred to above, no response has been received from any of the manufacturers indicating their state of preparedness to supply the product after complying with all the stipulated requirements, Ministry is constrained to request that the amount of advance of Rs.10.00 crore granted plus interest at the rate of 12% from the date of payment of advance till the date of refund of advance may be refunded to this Ministry as per the condition laid down in the clause 4.2 of the Advance Market Commitment Agreement

Encl.: as above.

Yours faithfully,

Sd/-

Secretary

Annexure-4

08-02-2021

To

The Secretary,

MH&FW, Government of Bigland

Sub:- Advance Market Commitment Agreement (AMC) for influenza Vaccine;

Ref:- Your letter dated 28th January 2021

Sir,

We have received your above referred letter dated 28th January 2021 on 7th February 2021 and noted the contents. We are extremely concerned at the contents of the letter and the conclusions drawn thereof. Our response is as follows.

1. We are pleased to inform that indigenous manufacturers have developed vaccine. A copy of our Manufacturing License is attached herewith for your kind perusal. (Annexure I).
2. With regard to your above referred letter, we wish to inform you that we have not received your earlier communications dated 16th June, 30th June and 17th October 2020. We have seen the copies of the same only when the same were sent to us as attachment to your above referred letter via Registered Post. Our Company is located far off from the city limits and perhaps this could be a reason for the non-delivery of earlier letters. Similar problem of non-receipt of letters by us has been reported by Director, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, Government of Bigland.
3. In the context of giving periodic updates of our vaccine development program, we wish to inform you that, without fail, every few weeks over the past 12 months, we had been informing BCMR and DCG the progress of our vaccine development. Copies of such correspondence attached herewith for your kind perusal (Annexure III).
4. We have also been informing the status to the officials of Ministry through e-mail and telephonic communications.
5. Hence, the question of Ministry not getting feedback on our vaccine development program is not a fair conclusion.
6. We have allocated huge amount of resources, financial, manpower and time in the vaccine developmental work and clinical evaluation of the product.
7. We have manufactured several batches of the vaccine and we huge stocks available with us details of batches manufactured with dates and number of doses, are given in Annexure IV.

In spite of all the investments made by us in the project and having successfully developed the vaccine and that too of a unique nature, and also our readiness to supply vaccines to MOH&FW, we are concerned to receive such a letter from the Ministry of Health and Family Welfare.

In view of the above we believe that the Clause 4.1 of AMC will not be applicable in our case.

We look forward for your favorable response in this matter by way of placing the supply orders on us/ including our name in tender participation.

Thanking you,

Yours faithfully,
Indigenous Manufacturers

Annexure-5

**Government of Bigland
Ministry of Health & Family Welfare**

INVITATION FOR BID

Ref. : Tender Enquiry Influenza Vaccine / 2021-22.

To

Indigenous Vaccine Manufacturers

Subject : Invitation of bids for supply of Influenza Vaccine.

Dear Sir,

1. The bids are invited for the supply of Influenza Vaccine as per details in the list of requirements at Annexure D in terms of Advance Market Commitment Agreement dated 1st January 2020 entered into between the ministry and your company for indigenous development Vaccine.
2. It is proposed to now enter into a Price Agreement for supply of vaccine. The eligibility criteria have been given in the tender documents annexed. Firms intending to participate in the Contract should ensure that they fulfil all the eligibility criteria as per enclosed documents as prescribed under the tender documents annexed, otherwise the tenders will be summarily rejected.
 - 2.1 The Price Agreement will be governed by the terms and conditions enclosed with this Tender Enquiry and Advance Market Commitment Agreement dated 1st January 2020 and no modifications / alterations etc. are allowed in any case.
 - 2.2 Tenderers are therefore advised to tender rate quotations only if the terms and conditions as prescribed are acceptable to them entirely and they fulfil all the eligibility criteria.
 - 2.3 Tenderers should submit the Bids in sealed envelope superscribing "Tender Enquiry Vaccine /2021-22 due for opening on (to be decided) at 24th May 2021 at 3.00 PM.
 - 2.4 The following documents should be enclosed alongwith the bid.
 - (i)
 - (ii) Monthly rate of supplies and time required for commencement of supplies and to indicate the guaranteed date by which the delivery can be completed from the date of issue of formal order.

OTHER TERMS AND CONDITIONS

1. PRICES:

1.1 In terms of the Advance Market Commitment Agreement dated 24th February 2020, the Purchaser and you have already agreed to the following

(a) Para no. 2.2. The amount of Rs.1.00 crore with interest accruing thereon shall be adjusted against the consideration amount in respect of supplies of the Product to be made in terms of the agreement.

(b) Para no. 2.3. Indigenous Vaccine Manufacturers (IVM henceforth) shall take all reasonable steps and make their best efforts to develop the Product, at their own cost and supply the mutually agreed quantities of the Product to Ministry post-interim licensee after completion of Phase I/II human clinical trials, by April 2020 subject to grant to license from National Regulatory Authority (NRA) and confirmation of required quantities by Ministry.

(c) Para no. 3.1. After the development of the Product, Ministry would ask each of the IVM to quote their price for the Product following the standard tender process. Ministry would evaluate the price so quoted by each of the eligible IVM and then announce the lowest price (L1) so determined and ask the other two qualifying IVM (L2 and L3) to match the price of L1 to supply the Product at the price so determined.

(d) Para no. 4.4. In case due to commercial viability reasons, it is not feasible for any of the IVMs to match the prices of L1, such IVMs will have the option to withdraw from supply agreement of Pandemic Influenza vaccine and would refund the advance amount of Rs.1.00 crore to Ministry within 30 days from the date Ministry asks the IVMs under Article 3.1 of the agreement to match the L1 price with interest at the rate of 12% per annum from the date of release of advance till the date of adjustment/reimbursement of the advance to Ministry on this advance payment or alternatively such IVMs will have the option to get the amount of Rs.1.00 crore with interest at the rate of 12% from the date of release of advance till the date of adjustment/reimbursement of the advance, adjusted against future supplies to Ministry. In case, any of the IVM fails to refund the AMC amount of Rs.1.00 crore with interest cited or exercise the option within 30 days from the date of receipt of such claim, the Ministry shall recover the amount with interest at the rate of 12% per annum from the date of release of advance till the date of adjustment/reimbursement of the advance from the supply/supplies of other vaccines to the Ministry or other Ministries/Department of Government of Bigland.

2. DELIVERY PERIOD:

The tenderer should indicate their guaranteed monthly date of supply with lead period, if any, required by them for commencement of supplies from date of placement of supply order.

3. SHELF LIFE

3.1 Minimum shelf life of the product should be Twelve months from the date on which the potency test for antigen was started.

3.2 The tenderer should note that at the time when the stores are offered for inspection, the shelf life of the vaccine shall not have passed more than one sixth (1/6th) of the total shelf life of the vaccine counted from the date of manufacture.

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13. DELAYS IN THE SUPPLIES/ PERFORMANCE OF THE CONTRACT:

13.1 Delivery of the stores shall be made by the supplier in accordance with the time scheduled, as per the contract. Any deviation performance of its delivery obligations shall render the supplier liable to any or all of the following action :

- (a) Imposition of liquidated damages and/or
- (b) Termination of the contract for default.

14. Termination for Default

14.1 The purchaser may without prejudice to any other remedy for breach of contract, by written notice of default sent to the supplier, terminate the contract in whole or in part

a. If the supplier fails to deliver any or all of the goods within the time periods specified in the contract or any extension thereof granted by the purchaser pursuant to clause 8.

OR

b. If the supplier fails to promptly replace any goods within the time periods specified in the contract or any extension thereof granted by the purchaser pursuant to clause 8.

c. If the supplier fails to promptly replace any goods rejected submitted for testing or subject to recall ordered by the applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of adverse vaccines reaction after giving prompt notice of the recall.

d. If the supplier fails to perform any other obligation(s) under the contract.

14.2 In the event, the purchaser terminates the contract in whole or in part, pursuant to above clause and without prejudice to the purchaser's other remedies, the purchaser may procure upon such terms and in such manner as it deems appropriate, goods or services, similar to those undelivered or unformed, the supplier shall be liable to the purchaser for any excess cost for such similar goods. However, the supplier shall continue performance of the contract to the extent not terminated.

**Government of Bigland
Ministry of Health & Family Welfare**

Dated: 24th August, 2021

To

Indigenous Manufacturers

Subject: Procurement of Influenza vaccine as per Advance Market Commitment (AMC) agreement – reg.

Sir,

I am directed to refer to the subject mentioned above to convey that Ministry has decided to place an order for supply of 1 crore doses Influenza vaccine at a total cost of Rs. 250,00,00,000/- as per the following details :

Company'sname	Dosage	Quantity	Cost Price
Indigenous Manufacturer	1 dose of vaccine	1 crore	250,00,00,000/-

The consignment should be delivered during the period October – December, 2021

Yours faithfully,

Secretary to the Govt. of Bigland

Annexure-7

Date: 28.09.2021

To

The Secretary,
MH&FW, Govt. of Bigland

Ref: Tender Enquiry Influenza Vaccine / 2021-22, due on 24.05.21.

Sir,

We are in receipt of your above referred letter dt. 24.08.2021, from confirming that the Ministry has decided to place an order with us for supply of 1 crore doses Influenza Vaccine.

As per the above referred letter we have been directed to approach you for orders. We humbly request you to please issue formal supply order with full-details of the consignee list to deliver the stocks.

We would be able to supply the same after 150 days from the date of the order since the testing period for the vaccine is 150 days from the date of batch manufacturing.

Please issue supply order at the earliest, giving minimum 150 days' time for the first supply order and oblige.

Thanking you,

Yours sincerely,

Sd/- Indigenous Manufacturer

**Government of Bigland
Ministry of Health & Family Welfare**

Dated: 05.10.2021

Formal Supply Order

To

Indigenous Manufacturer

Supply Order No. dated 05.10.2021 in response to Ministry letter 24th August, 2021. Please acknowledge the receipt of this supply order and arrange to deliver the stores during the period October-December, 2021

Sl. No.	VMS No. & Description of stores	Quantity	Cost Price
1.	Influenza Vaccine	1 crore	250,00,00,000/-

Sd/-

Dy. Asstt. Director General (Stores)

Date: 25.10.2021

To

The Secretary,
MH&FW, Govt. of Bigland

Sub: Order dtd. 05-10-21 for procurement of Influenza Vaccine
as per Advance Market Commitment Agreement – reg

We are in receipt of above referred Supply Order for supply of 1 crore doses Influenza Vaccine, and thank you for the same.

However, in this regard we wish to draw your attention that through our above referred letter dated 28.09.2021, we requested for minimum 150 days time for the first supply, from the date of Supply Order.

The reason for this request is on account of following facts:

This being non-routine vaccine, we initiate production process only after receipt of order; which includes procurement of raw material, sourcing of major inputs and many other processes and then certification, and dispatch under cold chain system.

Please consider the fact that due to various issues involved as listed above, it may not be possible to supply 1 crore doses between October — December' 2021, more particularly when we have received Supply Order in October' 2021 itself.

In view of the facts given above, an early amendment in the supply order with the terms & conditions of the lead period, giving us a minimum of 140 days from the date of this amendment for the first supply, there after 50 000 doses every month; may kindly be issued. If there is any delay in this regard for issue of amendment as per our request, please understand that we as a manufacturer will not afford any penalty, liquidated damages, or any other action detrimental to our company since there is-no delay at our end in processing this order. We reiterate that we remain, committed for supplying vaccine but definitely with the terms & conditions requested by us and earlier assured by Government.

Yours sincerely,

Sd/-

Indigenous Manufacturer

**Government of Bigland
Ministry of Health & Family Welfare**

Dated: 28.11.2021

To

The Indigenous Manufacturer

Sir,

Please refer your letter dated 05.10.2021 on the subject mentioned. In this connection it is to inform that the delivery schedule cannot be changed. Further it is to inform that the Ministry has expressed its displeasure for the deliberate delay by you in supplying the Vaccine despite having given adequate time and opportunity for production and supply of the vaccine.

Yours faithfully,

Secretary to the Govt. of Bigland

**Government of Bigland
Ministry of Health & Family Welfare**

By Registered Post With Acknowledgement

Dated: 09.02.2022

NOTICE

Whereas, an Advance Market Commitment (AMC) Agreement ('agreement' henceforth) was signed between the Ministry and five indigenous manufacturers for development of vaccine.

Whereas, as per Clause No.2.1 of the agreement, an amount of Rs.10.00 Crore was advanced to each vaccine manufacturer which was to be adjusted against the consideration of supplies of the vaccine in future.

After comparison of price offered, Rs.250/- was determined to be the lowest price for each set of complete dose of vaccine by Ministry.

Procurement letter was issued by ministry dt. 24th August, 2021 asking for supply 1 crore doses of the vaccine during October — December, 2021 and accordingly informed the Firm to deliver requisite quantity of the vaccine vide order dated 5th October, 2021.

Whereas, it was infirmed to the indigenous manufacturers that the delivery schedule could not be changed.

Whereas, vide letter dt.16th January, 2022 the receipt of Ministry's procurement dt. 24th August, 2021 and represented that they had vide letters dt.15th October, 2021 and 29th December, 2021 sought time for supplying the vaccine. However, the said letters of the Firm dt. 15th October, 2021 and 29th December, 2021 have not been received in MoH&FW.

Vide letter dated 2nd January, 2022 ministry was informed that the requisite quantity of the vaccine has not been supplied within the stipulated time i.e., from October to December, 2021.

In view of the above, it is clear that the indigenous manufacturer has failed to keep its commitment for supplying the vaccine to Ministry as per the provisions of the agreement in spite of having been informed by Ministry as early as in April, 2021.

Therefore, as per the provision contained in Clause no.4.2 of Article IV of the agreement, Indigenous Manufacturer is hereby directed to refund Rs.10.00 Crore along with the interest accrued thereon to be calculated @ 12% per annum from the date of release of the amount to the actual date of refund.

Sd/-

Disclaimer: This proposition, including the names and annexures used, is hypothetical. Any resemblance to any person or association is purely unintentional and only for academic/educational purposes.