

**Distribution Agreement** 

[NON-EU]

Between:

**PROCARE HEALTH IBERIA, S.L.**, a Spanish company having its registered office at Avenida Miguel Hernández 21 bajo, 46450 Benifaió (Valencia), Spain, registered in the Commercial Register of Valencia, Spain with number ESB66278995.

On the one hand

(hereinafter referred to as "PROCARE"),

and

**BIOVAXYS,** a Canadian company having its registered office at 905 West Pender Street, Suite 503, Vancouver, British Columbia V6C 1L6 Canada, registered in the province of British Columbia.

on the other hand

(hereinafter referred to as "BIOVAXYS" or "DISTRIBUTOR").

PROCARE and the BIOVAXYS hereafter collectively referred to as the "Parties".

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#### RECITALS

- A. PROCARE is a company engaged in the development, sale and distribution of specific medical devices and pharmaceutical products, especially the product described in <u>Exhibit "A"</u> hereto. PROCARE operates at a high level of quality assurance, achieving its objectives by establishing and maintaining quality management systems for the manufacture of devices. This policy ensures that products released for distribution are of appropriate quality.
- B. BIOVAXYS is a company engaged in the distribution, promotion and marketing of medical devices, food supplement and pharmaceutical products.
- C. On November 12<sup>th</sup> 2018, PROCARE and BIOVAXYS entered into a mutual confidentiality and non-disclosure agreement.
- D. On October 3<sup>rd</sup> 2022, PROCARE and BIOVAXYS signed a Letter Of Intent (LOI) agreeing on terms that are covered here in this Distribution Agreement.
- E. PROCARE is willing to appoint BIOVAXYS as its sole and exclusive distributor in the TERRITORY as described in Exhibit "C".
- F. As a consequence, the Parties hereby agree to enter into this Distribution Agreement whose purpose is to define the rights and obligations of the Parties with respect to registration, supply, promotion and distribution of the PRODUCT in the TERRITORY.
- G. The Parties agree that this preamble is part and parcel of this Distribution Agreement.

### 1 AGREEMENT

NOW, THEREFORE, in consideration of the covenants contained herein, the above recitals and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

#### 2 **DEFINITIONS**

Whenever used in this Distribution Agreement, the following terms shall have exclusively the meaning as specified hereafter:

- 2.1 "AFFILIATE" shall mean any company or business entity controlled by, controlling or under common control with a Party to this Agreement. For this purpose, "control" shall mean the direct or indirect ownership of more than 50% (fifty percent) of the voting stock of that company, or in the absence of ownership of more than 50% (fifty percent) of the voting stock of the company, the power, directly or indirectly, to direct or cause the direction of the management and policies of such company. The Party shall ensure that its Affiliate shall also to be bound to the terms and conditions of this Agreement; nevertheless, the Party concerned shall be responsible for all acts and/or omissions of its Affiliate towards the other Party.
- 2.2 **"AGREEMENT**" or the **"DISTRIBUTION AGREEMENT**" shall mean this distribution agreement made by and between the Parties.
- 2.3 **"EFFECTIVE DATE"** shall mean the date of the last signature of this Agreement by the Parties.
- 2.4 **"FOOD SUPPLEMENT"** shall mean foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities (definition given in Directive 2002/46/EC of the European Parliament) or the US equivalent as regulated by the FDA

- 2.5 **"IMPROVEMENTS"** shall mean all modifications, improvements and future developments of the PRODUCT introduced into PRODUCTS' range of products intended for HPV indication (defined as MEDICAL DEVICE and or OTC and excluding any Rx drug development).
- 2.6 **"KOLs**" means key opinion leaders such as medical experts within the field of Gynaecology and HPV management.
- 2.7 **"MARKETING PLAN**" shall mean the key marketing programs to support the brand as well as the number of reps that will support the brand in the TERRITORY and the participation to the International events organized by PROCARE at the international level to help establishing the TRADEMARK's credibility. The MARKETING PLAN shall be agreed by the Parties on a yearly-basis within 3 months for the relevant following calendar year.
- 2.8 **"MEDICAL DEVICE**" shall mean any product complying with the definition provided in the Regulation of Medical Device and its latest applicable revisions and which has been approved and/or marketed according to it.
- 2.9 **"NET SALES**" shall mean the gross amount invoiced by BIOVAXYS, on all sales of the PRODUCTS provided by PROCARE to BIOVAXYS under this Agreement, less (i) discounts actually allowed, (ii) credits for claims, allowances, retroactive price reductions or returned goods, (iii) prepaid freight and (iv) sales taxes or other governmental charges actually paid in connection with sales of the PRODUCTS with a maximum of 5% of the gross amount invoiced by BIOVAXYS. For the sake of clarity, the Parties agree that the figures included in sections (i) to (iv) above shall imply a maximum amount of the 5% of the gross amount invoiced by BIOVAXYS.
- 2.10 **"OPERATIONS**" shall mean all the activities carried out by BIOVAXYS as from the receipt of the PRODUCTS (Ex work) at PROCARE's warehouse in Spain, that is, included but not limited to storage, marketing, transportation from Spain to US, delivery with US, distribution in the TERRITORY and sale of the PRODUCTS.
- 2.11 "OTC" shall mean over-the-counter pharmaceuticals products.
- 2.12 "**PRODUCT**" shall mean the PRODUCT described in <u>Exhibit "A</u>" hereto.
- 2.13 **"TERRITORY**" shall mean the territory, or territories, set out in <u>Exhibit "C"</u> hereto.
- 2.14 **"TRADEMARK(S)**" shall mean the registered trademark(s) of PROCARE, details of which are set out in Exhibit "B" hereto.
- 2.15 "TRADE SALES" shall mean the total number of units of PRODUCTS sold by BIOVAXYS to its clients.
- 2.16 **"SUPPLY PERIOD**" shall mean the period beginning on date of 1<sup>st</sup> delivery of the PRODUCT by PROCARE to BIOVAXYS under this Agreement and ending on the date on which the termination of this Agreement is effective in accordance with the terms and conditions hereof.
- 2.17 "WHOLESALER PRICE (WSP) » shall mean the recommended prices listed in Exhibit D.

## **3** SUBJECT MATTER

3.1 PROCARE grants BIOVAXYS the exclusive right to (i) import, promote, sell and distribute the PRODUCTS in the TERRITORY, during the SUPPLY PERIOD. The said, exclusivity is granted to BIOVAXYS provided that it purchases the MINIMUM YEARLY PURCHASE QUANTITIES as defined in "Exhibit E" and (ii) use the TRADEMARK.

Additionally, the exclusivity means:

- i. PRODUCTS cannot be supplied to Distributor by any third party under same brand name,
- ii. PROCARE cannot supply any third party with the PRODUCTS under any name or trademark on the TERRITORY, and
- iii. Distributor shall not market nor distribute any other vulvar-vaginal treatments and hygiene (cosmetics, MD or drugs) products with the same PRODUCTS Indications during the Term of the Distribution Agreement without the prior written consent of PROCARE.
- 3.2 BIOVAXYS shall not actively commercialize or sell PRODUCTS outside of the TERRITORY without previous consent and amendment of this contract with PROCARE.
- 3.3 BIOVAXYS shall purchase the PRODUCTS exclusively from PROCARE, or from any other distributor expressly authorized in writing by PROCARE.

- 3.4 During the SUPPLY PERIOD, PROCARE, or any other person or entity designated by PROCARE, undertakes to supply BIOVAXYS with the PRODUCTS in the TERRITORY, everything in accordance with the terms and conditions contained herein.
- 3.5 BIOVAXYS shall distribute and sell the PRODUCTS in the TERRITORY under the TRADEMARKS.
- 3.6 BIOVAXYS undertakes to respect the exclusivity granted by PROCARE to other distributors. In this respect, BIOVAXYS undertakes during the SUPPLY PERIOD, not to actively promote sales (e.g. through the seeking of customers, advertising, or by establishing branches or distribution depots) or sell the PRODUCT outside the TERRITORY. In the event that BIOVAXYS receives an order, request for an order or any other inquiry from outside the TERRITORY, BIOVAXYS shall promptly refer such inquiry to PROCARE. As a consequence of the exclusivity granted to BIOVAXYS, PROCARE undertakes during the Term of this Agreement:
  - (a) not to promote, market, sell and distribute, either directly or indirectly (e.g. through the appointment of another distributor, agent or any other intermediary), the PRODUCTS within the TERRITORY;
  - (b) to impose on itself as well as all third parties it has appointed to promote, market, sell or distribute the PRODUCTS to desist pursuing an active sales policy to customers located in the TERRITORY.

In no case, however, shall these provisions be interpreted as a total territorial protection in favour of BIOVAXYS, and PROCARE shall jointly work with BIOVAXYS and use best efforts to help prevent any parallel import into the TERRITORY. In any case, PROCARE shall not be responsible for any damages to BIOVAXYS due to parallel imports as PROCARE cannot have any control on them.

- 3.7 BIOVAXYS shall have a first refusal right for the distribution of the IMPROVEMENTS of the PRODUCT in the TERRITORY. To that extent, BIOVAXYS shall notify its intention to distribute the IMPROVEMENTS in the TERRITORY within thirty (30) calendar days as from PROCARE's notification. If BIOVAXYS does not notify its intention to distribute the IMPROVEMENTS within the abovementioned term, PROCARE shall be free for appointing any other distributor for them in the TERRITORY under a different trademark.
- 3.8 Additionally, BIOVAXYS shall have the exclusive rights for the co-development and co-commercialization of the Papilocare line (or an alternative derived product) developed as a drug (NDA) and not as a Medical Device subject to the formalization of a new agreement to be negotiated in good faith. To that extent, BIOVAXYS shall notify its intention to execute their ROFR in the TERRITORY within thirty (30) calendar days as from PROCARE's notification. If BIOVAXYS does not notify its intention to co-develop and co-commercialize of the Papilocare line (or an alternative derived product) developed as a drug (NDA) within the abovementioned term, PROCARE shall be free for co-developing and co-commercializing the Papilocare line (or an alternative derived product) developed as a drug (NDA) with a third party under a different trademark.
- 3.9 Finally, PROCARE is willing to grant to BIOVAXYS the right of first refusal for the distribution in the TERRITORY of Ovosicare and Libicare ("**New Products ROFR**") subject to the formalization of a new distribution agreement to be negotiated in good faith and are not part of this specific Agreement. To that extent, BIOVAXYS shall notify its intention to execute their New Products ROFR in the TERRITORY within thirty (30) calendar days as from PROCARE's notification. If BIOVAXYS does not notify its intention to execute the New Products ROFR within the abovementioned term, PROCARE shall be free for appointing any other distributor for Ovosicare and Libicare in the TERRITORY.

# 4 SECRECY OF KNOW-HOW & PROPERTY

- 4.1. During the term of this Distribution Agreement for a minimum period of **ten (10) years** thereafter or for as long as the Confidential Information keeps its confidential and proprietary character:
  - (a) BIOVAXYS shall neither use nor disclose to any third party any Confidential Information concerning the PRODUCT. BIOVAXYS acknowledges and understands that any right, title and interest in and to the aforesaid Confidential Information is vested in PROCARE and that such information is the sole property of PROCARE. BIOVAXYS guarantees not to use the technical files related to Products provided by PROCARE to apply for any intellectual property, or any other registration not related with this Agreement.

- (b) PROCARE shall neither use nor disclose to any third party any Confidential Information concerning the OPERATIONS. PROCARE acknowledges and understands that any right, title and interest in and to the aforesaid Confidential Information is vested in BIOVAXYS and that such information is the sole property of BIOVAXYS.
- (c) neither Party will communicate, divulge nor make public to any third party any part of the Confidential +Information without the express prior written consent of the other Party
- (d) each Party will take all necessary measures to apply and preserve, in the strictest way, the confidential character of the Confidential Information. In particular, each Party:
  - a. use the Confidential Information only in connection with the performance of this Distribution Agreement,
  - b. use at least the same amount of diligence in preserving the confidentiality of the Confidentiality Information, as it uses to preserve its own Confidential Information,
  - c. restrict the distribution of Confidential Information to its directors, officers, employees, shareholders who have a definite need to know such Confidential Information and provided that such persons are bound to respect the confidential nature of this information under terms equivalent to these of this present Agreement,
  - d. shall take any and all necessary precautions to prevent any such disclosure by any and all of its employees, officers, directors, representatives, agents, or sub-distributors,
  - e. limit the number of copies, if any, of the Confidential Information to what is necessary for the performance of this Agreement, and indicate the confidential character of such information on any copy.
- 4.2. For the purpose of this Agreement, the term "**Confidential Information**" means any and all information, documentation and data, whatever its nature (graphic, text, verbal or other) and its support (paper, electronic or other), which is disclosed or otherwise made available by one Party or its employees, officers, representatives, agents, or Affiliates, either directly or indirectly, to the other Party and that is not either at the time of disclosure or subsequently explicitly acknowledged or confirmed by the other Party in writing as being non-confidential. "Confidential Information" shall include, but is not limited to, business information and data, trade secrets, unpatentable intellectual property, know-how and formulae, financial information, commercial and marketing know-how and material. However, in case proved by appropriate documentary evidence, the notion of Confidential Information does not refer to:
  - (a) all information which is or becomes part of the public knowledge through no wrongful act of the receiving Party and/or its Affiliates,
  - (b) all information that, at the time of disclosure, was in receiving Party's possession and was not received from the disclosing Party or from third parties on behalf of the disclosing Party,
  - (c) all information, which will be made lawfully available to the receiving Party by a third-party having rights to disclose the same, or
  - (d) all information which is required to be disclosed by law, by order of any court or regulatory body, or by rule of a national securities exchange
  - (e) any information which has been independently developed in good faith by employees of the receiving Party and/or its Affiliates who did not have access to the Confidential Information; or
  - (f) any information which is approved for release or use by written authorization of the disclosing Party.

## 5 SPECIFIC OBLIGATIONS OF BIOVAXYS

- 5.1. Additionally, to all other obligations of BIOVAXYS included in this Agreement but not specifically included in this clause, BIOVAXYS undertakes to carry out the distribution of the PRODUCT in the TERRITORY according to the following terms and conditions:
  - (i) <u>Selling effort</u>: Detailing the PRODUCT as first/second product among Physicians specialized in Colposcopies and as first/second product among target gynaecologists in the TERRITORY. Promotion will be done via detailing, e-detailing, scientific reprints, sampling and brand reminders and all other necessary means to promote PRODUCTS in the Territory. In order this commitment to be considered as fulfilled, BIOVAXYS must comply

the visits and activities included in the MARKETING PLAN agreed by the Parties in with writing for each annuity.

- (ii) Medical/Marketing effort: Developing KOLs' advocacy via congresses, publication and CME educational programs. Driving patients' awareness and activation. To that extent, BIOVAXYS commits to share the results of its operations via communicating on a semester basis the outcome of its investments in order to evidence that it is complying with the MARKETING PLAN agreed by the Parties in writing for each annuity.
- (iii) <u>Registration of the PRODUCT</u>: The registration of PRODUCT before the Health Authorities (the "FDA") in the TERRITORY shall be carried out by BIOVAXYS on behalf of PROCARE as manufacturer of the PRODUCT (the "Registration Deadline"). In this regard, the Parties agree that:
  - a) BIOVAXYS will have no rights to the registration of the PRODUCT, which must be done exclusively in favour of PROCARE.
  - b) All costs relative to such registration shall be borne by BIOVAXYS.
  - c) BIOVAXYS in collaboration with PROCARE, and upon PROCARE's prior approval, shall prepare all documents for presentation to the FDA in view of registration of the PRODUCTS in the country.
  - d) PROCARE shall provide BIOVAXYS with any current data in PROCARE's possession required by the FDA for Product registration or to reasonably support FDA Product registration.

If the PRODUCT is not registered before the FDA on or before the Registration Deadline for causes directly attributable to FDA or the need for additional data from PROCARE, the Parties will discuss and negotiate in good faith an extension of the for this Agreement.

5.2. Moreover, to the payment of the prices of the PRODUCTS supplied as detailed in this Agreement, BIOVAXYS pays as of the date hereof or shall pay (as detailed below) an amount (the "Down Payment") in accordance with the following payment schedule:

(i)	
	TERRITORY shall be paid as follows:
	a) upon the signature of this Agreement,
	shall be payable in BIOVAXYS shares of common stock, the number of shares payable to PROCARE to be equal divided by the greater of (A) the 20-day volume-weighted average price of the shares on
	the Canadian Stock Exchange ("CSE") calculated from the 20 days prior to the day of the FDA approval; and (B)
	the minimum price per share permitted by
	no later than (15) calendar days from receipt by BIOVAXYS of the relevant invoice issues by PROCARE. To
	In order to carry out the abovementioned payment, the Parties hereby agree that

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- i. BIOVAXYS shall advise PROCARE in any and all the requirements to be complied under Canadian Law,
- BIOVAXYS shall bear any and all the costs derived from such payment. For the sake of clarity, the ii. payment shall be made net of any costs and/or taxes,

In case BIOVAXYS does not provide such certificate or any other required documentation evidencing the ownership within the term established in Clause 5.2 (ii) (b), BIOVAXYS shall immediately and automatically

5.3. Additionally, to the Initial Amount detailed in the section 5.2, BIOVAXYS hereby irrevocably and unconditionally undertakes to pay the following amounts (the "Additional Amounts"):

Sales Amount cumulative (NET SALES) in the TERRITORY	Additional Amount Payment by BIOVAXYS to PROCARE		
When reaching US\$ of NET SALES			
When reaching US\$ of NET SALES			
When reaching US\$ of NET SALES			

The Additional Amounts shall be calculated by BIOVAXYS within a period of thirty (30) calendar days as from the end of respective quarter in which BIOVAXYS achieved the relevant figure of cumulative NET SALES and shall be paid by BIOVAXYS to PROCARE within thirty (30) days from the receipt of the respective invoice issued by PROCARE. BIOVAXYS shall notify PROCARE of the achievement of cumulative Net Sales in US dollars (US\$) in each quarterly report as detailed in Clause 10 below.

5.4 In addition to the Additional Amounts, BIOVAXYS hereby irrevocably and unconditionally undertakes to pay a Royalties on the received NET SALES within the TERRITORY (the "**ROYALTIES**").

In this regard, BIOVAXYS shall pay to PROCARE the ROYALTIES (i) on a quarterly basis of each calendar year and (ii) within a period of thirty (30) calendar days as from the issuance of the relevant invoice by PROCARE. For the sake of clarity, as from the first quarter of the first year of duration of this Agreement, BIOVAXYS shall provide PROCARE within a period of fifteen (15) days as from the last day of the relevant quarter, with the WSP and the NET SALES as well as with the (ii) amount of the relevant ROYALTY already calculated in order to be reviewed by PROCARE. To that, PROCARE shall issue the relevant invoice as soon as possible.

To that extent, BIOVAXYS shall notify PROCARE the WSP and the NET SALES in US\$ in each quarterly report as detailed in Section 5.4. (i) above.

- 5.4. The Parties hereby agree that the Down Payment shall (i) be paid by bank transfer and (ii) not be refundable by PROCARE under no circumstances (except in case of breach of PROCARE). All Bank fees, commissions and other transfer expenses should be borne by BIOVAXYS, or PROCARE will have the right to invoice this separately at a later stage, if applicable.
- 5.5. Notwithstanding the terms and conditions for the payment of the Down Payment as detailed in Clause 5.2 above, the other payments due by BIOVAXYS to PROCARE on the basis of the relevant Purchase Orders (issued in accordance with this Agreement) shall be paid in EUROS by the former in two instalments as follows:
  - a) The first instalment of such payment in EUROS (€) shall be equal to the fifty percent (50 %) of the amount payable and shall be paid by BIOVAXYS upon the receipt of the relevant pro-forma invoice, which shall be issued upon the receipt of the respective Purchase Order. Purchase order will only be considered confirmed once this amount is paid and received.
  - b) The second instalment of such payment shall be equal to the fifty percent (50 %) of the amount payable and shall be paid by BIOVAXYS against invoice, within thirty (30) calendar days as from invoice date. Such invoice shall be issued by PROCARE stating the full amount in EUROS of the respective Purchase Order and the amount already paid against the pro-forma invoice. BIOVAXYS shall pay the balance amount in EUROS of such invoice to PROCARE.

- 5.6. Additionally to the different terms of payments of the different payments to be carried out by BIOVAXYS (that is, the Down Payment and payments related to Purchase Orders), the Parties hereby agree that:
  - a) any and all delay in such payments by BIOVAXYS shall imply a default interest consisting of EURIBOR+3% per year to be applied on the amount not paid on time, and
  - b) in the event that a Purchase order had not been paid in full in accordance with the payment calendar established in Clause 5.5., no Purchase Order shall be proceeded by PROCARE and any and all payments received by PROCARE shall be deemed applicable for the payments delayed and not for new orders of PRODUCT.

## **6 RESPONSIBILITY**

- 6.1. It shall be BIOVAXYS' own responsibility to observe all local rules and regulations regarding OPERATIONS within the TERRITORY. For the purpose of complying with such rules and regulations, PROCARE shall provide BIOVAXYS all such technical and scientific support and information required in relation to obtaining the necessary permits, certificates and/or licenses.
- 6.2. Any and all sales contracts and other liabilities entered into by BIOVAXYS relating to the OPERATIONS are BIOVAXYS's own and whole responsibility, given the fact that all technical and scientific support and information to be provided by PROCARE was correct, true and accurate and has been provided on time.
- 6.3. BIOVAXYS shall have a proper insurance protecting BIOVAXYS in a satisfactory amount against any and all potential damages resulting from the OPERATIONS.
- 6.4. It shall be BIOVAXYS's own responsibility to ensure that the quality of the PRODUCT is not adversely affected during their distribution and to ensure that appropriate records of all significant activities or events are kept.
- 6.5. BIOVAXYS shall ensure that specified storage conditions are observed at all times, including during transportation, and that contamination from other products or activities is avoided.
- 6.6. It shall be BIOVAXYS's own responsibility to ensure that PRODUCTS beyond their expiry date, with broken seals, damaged packaging or suspected of possible contamination are separated from usable stock in clearly separated areas and neither sold nor supplied.
- 6.7. For all supplies to customers a document must be enclosed, making it possible to ascertain the date, the name of the medical device, the quantity supplied, the lot number and the name and address of the supplier and addressee. Proof of delivery transactions shall be used.
- 6.8. It shall be BIOVAXYS's own responsibility to ensure that manufacturing product identification is not lost in the supply chain.
- 6.9. It shall be BIOVAXYS's own responsibility to set up all procedures ensuring the quality of its services, receipt and checking of deliveries, storage, cleaning and maintenance of the premises. The person in charge of the application and administration of these documents is:

Mr.: Kenneth Kovan Address: 1177 Avenue of the Americas, 5th Floor, New York NY 10036 USA Mobile phone: +

For Pharmacovigilance and regulatory interaction with FDA will be responsible:

Dr. David Berd

Address: 1177 Avenue of the Americas, 5th Floor, New York NY 10036 USA Mobile phone: +

These persons engage to confirm the receipt of any information from PROCARE related to the PRODUCTS as well as to answer any requests from PROCARE concerning the PRODUCTS within two (2) weeks, and particularly in case of batch recall.

6.10. Not later than three (3) months before the PRODUCT is launched in the TERRITORY, the Parties shall enter into the relevant Quality and Pharmacovigilance Agreement for the TERRITORY, which shall specify arrangements for all quality matters.

# 7 ADVERSE EVENTS REPORTING & PRODUCT WARRANTY

- 7.1. BIOVAXYS accepts the specifications, indications, contraindications, precaution for use, storage and all the information of the PRODUCTS provided and defined in the specific product leaflet supplied by PROCARE, with each PRODUCT. The leaflets supplied to BIOVAXYS with the products by PROCARE will be adjusted to languages of the TERRITORY, with any final local language adjustment to be provided by BIOVAXYS and approved by PROCARE (such adjustment shall be in line with FDA's requirements).
- 7.2. The Parties intend to fully comply with the applicable medical event reporting requirements in the country of origin of the PRODUCTS and in the TERRITORY and agree to exchange such information as may be necessary to achieve that aim, and to ensure that both Parties are fully and completely informed regarding worldwide medical experience with the PRODUCTS.
- 7.3. BIOVAXYS agrees to ensure traceability of the delivered batches of the PRODUCTS for ensuring the traceability of the PRODUCTS in the TERRITORY. BIOVAXYS shall ensure such obligation for a period of at least fifteen (15) years, for each PRODUCT sold. Such traceability shall include the consignee address as well as the batch and/or the serial number of each forwarded PRODUCT. PROCARE is allowed by BIOVAXYS to proceed at least once a year with a dummy recall in order to check that the above dispositions are in place for each PRODUCT in the TERRITORY. After termination of this Distribution Agreement, BIOVAXYS shall preserve the data of such traceability in order to achieve ten (10) years or shall be entitled at its option to send back this data to PROCARE. Upon PROCARE request (if required by the relevant Authority), BIOVAXYS shall provide PROCARE with traceability data within 10 working days after request.
- 7.4. BIOVAXYS shall write a recall procedure. Any recall operation shall be carried out only after full consultation with PROCARE and in accordance with the laws of the TERRITORY, and shall be recorded at the time it is carried out and records shall be made available promptly to PROCARE.
- 7.5. BIOVAXYS shall be able to identify and contact all those involved in the supply chain. In case of a recall, BIOVAXYS shall decide in consultation with PROCARE to inform either all its customers of the recall or only those having received the batch to be recalled.
- 7.6. All customers to whom a concerned PRODUCT was distributed shall be informed with the appropriate degree of urgency.
- 7.7. The message shall require the recalled PRODUCTS to be removed immediately from usable stock and stored separately in a secure area until they are disposed of in accordance with PROCARE's instructions.
- 7.8. PROCARE hereby warrants to BIOVAXYS:
  - (a) that at the time of delivery all PRODUCTS supplied to BIOVAXYS will comply with the local regulation.
  - (b) that at the time of delivery all PRODUCTS supplied to BIOVAXYS will conform to the specifications set forth as part of the PRODUCTS leaflet,
  - (c) that at the time of delivery all PRODUCTS supplied to BIOVAXYS will be free from defects in material and workmanship,
  - (d) that the PRODUCTS are manufactured in accordance with applicable regulatory requirements in the country of origin and in the TERRITORY.
  - (e) that the TRADEMARKS are genuine and valid and that PROCARE has full right, authority and power to enter into this Distribution Agreement
  - (f) to provide the quantities in the forecast provided by BIOVAXYS complying with (i) its obligations of Clause 11.2 hereof and (ii) the MINIMUM YEARLY PURCHASE QUANTITIES detailed in Exhibit "E"

7.9. In the event the Parties, after due consultation between their respective technical personnel, cannot agree concerning a question of conformity with the above warranty of a particular shipment of the PRODUCTS, such conformity shall be determined by a mutually acceptable independent laboratory.

The cost of the independent laboratory's investigation shall be borne by PROCARE if the investigation determines non-compliance with the above warranty and by BIOVAXYS if it determines compliance with such warranty.

- 7.10. In the event that any PRODUCTS are not complying with the terms of Section 7.8 above, BIOVAXYS shall be entitled to require PROCARE either:
  - (a) to replace such PRODUCTS at PROCARE's expense with PRODUCTS complying with the terms of the said warranty; or
  - (b) to repay forthwith upon demand any sums paid by BIOVAXYS to PROCARE in respect of such PRODUCTS.
- 7.11. All of the above details defined from Clauses 7.1 to 7.10 above, will be covered within a separate Quality and Vigilance Agreement, which will be signed before the commercialization in the TERRITORY and upon the Distribution Agreement formalization.

## 8 INDEMNIFICATION & INSURANCE

- 8.1. PROCARE shall, during and after the term of this Distribution Agreement, indemnify and hold BIOVAXYS and its affiliates harmless from and against any and all claims, demands, causes of action, actions or suits, judgements, decrees, damages, penalties or other adverse actions by governmental bodies, or any liability whatsoever asserted or entered against BIOVAXYS, or any of its affiliates, by or on the behalf of, or in favour of any person, firm or corporation arising out of the sale or use of the PRODUCTS by BIOVAXYS or by any holder of an item of the PRODUCTS which in its chain of distribution, came through or from BIOVAXYS, to the extent attributable to (i) a gross negligent or intentionally harmful act or omission of the manufacturing of the PRODUCT and (ii) the breach of the warranty detailed in Clause 7.8 above.
- 8.2. BIOVAXYS shall hold PROCARE and its affiliates during and after the term of this Distribution Agreement harmless from and against any and all claims, demands, causes of action, actions or suits, judgements, decrees, damages, penalties or other adverse actions by governmental bodies, or any liability whatsoever asserted or entered against PROCARE or any of its affiliates by or on the behalf of, or in favour of any person, firm or corporation arising out of the sale or use of the PRODUCTS by BIOVAXYS or by any holder of an item of the PRODUCTS which in its chain of distribution, came through or from BIOVAXYS to the extent attributable to an act or omission of BIOVAXYS or its employees or agents in connection with the distribution, storage, promotion of the PRODUCTS or any OPERATIONS in the TERRITORY.
- 8.3. In order to cover possible risks in case of a product liability claim arising out of a sale of the PRODUCTS, as from the launch of the PRODUCT in the TERRITORY, both BIOVAXYS and PROCARE maintain adequate and sufficient product liability insurance cover and each Party shall supply the other Party with proof of such insurance cover.
- 8.4. Each Party shall promptly notify the other Party, in writing, of all customer complaints and all claims or actions asserted or threatened in respect of the PRODUCTS. Upon PROCARE's request, and at PROCARE's expense, BIOVAXYS shall render all reasonable assistance in the defence of any claim or action asserted or threatened in respect of the PRODUCTS, but PROCARE shall, at its election, have exclusive control over the defence and settlement (except in relation to claims regarding the OPERATIONS) and therefore and expenses will reside with PROCARE. Additionally, PROCARE shall render all reasonable assistance in the defence of any claim or action asserted or threatened in threatened in respect of the OPERATIONS, but BIOVAXYS shall, at its election, have exclusive control over the defence and settlement or threatened in respect of the OPERATIONS, but BIOVAXYS shall, at its election, have exclusive control over the defence and settlement and therefore and expenses will reside with BIOVAXYS.

For the sake of clarity, the Parties hereby represent that:

- i. PROCARE shall be responsible for any and all claim derived from the manufacturing of the PRODUCT, and consequently shall maintain BIOVAXYS harmless from any claim derived therefrom, and
- ii. BIOVAXYS shall be responsible for any and all claim derived from the OPERATIONS and consequently shall maintain PROCARE harmless from any claim derived therefrom.

8.5. BIOVAXYS agrees to transmit without any delay, i.e. at the latest five (5) working days after having been informed, any element affecting the quality of the delivered PRODUCTS and especially any return of information from customers to PROCARE, in writing.

The reporting customers have to be informed by BIOVAXYS (with hardcopy to PROCARE) that, in case of near incidents which may be associated with the PRODUCTS, according to the European Guidelines on a medical device vigilance system MEDDEV 2.12/1 -latest revision, PROCARE has to forward this information to the competent authorities.

Upon receipt of this information, PROCARE shall inform BIOVAXYS of the measures to undertake regarding the concerned products and, if necessary, shall advise the competent authorities.

8.6. If PROCARE by obligation of the relevant EU (CE) Authority, determine that in the interest of consumers protection the sale or use of any PRODUCTS in the TERRITORY should be temporarily or permanently discontinued, BIOVAXYS shall promptly take all actions as such relevant Authority may request to discontinue, or cause the discontinuance of, such sale or use and, at PROCARE's election and expense, shall promptly return to PROCARE or its designee all of such PRODUCT in BIOVAXYS's possession or control, at a resale price equal to the original purchase price paid therefore by BIOVAXYS.

Any outstanding orders for such PRODUCT which may have previously been accepted by PROCARE shall be deemed cancelled upon such request by BIOVAXYS, and PROCARE shall have no further liability to BIOVAXYS in respect of such cancelled orders.

# 9 STOCK

- 9.1. BIOVAXYS will maintain a sufficient stock of the PRODUCT to assure an uninterrupted supply of the PRODUCT in the TERRITORY, and in any case more quantities superior to ninety (90) days of future sales.
- 9.2. BIOVAXYS engages itself to verify unitary the "use-by-date" of the PRODUCT it delivers to its customers, during each delivery preparation.
- 9.3. BIOVAXYS agrees to respect the conditions specified by PROCARE for the storage, transportation, handling and the forwarding of the PRODUCT included in the leaflet delivered with the PRODUCT, and to implement the verified and suited means to meet these conditions.

# **10 REPORTING OBLIGATIONS**

- 10.1. BIOVAXYS will provide a monthly reporting of (i) its SALES (ex-Factory and IQVIA sales) of PRODUCTS and (ii) its remaining stock of PRODUCT.
- 10.2. BIOVAXYS will provide an annual reporting of its SALES (ex-Factory and IMS sales) and marketing activities on regards to the PRODUCT in the TERRITORY, which shall include at least, but not limited to, a summary of the sales & marketing activities of the past year (i.e. list of activities, what has been successful, what has not been, market size in total and per market segment, in units and in amount of prescriber on an annual basis, etc.) and of the MARKETING PLAN designed for the coming year (i.e. objectives, action plan, etc.).
- 10.3. Additionally to the report obligations of BIOVAXYS detailed in Clauses 10.1 and 10.2 above, PROCARE shall be entitled, at its discretion and at it sole cost, to carry out an audit of BIOVAXYS in connection with the PRODUCT in relation to which BIOVAXYS shall be obliged to provide PROCARE with any and all reasonable information and/or documentation that PROCARE requires for carrying out the said audit.
- 10.4. In the event BIOVAXYS does not comply with its obligations contained in Clauses 10.1 to 10.3 above PROCARE shall require BIOVAXYS to comply but if breach persists for more than thirty (30) calendar days, PROCARE shall be entitled to withdraw the exclusivity granted in favor of BIOVAXYS hereunder.

## **11 ORDER FORECAST**

11.1. The Parties agree that the BIOVAXYS'S MINIMUM YEARLY PURCHASE QUANTITIES are those included in Exhibit "E".

- 11.2. BIOVAXYS commits itself on a quarterly basis, to submit to PROCARE a written 12-month purchase rolling forecast, taking into consideration the demand and opportunities of the market, with a view to maintaining a sufficient stock, showing estimated quantities needed per PRODUCT reference. Such forecast shall be submitted, at least, 90 (ninety) days before the beginning of each calendar quarter. For the sake of clarity, BIOVAXYS shall provide PROCARE with 12-months rolling forecasts on a quarterly basis, at the latest on:
  - March 31 for Q3n, Q4n, Q1n+1, Q2n+1
  - June 30 for Q4n, Q1n+1, Q2n+1, Q3n+1
  - September 30 for Q1n+1, Q2n+1, Q3n+1, Q4n+1
  - December 31 for Q2n+1, Q3n+1, Q4n+1, Q1n+2

In the case BIOVAXYS fails to comply with sections 11.1 and 11.2 hereof not solving such situation within a period of one (1) month as from the said breach, PROCARE, at its discretion, shall be entitled to (i) withdraw the exclusivity granted in favour of BIOVAXYS hereunder and/or (ii) terminate this Agreement without obligation to pay any penalty but with the right to claim any damages caused to PROCARE.

### **12 MINIMUM YEARLY PURCHASE QUANTITIES**

12.1 BIOVAXYS shall buy and take delivery of the annual contractual minimum quantities of the PRODUCTS as defined in Exhibit "E" hereto (the "MINIMUM YEARLY PURCHASE QUANTITIES").

MINIMUM YEARLY PURCHASE QUANTITIES (as well as the prices) for the following years ("**Prolongation Term**") shall be negotiated in good faith between the Parties taking into account market conditions and evolutions, and shall be mutually agreed at least 6 months prior to the expiration of the Term. No Prolongation Term shall take place (i) without mutual agreement of the Parties (ii) in the event that BIOVAXYS had not complied with any and all the terms and conditions of this Distribution Agreement.

12.2 In the event BIOVAXYS fails to purchase the MINIMUM YEARLY PURCHASE QUANTITIES as defined in Exhibit "E", in the TERRITORY, PROCARE shall be entitled, at its discretion to terminate this Agreement.

## **13 SUPPLY PRICE, TERMS OF PAYMENT & DELIVERY, PURCHASE ORDERS**

- 13.1. All sales of the PRODUCTS by PROCARE to BIOVAXYS shall be made at Ex-Works (EXW) prices, in the currency (Euros) and further conditions set forth in <u>Exhibit "D"</u> hereto and provided the fulfilment by BIOVAXYS of the MINIMUM YEARLY PURCHASE QUANTITIES of the PRODUCT per year detailed in <u>Exhibit "E"</u> hereto.
- 13.2. The price mentioned in <u>Exhibit "D"</u> hereto might be revised upwards according to the evolution of the components of the PRODUCT as determined by PROCARE and revised on a yearly basis.
- 13.3 BIOVAXYS shall place firm purchase orders for the PRODUCTS to PROCARE in writing together with relevant delivery instructions. Orders placed by BIOVAXYS shall bind the Parties only after written acceptance of PROCARE within 5 days from the order.
- 13.4 PROCARE shall deliver each order according to the lead time set in <u>Exhibit "D"</u> hereto. If any purchase order exceeds the forecasts given by BIOVAXYS under Section 11.2 above, then the lead time for delivery of the amount that is in excess of the forecasts shall be negotiated in good faith between the Parties.
- 13.5 Any and all the payments to be made by BIOVAXYS to PROCARE shall be made by bank transfer.
- 13.6 Terms of payment shall be observed by BIOVAXYS as described in <u>Exhibit "D"</u> hereto. All bank transfers charges shall be borne by BIOVAXYS, that is, for the sake of clarity, any and all the amounts to be received by PROCARE shall be those detailed in this Agreement net of whatever tax or cost.

#### 14 PRESENTATION

14.1. PRODUCT shall be distributed and sold as delivered, without any modification. The text of the packaging, outer wrapping, insert and all other matters with respect to the PRODUCTS, will be elaborated by PROCARE, and submitted

to BIOVAXYS for approval. BIOVAXYS shall be responsible for and shall ensure that the packaging and labelling of the PRODUCT comply with the legislation, laws, rules and regulations in force in the TERRITORY.

14.2. In case of adding stickers ("distributed by: ...") etc., BIOVAXYS shall ensure that original labelling of the box stays visible and unchanged.

### **15 TRADEMARK & PATENT**

- 15.1. BIOVAXYS undertakes to market, distribute and sell the PRODUCT in the TERRITORY exclusively under the TRADEMARKS or any other name under the control of PROCARE. In particular, BIOVAXYS hereby acknowledges that the PRODUCT corresponds to the exclusive use of the trademark PAPILOCARE **PATENT** (
- 15.2. BIOVAXYS recognises the exclusive right of PROCARE on the TRADEMARKS. The use of the TRADEMARKS thereof shall always be on behalf and for the benefit of PROCARE. BIOVAXYS recognises and accepts that it is not entitled to register PROCARE's trademarks in the TERRITORY neither under BIOVAXYS's name nor BIOVAXYS's company name or any other name except PROCARE. Any right, which may accrue to BIOVAXYS, shall be immediately assigned to PROCARE free of charge.
- 15.3. PROCARE represents and warrants that the TRADEMARKS are genuine and valid and that PROCARE has full right, authority and power to enter into this Distribution Agreement.
- 15.4. PRODUCTS must exclusively be sold by BIOVAXYS under PROCARE packaging (see Section 14 above). To that extent, all advertisement, marketing tool, mailing, head paper, shopping bags, advertising materials... etc. used by the BIOVAXYS must refer to the property of the trademarks and everything with the same layout and artwork, colours and size as the original, as agreed when producing the first artwork of the PRODUCTS.
- 15.5. Upon termination or expiration of this Agreement, the BIOVAXYS shall immediately stop using the Trademark and any other distinctive sign of PROCARE, shall immediately stop identifying the BIOVAXYS's company and/or business as PROCARE's distributor, regardless of any controversy about the reasons for termination hereof, and shall destroy any material that is in the BIOVAXYS's possession, including the advertising materials, which bears the Trademark.
- 15.6. In case BIOVAXYS has found that the TRADEMARKS are infringed upon by any third party, BIOVAXYS shall promptly inform PROCARE of such infringement and assist PROCARE in taking necessary steps to protect this right effectively.

## **16 LAUNCHING & SALES PROMOTION**

- 16.1. BIOVAXYS shall distribute and promote the sale of the PRODUCTS at its own cost and to the best of its ability in accordance with the medical device and food supplement fields practices in the TERRITORY, and if agreed upon by PROCARE and BIOVAXYS in the Marketing Plan, shall promote the PRODUCTS through a well-trained sales and distribution force and will allocate an appropriate portion of promotional effort to the PRODUCTS.
- 16.2. The launch in the Territory shall start no later than six (6) months after the obtention of Approval in the Territory (FDA approval).
- 16.3. BIOVAXYS shall be entitled to create its own advertising material, brochures, visual aids, journal ads, etc. which shall be approved by PROCARE. Therefore, BIOVAXYS commits itself:
  - (a) to translate marketing documents into its local language while respecting scrupulously its meaning and without omitting nor adding any elements to the content without the prior written permission of PROCARE; and
  - (b) to respect the corporate identity, graphic design, layout and other distinctive signs of PROCARE and PRODUCTS; and
  - (c) to submit for prior approval to PROCARE any material amendment with respect to the initial versions provided by PROCARE before printing or releasing. This submission for approval will be done in English; and
  - (d) to provide two (2) units or pictures of the new marketing material within one (1) month after the first release.
  - (e) to include PROCARE's logo in any and all advertising material, brochures, visual aids, journal ads, etc.

- 16.4. PROCARE shall be entitled to require from BIOVAXYS any reasonable modification of the advertising material in order (i) to comply with legal approval of indications and warnings and (ii) to ensure the unity of its brand image. PROCARE commits itself to give approval or request modifications if any within fifteen (15) working days upon submission of the project to PROCARE.
- 16.5. BIOVAXYS shall provide PROCARE with launch plan at the latest three (3) months prior to commercial launch in the TERRITORY of any PRODUCT, and as provided in Section 10.2 an annual reporting of sales & marketing activities.
- 16.6. PROCARE will be responsible to provide BIOVAXYS with all developed medical and marketing materials and medical information in order to prepare promotional activities.

# **17 COMPETITIVE PRODUCTS**

During the term of this Distribution Agreement, unless duly authorized by PROCARE in writing, BIOVAXYS undertakes not to distribute and/or sell directly or indirectly in the TERRITORY any other similar product and or any product with the same range of indications. BIOVAXYS shall not actively promote any other HPV Product than the ones manufactured or purchased by PROCARE during the Term of this Agreement within the indication of HPV.

## 18 DURATION

- 18.1. This Distribution Agreement shall be valid for an initial fixed term of **ten (10) years** (hereinafter referred to as the "Initial Term").
- 18.2. At the end of the Initial Term of the Distribution Agreement, and provided that all terms and conditions have been fulfilled by the Parties during the Initial Term, the Parties hereby agree that a potential additional term to the Initial Term of the Distribution Agreement will be discussed in good faith.
- 18.3. The Parties hereby undertake to negotiate in good faith the minimum quantities and the prices thereof for the Prolongation Term maintaining any and all other term and conditions of this Distribution Agreement in full force and effect. The Parties hereby undertake that the prices shall be amended in accordance to Section 13.2 above.

## **19 TERMINATION**

- 19.1. This Distribution Agreement may at any time be terminated prior to the expiration of the Initial Term or Prolongation Term in case of mutual agreement between the Parties.
- 19.2. Either Party shall be entitled to terminate this Distribution Agreement for breach, immediately, without respecting any further period of notice, without any intervention of a court or arbitral tribunal being required and without prejudice to the rights of either Party hereto in respect of any breach of any of the terms herein contained, by simple written communication served by registered letter, if the other Party commits any substantial breach of any of the provisions of this Distribution Agreement, and does not remedy such breach within thirty (30) days from receipt of the notice of default served by registered letter from the Party requiring the same to be remedied.

The notice of default shall give a detailed description of the breach as well as reasonable modalities to remedy the same.

- 19.3. Notwithstanding any provisions to the contrary, either Party shall be entitled to terminate this Distribution Agreement for cause immediately, without notice of default, without respecting a period of notice, and without any intervention of a court or arbitral tribunal being required, if the other Party
  - (a) becomes insolvent, makes any assignment for the benefit of its creditors, or is placed in receivership, liquidation or bankruptcy,
  - (b) ceases to trade the Products in the TERRITORY,
  - (c) is in breach of its obligations on exclusivity as provided for in Section 3 above,
  - (d) is in breach of its confidentiality obligation as provided for in Section 4,
  - (e) the sale of all PRODUCTS of PROCARE would become prohibited in the TERRITORY.

- (f) There is non-fulfillment of other party's obligations due to a force majeure and it last for more than three months;
- 19.4. Additionally, PROCARE shall be entitled to terminate this Agreement in the event that BIOVAXYS does not comply with (i) the Registration Deadline for commercialization of the PRODUCTS before the Health authorities (FDA) in the TERRITORY as well as any other applicable Authority and (ii) the commercial launch of the PRODUCTS in the TERRITORY within a period of Six (6) months as from FDA approval, and (iii) the MINIMUM YEARLY PURCHASE QUANTITIES detailed in Exhibit "E".

PROCARE shall be entitled to terminate this Agreement (i) if BIOVAXYS assigns its rights under this Distribution Agreement to any third party without the prior written consent of PROCARE and (ii) in case of change of control of BIOVAXYS as detailed in Section 28. Both Parties are entitled to check that the obligations described in this Distribution Agreement are respected, through an inspection and control of the other Party's premises upon a prior written notice of ten (10) working days. The termination and/or expiration of this Distribution Agreement, for whatever reason, will not impair the rights that each Party has already accrued at the moment of terminating this Distribution Agreement.

- 19.5. Upon termination and/or expiration of this Distribution Agreement, for any reason whatsoever, BIOVAXYS shall inform the competent authorities thereof and take all steps necessary for the free transfer of all sanitary registration certificates and rights of the PRODUCTS to PROCARE, or to any other company or person designated by PROCARE.
- 19.6. Within 30 days from notification of termination and/or expiration of this Distribution Agreement, BIOVAXYS shall deliver PROCARE an inventory of all stocks of PRODUCTS in the BIOVAXYS's possession. The parties shall agree on
  - (a) either repurchase or cause its designee to repurchase PRODUCTS corresponding to a three (3)-month stock – already delivered and paid for by BIOVAXYS (with the exception of the PRODUCTS that the BIOVAXYS needs to fulfil binding orders that exist at the moment of the termination). Repurchasing will be made according to the same conditions that were granted to BIOVAXYS provided that returned PRODUCTS are compliant with PROCARE quality standards.
  - (b) authorize BIOVAXYS to sell the remaining stock of PRODUCTS during three (3) months after the effective date of expiration or termination of this Distribution Agreement.
- 19.7. Upon termination and/or expiration of this Distribution Agreement, for whatever reason, either Party shall refrain from using any of the Confidential Information and shall immediately return to the other Party or dispose of according to the other Party's instructions all the instruction manuals, technical files, catalogues, advertising folders, technical descriptions, documents, papers, and all other materials that the other Party sent or gave to such Party for the purpose of exercising his activity and that such Party has in its possession or under its control.

# 20 INDEPENDENT CONTRACTOR RELATIONSHIP

BIOVAXYS agrees that, with respect to all matters relating to this Distribution Agreement, BIOVAXYS shall be deemed to be an independent contractor and shall bear all of its expenses in connection with this Distribution Agreement. BIOVAXYS shall have no authority, whether express or implied, to assume or create any obligation on behalf of PROCARE. Unless otherwise agreed, BIOVAXYS shall pay any and all of its costs and expenses under this Distribution Agreement and shall be solely responsible for the acts and expenses of its officers, employees, agents and representatives.

# 21 FORCE MAJEURE

21.1 Neither Party shall be liable towards the other Party for any lack of performance of its obligations pursuant to this Distribution Agreement if the lack is inescapably due to causes beyond the control of the Party in default, provided however that any Party seeking to rely on this provision shall give immediate written notice to the other Party giving full particulars of the act or matter involved in and provided further (but subject to Section 22.2) that this provision shall immediately cease to apply when such act or matter has ceased to have effect on the performance of the obligations pursuant to this Distribution Agreement.22.2. If any act or matter relied upon by either Party for the purpose of Section 22.1 above shall continue for more than three (3) months, the other Party shall be entitled to

terminate this Distribution Agreement by a one (1)-month notice in writing; in that event, Sections 19.5 to 19.8 above shall apply.

- 21.2 The contracting Party having failed to fulfil its obligations shall not be responsible in case of force majeure.
- 21.3 Furthermore, it is understood that neither Party shall be liable for consequential damages of any kind or lost profits under such circumstances.

### 22 LIABILITY

22.1 Each Party shall be liable for the direct losses or damages incurred as a result of the negligence of such Party.

Each Party shall be liable for any and all losses and damages incurred as a result of its intentional breach of this Agreement and/or as a result of wilful misconduct or serious negligence of such Party, including consequential losses and economic losses after the performance of the contract, litigation/arbitration expenses, lawyer's fee and traveling expenses, etc.

- 22.2 Except in case of wilful or intentionally wrongful breach of this Agreement, the Parties shall not be liable to each other for any indirect or punitive damages or loss of profits, whether based on contract or tort, or arising under applicable law or otherwise.
- 22.3 For the avoidance of doubt, the limitation of liability set forth in this Agreement shall not apply
  - to the injury to life or health by a Party; or
  - to a Party's intentional violation of its contractual obligations according to this Agreement; or
  - to the direct losses resulting from a Party's gross negligence in the fulfilment of its contractual obligations under this Agreement; or
  - to such cases where strict liability under law applies (e.g. Product Liability).

#### 23 SEVERABILITY

If any provision of this Distribution Agreement is determined to be invalid or unenforceable, the provision shall be deemed to be severable from the remainder of this Distribution Agreement and shall not cause the invalidity or unenforceability of the remainder of this Distribution Agreement.

#### 24 ENTIRE AGREEMENT & AMENDMENT

This Distribution Agreement contains the entire understanding between the Parties with respect to the subject matter hereof and supersedes all prior and contemporaneous written or oral negotiations and agreements between the Parties regarding the subject matter hereof.

This Distribution Agreement may be amended only by a writing signed by both Parties.

## 25 LANGUAGE

This Distribution Agreement is written and executed in the English language and the English language version thereof will prevail over any translation into any other language.

#### 26 WAIVER

- 26.1 Any failure or delay by either Party in exercising any right under this Distribution Agreement, any single or partial exercise of any right under this Distribution Agreement or any partial reaction or absence of reaction by either Party in the event of a violation by the other Party of one or more provisions of this Distribution Agreement shall not operate or be interpreted as a waiver whether express or implied, in whole or in part of any of its right under this Distribution Agreement or under said provision(s), nor shall it preclude the further exercise of any such rights.
- 26.2 Any waiver of a right must be express and in writing.

26.3 If one Party has expressly waived a right in writing following a specific failure by the other Party, this waiver cannot be invoked by the latter Party in favour of a new failure, similar to the previous one, or any other failure.

## 27 NOTICES

Any formal notice or other communications between the PARTIES shall be delivered in English language to the respective addresses indicated herein, and any PARTY may modify its address upon a written notice to the other PARTY.

Unless specifically provided otherwise, all notices required or permitted by the AGREEMENT shall be in writing and may be delivered personally, or may be sent by fax, e-mail or by registered mail, at the following addresses, or at such other address as that PARTY may, by written notice, have directed:

✓ if to the PROCARE, to:

Attn:	Mr. Yann GASLAIN	
Address:	PROCARE HEALTH IBERIA SL	
	Paseo Ferrocarril 339 – 08860 Castelldefels, Spain	
Tel :		
E-mail: gaslain.y@procarehealth.com		

✓ if to the BIOVAXYS, to:

Attn:	Mr. James PASSIN
Address:	1177 Avenue of the Americas, 5th Floor, New York NY 10036 USA
Tel:	
E-mail:	jpassin@biovaxys.com

Any notice shall be considered to have been delivered to the receiving Party's address on the date of delivery if delivered in person, on the next day in the place to which it is sent by fax or e-mail and three working days following the mailing date if sent by registered mail.

## 28 CHANGE OF CONTROL

This Agreement shall be binding on and shall inure to the benefit of the Parties and their legal successors. Any successor shall be deemed substituted for the respective Party under the provisions of this Agreement.

However, if a change in control (under this Section "control" means the ownership, directly or indirectly, of 50% (fifty per cent) or more of the voting stock or equity interest of the subject) in favor of a PROCARE'S Competitor shall occur with respect to BIOVAXYS, then PROCARE shall have the right, but not the obligation, for a period of 90 (ninety) days following the receipt of written information about such change in control, to terminate this Agreement forthwith by giving written notice of such termination within such 90 (ninety) day period. Should PROCARE not request the termination of this Agreement, after such a 90 (ninety) day period, the termination right shall become void and this Agreement shall remain valid.

For the purpose of this clause "**PROCARE's Competitor**" means any manufacturer and/or distributor and/ which has relation with HPV, fertility and/or menopause management field.

# 29 CHOICE OF LAW / RESOLUTION OF DISPUTE

All disputes that may arise out of this Agreement shall primarily be settled amicably. In case of failure to reach an amicable settlement, the dispute arising out of this Agreement shall be resolved by International Chamber of Commerce Rules of Arbitration by one or more arbitrators, which will be appointed according to above mentioned rules. The place of the arbitration shall be in London and the language of the procedure shall be English. The applicable law is the law of London, excluding any regional law.

IN WITNESS WHEREOF, the Parties, intending to be bound hereby, have signed and stamped on this Distribution Agreement as of the date first written below.

[Signature page follows]

For PROCARE HEALTH IBERIA S.L,:	For BIOVAXYS:
Date:	Date:
Yann GASLAIN	James PASSIN
CEO	CEO

This Distribution Agreement has been issued in two (2) original copies.

#### **EXHIBIT "A" - PRODUCTS**

-PAPILOCARE VAGINAL GEL (7 cannulas x 5ml)
-PAPILOCARE VAGINAL GEL (21 cannulas x 5 ml)
-PAPILOCARE VAGINAL GEL (2X40ml + 2 applicators)
-PAPILOCARE INMUNOCAPS (30 caps)
-PAPILOCARE VAGINAL GEL SAMPLE (1X5ml)

#### STORAGE AND SHIPMENT:

PRODUCTS shall be stored, handled and shipped between +2°C and +25°C. Protect from light and freezing. Avoid knocks.

## **EXHIBIT "B" - TRADEMARKS**

PROCARE HEALTH <sup>™</sup> is a trademark of PROCARE HEALTH IBERIA S.L

PAPILOCARE<sup>™</sup> is a trademark of PROCARE HEALTH IBERIA S.L

## **EXHIBIT "C" - TERRITORY SPECIFICATION**

United States of America

#### EXHIBIT "D" - TERMS & CONDITIONS

#### **SPECIFIC TERMS & CONDITIONS:**

Reference Packs	Minimum order quantities* Price per box (in EUR)		Recommended Wholesaler Prices (in EUR)	
PAPILOCARE VAGINAL GEL (7x5mL)				
PAPILOCARE VAGINAL GEL (21x5mL)				
PAPILOCARE VAGINAL GEL (2x40mL+2 applicators)				
PAPILOCARE INMUNOCAPS (30 caps)				
PAPILOCARE VAGINAL GEL SAMPLE (1x5mL)			-	

However, based on the 1<sup>st</sup> supply date if later than January 1<sup>st</sup> 2024, supply price may be adjusted to compensate for manufacturing increase cost.

- Timing for delivery EXW: 1<sup>st</sup> batch order 150 days since order for the local pack. Timing for delivery for renewed orders: 100 days.
- Payment terms: 50% at the order and 50% at 30 days as from PROCARE'S invoice date.
- Delivery terms: EX-Works from PROCARE Health Warehouse (SPAIN)

\*Minimum quantity per order of the local US pack: Packs per SKU

### EXHIBIT "E" - SALES OBJECTIVES AND MINIMUM YEARLY PURCHASE QUANTITIES

## **SALES OBJECTIVES :**

#### PAPILOCARE VAGINAL GEL

Forecasts in Units*	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Years 7 to 10**
PAPILOCARE Vaginal Gel (based on equivalent 7 cannulas)							

\* 1 unit = 1 box of 7 cannulas for PAPILOCARE

\*\* Year 7 to 10: units per year

### MINIMUM YEARLY PURCHASE QUANTITIES:

"MINIMUM YEARLY PURCHASE QUANTITIES" means the SALES OBJECTIVES as defined in the above tables.

1<sup>st</sup> year: begins from the date of the first delivery at the specific market.