

## SUPPLY AGREEMENT Nr./č. 964/2021

This SUPPLY AGREEMENT (the “**Agreement**”) is entered into full legal force on -27 February 2021.

### BY AND BETWEEN:

(1) **LIMITED LIABILITY COMPANY “HUMAN VACCINE”**, a legal entity duly established and existing in accordance with the laws of Russia, registered under primary state registration number: 1207700324633, having taxpayer identity number: \_\_\_\_\_ registered at the address: 8, Presnenskaya emb. bld. 1, floor 7, premises I, part of room 3, work place 7.31, 123112 Moscow, Russia, represented by its management company, RDIF Corporate Center Limited Liability Company, main state registration number (OGRN): 1147746718294, with its registered address at: 123112, Moscow, 8 Presnenskaya emb., bldg.1, floor 6, premises I, room 9 represented by \_\_\_\_\_; (the “**Seller**”); corporate documents and certificates attesting these facts and the Comfort Letter by the Ministry of Economy of the Russian Federation form part of Schedule 4 of this Agreement.

(2) **MINISTRY OF HEALTH OF SLOVAK REPUBLIC**, a legal entity duly established and existing in accordance with the laws of Slovak Republic, with its registered office located at the address: Limbová 2, 837 52 Bratislava 37, represented by Mr. Marek Krajčí, the Minister of Health, holding all applicable licenses / validations necessary for the purpose of execution of this Agreement (“**Buyer**”),

(the Seller and the Buyer shall be jointly referred to as the “**Parties**” and individually – as the “**Party**”).

### RECITALS:

- (A) The Seller is engaged in the business of manufacturing, sale, marketing and distribution of the Products (as this term is defined in Definitions and Interpretation section).
- (B) The Seller is the owner or licensee of the Intellectual Property Rights (as this term is defined in Definitions and Interpretation section).
- (C) The Buyer is the central authority of Slovak Republic for health care and protection of health within the Territory.

**NOW THEREFORE** the Parties hereby agree as follows.

### DEFINITIONS AND INTERPRETATION

Unless the context requires otherwise, capitalized words and expressions used in this Agreement (including the Recitals) shall have the following meanings:

“**Adverse Event**” shall mean any observation in humans, whether or not considered to be product-related, that is unfavorable and unintended and that occurs after any use of a Product (on-label use only). Included are events related to noxious reactions in humans after being exposed to a Product, violations of approved residue limits, potential environmental problems and transmission of any infectious agent via a Product, as well as any other reactions, specified by law on medicines in Territory.



**“Commercialization”** or **“Commercialize”** means any and all activities that relate to labeling, marketing, promoting, distributing, importing, selling, offering for sale, having sold, or use of the Products. For the avoidance of doubt, all activities related to manufacturing of the Products are not included into this definition.

**“Marketing Authorisations”** means authorisations to place the Products on the market in the Territory in accordance with the applicable laws to be granted by any Regulatory Authority.

**“Marketing Authorization Holder”** shall mean the Party who holds the Marketing Authorization of a Product in the Territory.

**“Products”** means vectored Covid-19 vaccines (“Sputnik V”), consisting out of the two components according to the Schedule 1 of this Agreement. For the first time worldwide the Product has been introduced into civil circulation in the territory of the Russian Federation (marketing authorization issued by the Ministry of Health of the Russian Federation No. LP-006395 of August 11, 2020). The Parties hereby acknowledge and agree that for the purpose of registration of the Product in the Territory compound and other certain aspects of the Product may be subject to change.

**“Royalty”** shall have the meaning described in clause 4.1 of this Agreement.

**“Seller’s Intellectual Property Rights”** means: (i) the Seller’s Patents, (ii) the Seller’s Know-How; (iii) the Seller’s Trademarks;

**“Seller’s Know-How”** means any scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, that is not in the public domain or otherwise publicly known, including, without limitation, discoveries, inventions (whether patentable or not), trade secrets, databases, practices, protocols, regulatory filings, methods, processes, techniques, specifications, formulations, formulae, data (including pharmacological, biological, chemical, toxicological and clinical) analytical, quality control, and stability data) dosing and target patient information, studies and procedures, and manufacturing process and development information, results and data, whether or not patentable, in each of the foregoing cases to the extent not claimed or disclosed in a patent. The Seller’s Know-How includes both the know-how held by the Seller as an owner or licensee.

**“Seller’s Patents”** means: (i) an issued or granted patent (whether to invention, the industrial design or other patentable intellectual property), including any extension, supplemental protection certificate, registration, confirmation, reissue, reexamination, extension, or renewal thereof; (ii) a pending patent application, including any continuation, divisional, continuation-in-part, request for continued examination, substitute, or provisional application thereof; (iii) all pending or issued counterparts or foreign equivalents of any of the foregoing; (iv) a patent application in preparation; and / or (v) any similar rights in any country worldwide including the Territory, held by the Seller as an owner or licensee.

**“Seller’s Trademarks”** means “Sputnik-V” (trademark certificate No. 774579, registered by Russian Patent Agency (Rospatent)) and “Sputnik Vaccine” (trademark certificate No. 774569, registered by Russian Patent Agency (Rospatent)), or any other registered trademark related to the Product, held by the Seller, or pending applications in accordance national jurisdictions legislation or in accordance with Madrid Treaty Concerning the International Registration of Marks of April 14, 1891, or preparations for filling in the corresponding national jurisdictions.

**“State Authority”** means any public authority, including regulatory authorities, registration, antitrust, customs or other legislative, executive and judicial authority (including their territorial departments and offices and subordinate organizations), other persons acting on behalf of the mentioned authorities as well as any judicial authority or local self-government authorities having necessary public powers and competent jurisdiction in the relevant regulatory scope of matters in accordance with applicable law.



“Territory” means Slovak Republic.

## 1. SUPPLY OF THE PRODUCTS

### Framework arrangements

- 1.1. This Agreement determines the general terms and conditions of the legally binding relationship between the Seller and the Buyer arising out of, and in connection with, the supply of the Products by the Seller to the Buyer.
- 1.2. The Seller shall sell, and the Buyer shall purchase, the Products under the terms and conditions of this Agreement. The Buyer undertakes to exercise control over the parallel import cases of the Product: a) arising out of the unauthorised supplies by the third party out of the Territory, b) arising out of the unauthorised supplies to the Territory, including by means of establishing corresponding clauses in the agreements with third parties, monitoring the supply chain of the Products, providing legal remedies in parallel import cases in close coordination with the Seller. For the purpose of this clause “unauthorized supplies” means those supplies which have not been specifically authorized by the Seller in writing.
- 1.3. The Buyer is entitled to appoint an entity to distribute or donate the Products to third parties (within the Territory) which provide health care services, namely hospitals, clinics and vaccination centers. The Buyer shall do so only under the “Sputnik V” trademark. The Buyer is entitled to sell the Products to third parties (both within and outside the Territory) according to the law; the Buyer shall do so only under the “Sputnik V” trademark. If the use of the “Sputnik V” trademark due to local specifics is impossible, the Parties undertake to mutually agree in writing on a different trademark of the Product to be used in the Territory.
- 1.4. The Buyer is at any time during the term of validity (as defined in clause 9.2.) entitled to send experts from the State Authority responsible for inspection of medical drugs in Slovak Republic (in Slovak: Štátny ústav pre kontrolu liečiv) (hereinafter referred to as the “**Experts of the Buyer**”) to undertake inspection of any production facility/site of the Seller (or of any of its subcontractors as listed in Schedule 5) in which the Products are produced for the Buyer and to request documentation as listed in Schedule 6 (medical, pharmaceutical, virological, chemical and similar) related to the Seller’s production of the Products. The Seller is obligated to ensure full access to the production facilities/sites of the Seller (or of any of its subcontractors) and release to the Experts of the Buyer any requested documentation.

### Formation of the Specifications

- 1.5. The Seller at any time during the term of validity (as defined in clause 9.2.) may send to the Buyer a notice of readiness to shipment (the “**Notice of Readiness**”) together with a specification (the “**Specification**”) in the forms set out in Schedule 1.
- 1.6. The Buyer that has received the Specification from the Seller in accordance with clause 1.5 shall consider it within five (5) Business Days from the time of delivery of the Specification.

- 1.7. The Buyer represented by one of the Buyer's authorised representatives shall send to the Seller by e-mail to the corporate e-mail address of the respective Seller's authorised representatives within the term specified in a clause 1.6. above:
- (a) the Specification, agreed in full and duly signed by one of the authorised representatives of the Buyer (in PDF format), with the Buyer's seal affixed (if applicable), or
  - (b) a notice that the Buyer reasonably objects to the Specification received from the Seller in case the Buyer has any objections.
- 1.8. In case the Buyer has any reasonable objections specified in clause 1.8 (b), the Seller and the Buyer will make best efforts to settle outstanding terms and conditions and reach an agreement with regard to the related Specification in dispute within five (5) Business Days from the date of receipt of the notice. In case the Buyer has no reasonable objections specified in clause 1.7 (b), but has not sent to the Seller the Specification agreed and signed by the Buyer in accordance with a clause 1.7 (a) above within the term specified in a clause 1.6. above, the Specification is considered to be approved by the Parties from the date of expiration of the term specified in a clause 1.6 above.

## 2. TERMS AND CONDITIONS OF THE SPECIFICATIONS

- 2.1. Subject to the provisions of section 1, the Seller in accordance with the terms and conditions of the Specification and terms set out in this Agreement shall (acting as the seller of the Products) transfer into the Buyer's ownership the Products in question, and the Buyer (acting as the purchaser of the Products) shall accept such Products and pay to the Seller a certain agreed amount (price) for the Products as set out in this Agreement and the relevant Specification.
- 2.2. All the Products, supplied by the Seller in accordance with this Agreement, shall be supplied and transferred by the Seller on the delivery basis DPU (as defined in Incoterms 2020) at the destination point specified in the Specification or at any other place as may be additionally agreed by the Parties in writing (including via e-mail at the corporate e-mail addresses of the respective Buyer's and Seller's authorised representatives) (the "**Place of Delivery**").
- 2.3. For the avoidance of any doubt and without prejudice to the above the Parties confirm the following:
- (a) The moment of delivery of the Products is when the Products are accepted by the Buyer at the Place of Delivery in accordance with clause 1 (a) of the Schedule 2 ("**Moment of Delivery**"). With a due delivery at the Moment of Delivery, the Seller has fulfilled its obligation to deliver the Products and the risk or liability for the Products as well as the title to the Products are transferred from the Seller to the Buyer unless otherwise provided for by this Agreement.
  - (b) The Seller shall be responsible for the export clearance of the deliveries. The Buyer bears all costs for storage and transportation of the Products. The Seller may organize delivery of Products to the place additionally agreed by the Parties as specified in clause 2.2. Such costs shall be compensated by the Buyer. In this case the risk or liability for the Products are transferred to the Buyer since the time of the delivery of goods at the Place of Delivery to the Buyer.



The Buyer shall issue all respective power of attorneys or otherwise provide representative powers for the purposes of acceptance of the Products.

- (c) The storage and transportation of the Products shall be made in accordance with requirements specified in Schedule 3. The Buyer is responsible for transportation of the Products and everything else necessary to get the Products to the final destination from the Moment of Delivery.
- (d) The Buyer shall provide the Seller with access to temperature data loggers during the period of transportation of the Products to the final destination, and storage, and usage of the Products by the healthcare organizations (if relevant) of the Products. The Buyer shall ensure that the Seller has the aforesaid access.
- (e) The Buyer covenants that it will perform all the required storage and transportation requirements set out in Schedule 3. Each quality control failure shall be reported by the Buyer to the Seller and carefully investigated, taking into account the thermolability of the Product and applicable cold chain in the Territory.
- (f) Following the Moment of Delivery for the purpose of release of the batch in the country of the Buyer (Slovak Republic), the Buyer is entitled, at its full discretion, to subject the delivered batch of the Products to a laboratory assessment. Following such assessment the Buyer is entitled, at its full discretion, to mark the delivered batch of the Products as unsatisfactory and to return, at the expenses of the Seller, the whole delivered batch of the Products back to the Seller. The Seller is then obliged to replace the unsatisfactory batch with a new one. The Seller agrees to carry all the expenses of the replacement (incl. the transportation and storage costs); in case the Buyer incurs any costs/expenses in this respect, the Seller shall reimburse them to the Buyer within 30 days of the Buyer's notifying them to the Seller.

2.4. The Parties have agreed that the Seller has a right to deliver component I and component II of the Product separately. The Parties have agreed that the component II must though be delivered within two (2) weeks after delivery of the component I. The Parties have also agreed that because the supply of the Products is subject to the approval of the Product marketing by the State Authorities of the Territory - approval of application for a group permission for the therapeutic use of an unregistered medical product in the form of human pharmaceuticals, and the Product can only be supplied after receipt of the relevant authorization..

2.5. The price of the Products is indicated below and shall be paid in USD:

№	Type	Quantity	Price (USD)
	Two component COVID-19 vaccine	1 million treatments (1 million doses of the component I and 1 million doses of the component II)	<b>USD 19.90 per treatment</b> <b>(USD 9.95 per one dose of each component)</b>



- 2.6. The Buyer and the Seller hereby agree that the Buyer is obliged to purchase the Products in the quantity of 1,000,000 (one million) treatments (the “**Committed Quantity**”). The purchase of the Committed Quantity is a “take or pay” obligation on the part of the Buyer such that Buyer is absolutely and irrevocably required to accept and pay for the Committed Quantity over the period at the price set forth in clause 2.5 of this Agreement. In the event that Buyer fails to order the Committed Quantity, the Buyer is obliged to pay 100% of the total unfulfilled committed amount.
- 2.7. The “take or pay” obligation according to clause 2.6 of this Agreement is subject to the following conditions which must be fulfilled cumulatively:
- i. The Products have not been claimed as faulty;
  - ii. The deliveries of the Products were made on time;
  - iii. The Seller has adhered to all its obligations under this Agreement.
- 2.8. The Seller shall deliver the Products in the quantities and delivery times as set below:
- (a) The Committed Quantity of 1 million treatments (for 1 million people) shall be supplied until the end of June 2021;
  - (b) The Committed Quantity shall be supplied starting from February 2021, according to the next schedule:

<b>Delivery time</b>	<b>Quantity (treatments)</b>
until the end of February 2021	100.000 treatments (i.e. 100 000 doses of component I and 100 000 doses of component II)
until the end of March 2021	200.000 treatments (i.e. 200.000 doses of component I and 200.000 doses of component II)
until the end of April 2021	200.000 treatments (i.e. 200.000 doses of component I and 200.000 doses of component II)
until the end of May 2021	300.000. treatments (i.e. 300.000 doses of component I and 300.000 doses of component II)
until the end of June 2021	200.000 treatments (i.e. 200.000 doses of component I and 200.000 doses of component II)

The above schedule is binding and could be adjusted after written consent of the Buyer. The confirmation of the exact date of the supply schedule is a subject to coordination with the production sites.

The Buyer shall pay the agreed price for delivered quantities of the Products within seven (7) calendar days from the Moment of Delivery.

The Parties hereby agree and confirm that the price of the Product includes Royalty to be paid according to clause 4.1 of this Agreement.



- 2.10. The Buyer shall accept the Products in accordance with clause 1 (a) of the Schedule 2.
- 2.11. The Parties hereby agree that the price of the Products as defined in clause 2.5. of this Agreement is in any event a net price of the Products and it does not include any applicable taxes, customs duties, expenses related to customs clearance of the Products, transportation and delivery of the Products to the Place of Delivery
- 2.12. The Parties hereby agree and confirm that the total price of this Agreement consists of the purchase price of the Product specified in clause 2.5. above and expenses of the Seller related to transportation, delivery, customs duties and customs clearance of the Products, which the Buyer is obliged to pay. All of the aforesaid expenses shall be specified in the invoice with a respect to the relevant supply of the Products.

### **3. REGULATORY AFFAIRS AND QUALITY**

- 3.1. The Seller shall issue authorizations in favor of the Buyer to represent the interests in front of the State Authorities on the Territory if required in accordance with the applicable law. The Seller shall supply the Products (manufactured by the Seller or a respective third party) in accordance with applicable law (including GMP), Marketing Authorisation, all terms and conditions set forth in this Agreement and the applicable Specifications.
- 3.3. The Seller hereby declares and warrants compliance of manufacturing of the Product with good manufacturing practices and applicable law in the territory of the Seller.

### **4. INTELLECTUAL PROPERTY**

- 4.1 The Seller hereby grants to the Buyer a non-exclusive, royalty-bearing and non-transferrable sublicense to the Seller's Know-How, the Seller's Trademarks and the Seller's Patents to the extent it is necessary for the import and distribution of the Products in the Territory and for the Buyer's sale of the Products to third parties. The Seller is obliged to secure access of the Buyer to the information from Seller's Know-How and Patents within the limits required for the import and distribution of the Products in the Territory and for the Buyer's sale of the Products to third parties. The Buyer shall pay to the Seller a Royalty for the use of the Know-How, the Seller's Trademarks and the Seller's Patents ("Royalty") in the amount equal to 0.1% (zero point one percent) of the price per each Product supplied under this Agreement and is included in the price of the Product. The Royalty is considered to be paid to the Seller at the moment of receipt by the Seller of the purchase price as specified in clause 2.8 of this Agreement.
- 4.2 The same rules for the Seller's Trademarks shall be applied for the third parties authorized or contracted by the Buyer for the import and subsequent distribution of the Product within the Territory. The use of the Seller's Trademarks by such third parties is circumscribed to the same extent and through the same methods (or portion of them) as the Buyer is permitted to use by the Seller under this Agreement. Each such permission should be subject to consent of the Seller, and the Buyer shall maintain up-to-date list of the respective authorized or contracted parties.
- 4.3 The Buyer is entitled to examine all the information about the cases of counterfeit Products on the Territory. The Buyer shall collect and provide the Seller with all the data related to such cases and shall be liable for non-performance of this obligation.

### **5. PHARMACOVIGILANCE**



- 5.1. The Buyer shall, within one (1) Business Day or three (3) calendar days, whichever is shorter, from the date of receipt of notice or information concerning any Adverse Event relating to any Product and in accordance with applicable law of the Territory, notify the Seller of such Adverse Event. Such notice shall:
- (i) be forwarded to the Seller by email to the designated point of contact (“DPOC”) and
  - (ii) include the name, address and telephone number of the person making the complaint or report of an Adverse Event, the Product(s) involved, the nature of the Adverse Event and such other information as Seller may reasonably require.
- 5.2. The Buyer shall cooperate fully with, and provide all reasonable and necessary information and assistance to the Seller in connection with submission of complete, accurate and timely responses to requests for additional information and collection of samples of each Product. The Buyer shall:
- (i) take all steps necessary to assist Seller in meeting any reporting obligations and other obligations under applicable law of the Territory relating to Product; and
  - (ii) fulfill its reporting and other obligations under applicable law of the Territory relating to Product.
- 5.3. Each Party shall be responsible for the collection, storage and assessment of the Adverse Events data.
- 5.4. In the event Buyer receives from any State Authority any communication relating to any Adverse Event, Buyer shall, within one (1) Business Day from the date of receipt of such communication, notify Seller of such communication by e-mail to the DPOC. The notice shall include, in addition to the communication from the State Authority, a written summary of any conversations between Buyer or its Representatives and the State Authority and any other information relating to such communication.
- 5.5. The Buyer shall, within thirty (30) days from the date of receipt of a request by the Seller, provide to the Seller a print-out or computer disk of each Adverse Event reported to or known by Buyer for the twelve (12) month period prior to the date of such request. The Buyer shall, within ten (10) days from the date of receipt of a request by the Seller, make available to Seller or its designee, for inspection and copying (at Seller's cost and expense), records of Buyer (including computer disks) relating to each Adverse Event. The obligation of Buyer to disclose to Seller records and information concerning any Adverse Event shall continue as long as Seller continues to market any Product.
- 5.6. The Marketing Authorization Holder shall have the ultimate obligation to make or file any report or otherwise make any disclosure, with respect to any Adverse Event, to the relevant State Authorities.

## 6. LIABILITY

- 6.1. The Buyer is liable for any Adverse Events occurred within the Territory
- 6.2. The liability of the Seller for any action which is outside of its reasonable control, provided the Seller acts in good faith, is excluded.

- 6.3. Under no circumstances shall the liability of the Seller for the non-performance or improper performance of this Agreement exceed an amount equal to one hundred thousand (100,000) USD / 10% of the full price for the Committed Quantity.
- 6.4. In no instance, will the Seller be liable to the Buyer or any other person for indirect, consequential, remote losses such as but not limited to loss of opportunity, loss of revenue, loss of profit (i.e. income which would have been received by a person in the ordinary course of business if the right of such person had not been breached), loss imputed to time value of money, reputational issues etc.
- 6.5. For the sake of clarity, the Seller is not liable for the Product efficiency in any case.

## **7. SELLER'S IMMUNITY FROM LIABILITY**

- 7.1. None of the Seller or any of its Connected Persons shall be subject to any liability under this Agreement or otherwise for any Loss suffered by the Buyer or any person whatsoever (including patients and their relatives) resulting from the use of the Product (including liability for any claims that may be made against the Seller by any third persons).
- 7.2. For the purpose of the Agreement herein:
  - (a) "Connected Persons" means (in relation to a Party) the shareholders, officers, servants, employees, agents and advisers of that Party or any of its Affiliates;
  - (b) "Affiliates" means, in relation to any person, any other person that, directly or indirectly, control, are directly or indirectly controlled by or are under common direct or indirect control with that person, and "Affiliate" means any of them; for the purposes of this definition, "control" shall mean holding of more than 50% of the voting power in respect of, the right to appoint sole executive officer, to elect a majority of the members of the board of directors or management board or any other collegial management body, which under the applicable laws or constitutive documents of the relevant person has a similar authority, or the right to otherwise determine the principal conditions of the conduct of business of, a person and "controlled", "control" and "controlling" shall be construed accordingly;
  - (c) "Loss" means all losses, damages liabilities, costs (including legal costs and experts' and consultants' fees), charges, expenses, actions, proceedings, claims and demands, punitive damages, loss of profit, loss of goodwill, whether actual or prospective, consequential loss, product liability or any other detrimental effect (including any Adverse Effect);
  - (d) "Adverse Effect" means any observation in humans, whether or not considered to be product-related, that is unfavorable and unintended and that occurs after any use of the Product. Included are events related to noxious reactions in humans after being exposed to the Product, violations of approved residue limits, potential environmental problems and transmission of any infectious agent via the Product, as well as any other detrimental reactions.

## **8. WHOLE AGREEMENT**

- 8.1. This Agreement contains the whole agreement between the Parties relating to the subject matter of this Agreement at the date hereof to the exclusion of any terms implied by law which may be



excluded by contract and supersedes any previous written or oral agreement between the Parties in relation to the matters dealt with in this Agreement.

- 8.2. Each of the Parties agrees and acknowledges that its only right and remedy in relation to any representation, warranty or undertaking made or given in connection with this Agreement shall be for breach of the terms of this Agreement and each of the Parties waives all other rights and remedies (including those in tort or arising under statute) in relation to any such representation, warranty or undertaking. Except for any liability in respect of a breach of this Agreement, no Party (or any of its Connected Persons) shall owe any duty of care or have any liability in tort or otherwise to the other Party (or its respective Connected Persons) in relation to this Agreement.
- 8.3. Any terms or conditions implied by law in any jurisdiction in relation to the Agreement or any action envisaged by it are excluded to the fullest extent permitted by law or, if incapable of exclusion, any right, or remedies in relation to them are irrevocably waived.
- 8.4. Any and all claims whatsoever (whether in contract, tort or otherwise) arising out of or in any way connected with or relating to this Agreement shall be brought exclusively by the Parties strictly in accordance with the terms of this Agreement, and not by or against any other persons or under any other documents.
- 8.5. Each Party agrees to the terms of this clause on its own behalf and as agent for each of its Connected Persons.

## 9. INDEMNITY

- 9.1. The Buyer (on its own behalf and as agent for each of its Connected Persons) agrees to fully indemnify and keep indemnified the Seller and all of its Connected Persons from and against any Losses suffered by any of them as a result of acts or omissions of
  - (a) the Seller or any of its Connected Persons in breach of this Agreement, or
  - (b) any third person in connection with the subject matter of this Agreement or any use of the Product in the Territory by that or any other person whatsoever

## 10. TERM AND TERMINATION

- 10.1. This Agreement shall enter into force on the date on which this Agreement is duly executed by the Parties as specified on the title page of this Agreement (the “**Effective Date**”).
- 10.2. This Agreement shall remain in full force and effect until the date which falls three (3) years after the Effective Date (the “**Term of Validity**”).
- 10.3. The Seller may at any time unilaterally withdraw (through non-judicial procedure) from this Agreement and / or any of the Specifications in full by sending the termination notice (the “**Termination Notice**”) to the Buyer in any of the following cases:
  - (a) any delay by the Buyer in the performance of its obligations to pay for the Products under any Specifications which lasts longer than fifteen (15) calendar days; or
  - (b) the occurrence of one case of disclosure by the Buyer or failure by the Buyer to procure for the non-disclosure of the confidential information (as defined in clause 12.1 of the Agreement).

- 10.4. The Buyer may at any time unilaterally withdraw (through non-judicial procedure) from this Agreement and / or any of the Specifications in full by sending the Termination Notice to the Seller in case of the Seller 's failure to deliver at least 50 % of quantity of the Product specified in the schedule as defined in clause 2.8 per each month;
- 10.5. The Agreement shall be deemed terminated upon expiry of ten (10) Business Days from the date of receipt by the Buyer of the Termination Notice.

#### 11. RULES FOR SENDING MESSAGES AND DOCUMENTS

- 11.1. Unless this Agreement expressly provides otherwise, any messages or documents arising out of or in connection with the entry or performance of this Agreement and / or any Specification, which the Party may need or require to send to the other Party, shall be sent to the other Party: (i) in person (by hand); (ii) by e-mail; (iii) by registered post; (iv) by fax (with receipt confirmed) or (v) internationally recognized courier service to the following addresses:

**To the Seller:**

Address: 8, Presnenskaya nab. bld. 1, floor 7, premises I, part of room 3, work place 7.31, 123112, Moscow, Russia

Attn: Russian Direct Investment Fund and Human Vaccine LLC

E-mail

**To the Buyer:**

Address: Limbova 2, Limbová 2, 837 52 Bratislava 37

Attn: Mr. Marek Krajčí, the Minister of Health

CC: :

E-mail:

- 11.2. Unless this Agreement provides otherwise, all payments under this Agreement and/or all Specifications shall be made in accordance with the bank details of the Parties set out in this clause below.

**Bank details of the Seller:** Beneficiary: HUMAN VACCINE LLC

Beneficiary account number (USD):

Beneficiary bank:

Beneficiary bank address:

Beneficiary bank SWIFT:

Bank correspondent:

Correspondent bank SWIFT:

Correspondent bank account:



**Bank details of**

**Buyer:** Bank: Bank: Statna pokladnica / Public Treasury bank account

Account No. (USD):

SWIFT:

IBAN: s

**12. GOVERNING LAW AND DISPUTE RESOLUTION**

- 12.1. This Agreement shall be governed by and construed in accordance with the law of Slovak Republic, excluding all applicable collision (international private) law provisions.
- 12.2. The Parties agree that the United Nations Convention on Contracts for the International Sale of Goods (CISG) does not apply to this Agreement and any of the Specifications.
- 12.3. Any dispute arising out of or in connection with this contract, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by arbitration administered by the Singapore International Arbitration Centre ("SIAC") in accordance with the Arbitration Rules of the Singapore International Arbitration Centre ("SIAC Rules") for the time being in force, which rules are deemed to be incorporated by reference in this clause. The arbitral award shall be final and binding on both parties to the dispute. The decision contains the legal conclusions and the arguments of the findings of fact. Arbitration proceedings are conducted in English. All documents relating to the arbitration proceedings shall be submitted in English.
- 12.4. The arbitral tribunal shall consist of three arbitrators. The place of arbitration shall be Singapore. The arbitration shall be conducted in the English language. The arbitration award shall be final for the Parties.

**13. MISCELLANEOUS**

- 13.1. Any information relating to this Agreement, including the fact of existence of this Agreement, the terms and conditions of this Agreement, the content of oral and written negotiations or correspondence, any other documents, statements relating to this Agreement and the information (including but not limited to the term and quantity of supply of the Product, the price of the Product (including price per dose or component of the Product), other conditions of the supply of the Product, and section "Definitions and Interpretations", all of the Articles and Schedules of this

Agreement, any proprietary information and data of a financial, commercial or technical nature, know-how, scientific information, methods, processes, business plans, Intellectual Property Rights which is not publicly available and is owned or controlled by the disclosing Party) received by any Party in connection with this Agreement shall be deemed confidential (the “**Confidential Information**”) and must not be disclosed by either Party to any third parties without the prior written consent of the other Party, save for cases (i) of criminal prosecution of the Buyer for non-disclosure of the Confidential Information under applicable law and (ii) where such disclosure is required in connection with the lawful requests from the competent state authorities or courts under applicable law (the “**Permitted Disclosure**”). In case of Permitted Disclosure by the each Party, the Party shall notify the other Party on such disclosure (the “**Notice of Disclosure**”) within one (1) Business Day from the date of such disclosure. The Notice of Disclosure shall contain the information regarding grounds for disclosure of the Confidential Information, references to applicable laws and regulations, list of disclosed Confidential Information. In the event of breach of this clause 13.1 by the Buyer, the Buyer shall pay to the Seller for each event of the breach the following (the “**Liquidated Damages**”):

- (i) a compensation of the resulting losses of the other Party, or
  - (ii) a compensation in the amount of one million (1,000,000) USD,
- whichever is higher.

- 13.2. All costs and expenses in respect of any resulting negotiations and agreement, including without limitation, legal and accounting charges, shall be borne by the Party which incurs the same. Except as otherwise provided in this Agreement, each Party shall be responsible for its respective expenses, including payment of taxes, incurred in the course of exercising its rights and responsibilities under this Agreement.
- 13.3. All payments to be performed by one Party in favour of another Party (the Taxable Recipient) under this Agreement shall not include any withholding taxes imposed by the relevant tax legislation on such payment. If any of such withholding taxes is applicable, the Party, obliged to pay and withhold (Tax Agent), shall be required to gross up such payment to the extent of such taxes to ensure that the Taxable Recipient receives full amount stipulated by this Agreement.

In this case, the Taxable Recipient shall provide to the Tax Agent:

- (a) the certificate properly issued and authorized by the competent tax authority to prove that relevant double tax treaty is applicable to the income paid, and
- (b) the letter, signed by the Taxable Recipient, or other evidence to certify that the Taxable Recipient is the beneficial owner for such income.

After and if the tax is withheld, the Tax Agent, shall provide to the Taxable Recipient:

- (c) the letter (signed and stamped) with information about the amount of tax withheld and transferred to the budget, and
- (d) the confirmation of actual payment of such taxes to the budget, and
- (e) the certificate properly issued and authorized by the competent authority to prove that relevant double tax treaty is applicable to the income paid.

The letter and confirmation mentioned in subparagraphs (c) and (d) above shall be provided within the calendar quarter in which the payment was made, but in any case not later than 10 days from the end of such a quarter.



13.4. Any amendments to this Agreement shall be effective only if made in writing and are executed by both Parties, unless any of the Party has under this Agreement the right to unilaterally amend this Agreement.

13.5. This Agreement is made in two (2) original copies of equal legal force. Each Party shall be provided with one original copy of this Agreement.

IN WITNESS WHEREOF this Agreement have been executed by the Parties through their duly authorised officers on Effective Date.

[SIGNATURE PAGE TO FOLLOW]

SIGNED for and on behalf of:

SIGNED for and on behalf of:

Seller

Buyer

Name:

Name: Marek Krajčí

Title: on behalf of RDIF Corporate Center LLC, Title: the Minister of Health of the Slovak Republic  
management company of LIMITED LIABILITY COMPANY "HUMAN VACCINE"



*[Faint signature and stamp of the Buyer]*

Signature:

SCHEDULE 1

THE FORM OF THE NOTICE OF READINESS

NOTICE [4] dated [ ]

The Seller hereby notifies the Buyer that the following Products are ready for the shipment:

**SCHEDULE 1**

**THE FORM OF THE NOTICE OF READINESS**

**NOTICE № [◆] dated [◆]**

The Seller hereby notifies the Buyer that the following Products are ready for the shipment:

<b>№</b>	<b>Products (type; code; dosage form)</b>	<b>Description</b>	<b>Quantity</b>	<b>Subtotal (USD)</b>
	Two component COVID-19 vaccine	[◆]	[◆]	[◆]
				[0,00]
				<b>TOTAL (USD):</b>

The specific terms and conditions of the shipment of the Products specified above are set out in the Specification № [◆].

**SIGNED** for and on behalf of:

Seller

Name: [◆]

Title: [◆]

Signature: \_\_\_\_\_



**THE FORM OF THE SPECIFICATION**

**SPECIFICATION №[♦] dated [♦]**

<b>№</b>	<b>Products (type; code; dosage form)</b>	<b>Description</b>	<b>Quantity</b>	<b>Subtotal (USD)</b>
	Two component COVID-19 vaccine	[♦]	[♦]	[♦]
				[0,00]
				<b>TOTAL (USD):</b>

In accordance with clause 2.2 and 2.3 letter a) of this Agreement the Products shall be delivered by the Seller to the Buyer at the Place of Delivery located at the address [♦] within [•]days from the date when this Specification was agreed by the Parties.

The Seller may organize the delivery of the Products to the place, additionally agreed by the Parties, other than the place determined in the previous paragraph, for the sake of Buyer's convenience. The costs for that delivery shall be compensated by the Buyer. The shelf life of the Products supplied under this Specification shall not be less than [♦] from the Moment of Delivery.

**SIGNED** for and on behalf of:

**SIGNED** for and on behalf of:

Seller

Buyer

Name: [♦]

Name: [♦]

Title: [♦]

Title: [♦]

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

## **SCHEDULE 2**

### **1. ACCEPTANCE. COMPLAINTS**

- a) When accepting supply of the Products, the Buyer will check that the number of packages / pallets received corresponds to the number specified in the waybills / consignment notes and shall immediately record any numerical discrepancy or obvious external damage or that the Products have not been maintained in accordance with the Seller's cold chain requirements in the waybills / consignment notes and by giving written notice to the Seller in accordance with this Schedule. Failure to do so will result in the Buyer as being deemed to accept the Products.

If any such claim is so notified and accepted by the Seller, the Seller's sole responsibility will be limited to replacing or supplying lacking quantities of Products in question and the Buyer will not be entitled to any other compensation whatsoever. The Seller will not be liable for any claims howsoever caused not notified to the the Seller.

When accepting supply of the Products and in case of absence of objections in respect to the Products, the duly authorized representative of the Buyer shall sign the waybill(s) / consignment note(s) without reservations; such signature shall have no prejudice on any of the rights of the Buyer pursuant to this Agreement.

### **2. RECALL OF PRODUCTS**

In the event of any batch recall, the Buyer agrees to cooperate promptly with the Seller in taking all necessary steps to remove the relevant batch from the market place at the Seller's cost. In order to facilitate any possible batch recall the Buyer shall maintain suitable records including at least associated batch numbers and all the quantities in respect of all sales together with appropriate details of its customers in question and all other information required pursuant to the laws of the Territory. If the Buyer is required by any government agency or regulatory body acting within its proper authority to initiate or undertake a batch recall, it must immediately provide the Seller with written notice of such requirement. The Buyer shall not initiate or undertake any batch recall without prior consultation with and the written agreement of the Seller as to the most appropriate method and procedures for implementing the batch recall. Without prejudice to the above, each of the Seller and the Buyer shall keep all relevant records and provide all necessary assistance to the other to ensure compliance with laws of the Territory in relation to the recall of any Products.



## SCHEDULE 3

### REQUIREMENTS FOR STORAGE AND TRANSPORTATION

#### 1. STORAGE

1. The Products shall be stored in accordance with the storage conditions set out in the relevant instructions for use, regulatory documents and on the package of the Products.
2. The premises for storing the Products shall be designed in a way allowing the required storage conditions. The zones for storing the Products shall be labelled with the names of the Products and the temperature and humidity conditions for storing them.
3. The premises for storing the Products shall be equipped with an online system for controlling the temperature and humidity parameters. Such system shall have uninterruptable power supply.
4. The area of the premises used by the Parties for storing the Products shall correspond to the volume of the Products to be stored and shall be no less than 150 square meters.
5. The premises for storing the Products shall be mapped or examined for air flow distribution in compliance with the recommendations of the World Health Organisation (WHO).
6. Mapping shall be performed in the coldest and in the hottest periods. Mapping for coolers may be performed during any period once in three years. After the tests are carried out, the hot and the cold spots shall be determined in each zone for storing the Products. An instruction shall be devised for installing sensors (loggers) in the critical spots of each zone for storing the Products. Any areas where critical deviations are registered shall be considered unsuitable for storing the Products.
7. Temperature mapping for the premises for storing the Products shall be performed once in three years during the hot season and once in three years in the cold season, as well as whenever material changes are made to the structure of the premises or the temperature control equipment.
8. The Products shall be stored on shelves (in closets) or on dunnage racks (pallets). The Products may not be stored on the floor without a pallet. Pallets may be located on the floor in one row or on shelves in several tiers, depending on the height of the shelf. The pallets with the Products may not be located in several rows in height without using shelves.
9. The Products shall be appropriately stored in separate and expressly identified zones access to which is allowed only to staff authorised to have such access. Any system which replaces the physical separation of the storage zones (e.g. a computerised system), if it is used by any of the Parties, shall ensure an equivalent security level and be validated.
10. The validation and/or assessment shall be formalised in reports which summarise the results obtained as well as provide explanations of the deviations identified.

#### 2. TRANSPORTATION

- 2.1. The Products shall be transported in accordance with the conditions which ensure that the Products maintain their identity and attributes. The temperature regime for transportation is based on the requirements of regulatory bodies, information on the package of the Products and the provisions of regulatory documents.

- 2.2. When preparing for the transportation of the Products, the Parties shall ensure that the remaining shelf lives of the Products supplied have been ratified.
- 2.3. A transportation vehicle shall bear special equipment that ensures that the required temperature regimes for storing the Products are maintained. For instance, a transportation vehicle shall be equipped with temperature controls which ensure the provision of data confirming that the temperature regime is being observed at all stages of the transportation of the Products.
- 2.4. The equipment used to register and control the temperature regime shall be classed as measuring devices intended for use in the sphere of statutory regulation aimed at ensuring the consistency of measurements.
- 2.5. All the data concerning the maintenance of the temperature regime during the transportation of the Products shall be kept for no less than the shelf life of the Products plus one year past the expiration date.
- 2.6. To transport the Products on pallets, if there is a risk of the Products being exposed to high temperatures, at least one temperature sensor shall be installed on each pallet with the Products; such sensor shall react to exposure to high temperatures. The sensor shall be installed at the upper directional angle.



SCHEDULE 4

Limited Liability Company  
«Human Vaccine»  
8, Presnenskaya emb. bld. 1, floor 7, premises I, part of room 3, work place 7.31  
Moscow, Russia 123112  
ITN 9703017050

Letter # BЧ-14u/02-21, 27.02.2021  
2021

Date: 27 Feb

To: Ministry of Health of the Slovak Republic  
Limbová 2,  
837 52 Bratislava 37  
Slovak Republic

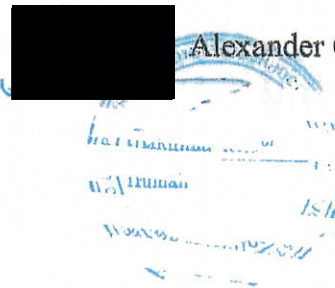
COMFORT LETTER

Dear Madam/Sir,

we hereby confirm to you that LIMITED LIABILITY COMPANY "HUMAN VACCINE", registration number: 1207700324633, taxpayer identity number: [REDACTED], registered at the address: 8, Presnenskaya emb. bld. 1, floor 7, premises I, part of room 3, work place 7.31, 123112 Moscow, Russia, represented by its management company, RDIF Corporate Center Limited Liability Company, main state registration number (OGRN): 1147746718294, with its registered address at: 123112, Moscow, 8 Presnenskaya emb., bldg.1, floor 6, premises I, room 9, represented by Mr. Alexander Chistyakov, is a legal entity ultimately beneficially owned and fully controlled by the Russian Federation and/or its government.

Sincerely,

General Director RDIF Corporate  
Center LLC, Management Company  
of "Human Vaccine" LLC

[REDACTED] Alexander Chistyakov  


## SCHEDULE 5

### Production facilities/sites of the Seller

1. Manufacturing site for API:

GENERIUM JSC  
Adress: 601125,  
Vladimir Oblast, Petushky District,  
Volginsky, ul. Zavodskaya, bld 26  
Russian Federation

1. Manufacturing site for filling:

Pharmstandard-UfaVITA JSC  
Address: 28, Khudayberdina str., Ufa,  
Republic of Bashkortostan, 450077  
Russian Federation



## SCHEDULE 6

### Safety, efficiency and pharmaceutical quality

Conditions necessary to assess safety, efficacy and pharmaceutical quality

#### 1. Assessment of Good Manufacturing Practice (GMP)

- on-site inspection to the extent of - 2 inspectors, 5 days.
- if only one supply of vaccine is to be assessed, the inspection may be reduced to 2 days.
- for the evaluation of GMP standards, documentation must be submitted:

CAP.3 ectd registration documentation

Process validation

Cleaning validation

Risk analysis for product vaccine sputnik

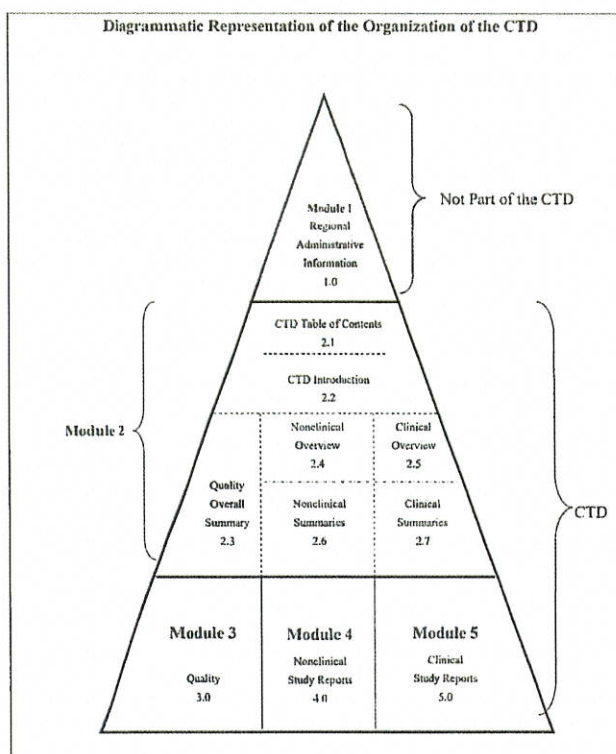
Sanitization program

Media fill simulation

Validation master plan

Quality manual

#### 1. documentation in eCTD



#### 2 A) to evaluate the quality of the vaccine

##### Quality (module 3)

1. Control of critical stages and intermediate products

## 2. Summary Process Flow Diagram

## 3. Long term stability -18C 3M

### 4. část 3.2.2 Instruction \_ENG\_20.01.21

Conclusion: a complete dossier must be submitted in CTD format in accordance with the Notice to Applicants

- emergency use is related to the lack / low number of clinical data on a sufficient number of participants in clinical trials - there is no reason for reduced drug quality or reduced drug quality requirements (or for example a preclinical), therefore a complete dossier must be submitted - list below

#### Required documentation

#### Module 3      Quality

##### Drug substance (CTD module 3.2.S)

- 3.2.S.1      General information
- 3.2.S.1.1    Nomenclature
- 3.2.S.1.2    Structure
- 3.2.S.2      Manufacture
- 3.2.S.2.1    Manufacturers
- 3.2.S.2.2    Description of the manufacturing process and in-process controls
- 3.2.S.2.3    Control of materials
- 3.2.S.2.4    Control of critical steps and intermediates
- 3.2.S.2.5    Process validation and/or evaluation
- 3.2.S.2.6    Manufacturing process development
- 3.2.S.3      Characterisation
- 3.2.S.3.1    Elucidation of structure
- 3.2.S.3.2    Impurities
- 3.2.S.4      Control of drug substance
- 3.2.S.4.1    Specification
- 3.2.S.4.2    Analytical procedures
- 3.2.S.4.3    Validation of analytical procedures
- 3.2.S.4.4    Batch analysis
- 3.2.S.4.5    Justification of specification
- 3.2.S.5      Reference standards or materials
- 3.2.S.6      Container closure system
- 3.2.S.7      Stability
- 3.2.S.7.1    Stability summary and conclusion
- 3.2.S.7.2    Post-approval stability protocol and stability commitments
- 3.2.S.7.3    Stability data

##### Drug product (CTD module 3.2.P)

- 3.2.P.1      Description and composition of the drug product
- 3.2.P.2      Pharmaceutical development
- 3.2.P.2.1    Components of the drug product.
- 3.2.P.2.2    Drug product
- 3.2.P.2.3    Manufacturing process development
- 3.2.P.2.4    Container closure system
- 3.2.P.2.5    Microbiological attributes
- 3.2.P.2.6    Compatibility
- 3.2.P.3      Manufacture
- 3.2.P.3.1    Manufacturers



3.2.P.3.2	Batch formula
3.2.P.3.3	Manufacturing process
3.2.P.3.4	Control of critical steps and intermediates
3.2.P.3.5	Process validation and/or evaluation
3.2.P.4	Excipients
3.2.P.4.1	Specification
3.2.P.4.2	Analytical procedures
3.2.P.4.3	Validation of analytical procedures
3.2.P.4.4	Justification of specification
3.2.P.4.5	Excipients of human and animal origin
3.2.P.4.6	Novel excipients – <i>appears not to be applicable</i>
3.2.P.5	Control of drug product
3.2.P.5.1	Specification
3.2.P.5.2	Analytical procedures
3.2.P.5.3	Validation of analytical procedures
3.2.P.5.4	Batch analysis
3.2.P.5.5	Impurities
3.2.P.5.6	Justification of specification
3.2.P.6	Reference standards or materials
3.2.P.7	Container closure system
3.2.P.8	Stability
3.2.P.8.1	Stability summary and conclusion
3.2.P.8.2	Post-approval stability protocol and stability commitment
3.2.P.8.3	Stability data

Appendices (CTD module 3.2.A)

A.1. Facilities and equipment

A.2. Adventitious agents safety evaluation

A.3. Novel excipients – *appears not to be applicable*

**2B) to evaluate preclinical part:**

Modul 4

Jednotlivé súčasti dokumentácie je nutné dodať vo forme dossieru, vid' nižšie:

Modul 4:	Non-clinical study reports
4.2.1	Pharmacology
4.2.1.1	Primary Pharmacodynamics
4.2.1.2	Secondary Pharmacodynamics
4.2.1.3	Safety Pharmacology
4.2.1.4	Pharmacodynamic Drug Interactions
4.2.2	Pharmacokinetics
4.2.2.1	Analytical Methods and Validation Reports (if separate reports are available)
4.2.2.2	Absorption
4.2.2.3	Distribution
4.2.2.4	Metabolism
4.2.2.5	Excretion
4.2.2.6	Pharmacokinetic Drug Interactions (nonclinical)
4.2.2.7	Other Pharmacokinetic Studies
4.2.3	Toxicology
4.2.3.1	Single-Dose Toxicity
4.2.3.2	Repeat-Dose Toxicity
4.2.3.3	Genotoxicity
4.2.3.4	Carcinogenicity

- 4.2.3.5 Reproductive and Developmental
- 4.2.3.6 Local Tolerance
- 4.2.3.7 Other Toxicity Studies (if available)

2B) to assess the preclinical part

#### Module 4

The individual components of the documentation must be delivered in the form of a dossier, see below:

#### Modul 5

- 5.2 Tabular Listing of All Clinical Studies
- 5.3 Clinical Study Reports
  - 5.3.1 Reports of Biopharmaceutic Studies
  - 5.3.2 Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials
  - 5.3.3 Reports of Human Pharmacokinetic (PK) Studies
  - 5.3.4 Reports of Human Pharmacodynamic (PD) Studies
  - 5.3.5 Reports of Efficacy and Safety Studies
  - 5.3.6 Reports of Post-Marketing Experience
  - 5.3.7 Case Report Forms and Individual Patient Listings

2D) to assess the safety of the vaccine (pharmacovigilance)

Modules 1, 2 and 5 required

There is a lack of essential pharmacovigilance documents that need to be provided in order to adequately assess safety.

The individual components of the documentation must be delivered in the form of a dossier, see below:

#### Modul 1

- 1.8 Information relating to Pharmacovigilance
  - 1.8.1 Pharmacovigilance System
  - 1.8.2 Risk-management System\*

#### Modul 2

- 2.4 Non-clinical Overview
- 2.5 Clinical Overview

#### Modul 5

- 5.3 Clinical Study Reports
- 5.3.6 Reports of Post-Marketing Experience\*\*

### **2E) to evaluate public documetation**

#### Module 1

- M1.3.1-spc-label-pl country
- M1.3.2-mockup country
  - (SPC) in national language



- (PL) in national language

2E) for the assessment of publicly available documents

Module 1

M1.3.1-spc-label-pl country

M1.3.2-mockup country

- Summary of Product Characteristics (SPC) in the national language
- Written information for the user (PL) in the national language