

AGREEMENT 6: DISTRIBUTORSHIP AGREEMENT

Source: Mahoney RT (ed.). 2004. Handbook of Best Practices for Management of Intellectual Property in Health Research and Development. MIHR: Oxford, U.K. Reproduced with permission.

A Public Sector Research Center intends neither to be a manufacturer or distributor. This sample agreement would be used in circumstances where the public sector institution is assisting a manufacturer to obtain one or more distributors or vice versa.

This Agreement is effective this _____ day of _____, 20__ (“Effective Date”), by and between [MANUFACTURER], a corporation organized and existing under the laws of [COUNTRY] (“Manufacturer”), and [DISTRIBUTOR], a corporation organized and existing under the laws of [COUNTRY] (“Distributor”).

WITNESSETH

WHEREAS the intellectual property related to product (as hereafter defined), including Trademarks, is owned or controlled by [TMOWNER] (“Trademark Owner”);

WHEREAS Trademark Owner has granted to Manufacturer the right to use and sell the Product in [COUNTRY] under the Trademarks using the Distributor; and

WHEREAS Manufacturer wishes to appoint Distributor to sell the Product in [COUNTRY], and Distributor is willing and able to import, promote, distribute, and sell Product under the Trademarks in [COUNTRY].

NOW, THEREFORE, the parties intending to be legally bound agree as follows:

ARTICLE I: DEFINITIONS

Wherever used in this Agreement, the following terms have the following meanings:

- 1.1 Product means [PRODUCT DEFINITION/COMPOSITION]
- 1.2 Public Sector [CURRENT DEFINITION]
- 1.3 Private Sector means all markets not defined as Public Sector.
- 1.4 Trademark means all trademarks, service marks, logotypes, commercial symbols, insignias, and designs pertaining thereto, including, but not limited to, the trademark [TM] _____ and the logotype associated therewith, now owned by Trademark Owner and licensed to Manufacturer, as the same may be amended, modified, revised, or improved hereafter that are associated and identified with the manufacture and sale of the Product.

ARTICLE II: APPOINTMENT OF DISTRIBUTOR

- 2.1 Subject to the terms and conditions of this Agreement, Manufacturer appoints Distributor as its nonexclusive agent for the importation, promotion, distribution, and sale of Product under the Trademarks in [COUNTRY].

DISTRIBUTORSHIP AGREEMENT

- 2.2 This Agreement grants the Distributor the right to package the Product but does not grant the Distributor the right to manufacture the Product or to have it manufactured by a third party.

ARTICLE III: USE OF TRADEMARK

- 3.1 Distributor recognizes the substantial value of the goodwill associated with the Trademark and acknowledges that the Trademark and all rights therein and the goodwill pertaining thereto belong exclusively to Trademark Owner. Distributor agrees not to commit any act or omission adverse or injurious to said rights.
- 3.2 Distributor agrees that every use of the Trademark by Distributor shall inure to the benefit of Trademark Owner, and that Distributor shall not at any time acquire any rights in the Trademark by virtue of any use Distributor may make of the Trademark.
- 3.3 Distributor agrees to cooperate fully and in good faith with Trademark Owner for the purpose of securing, preserving, and protecting Trademark Owner's rights in and to the Trademarks, including executing a trademark license with Trademark Owner and/or with the Manufacturer which license may be registered with the Patent and Trademark Office (or its equivalent) in [COUNTRY].
- 3.4 Distributor acknowledges that Distributor's failure to cease the use of the Trademark on the termination or expiration of this Agreement will result in immediate and irreparable damage to Trademark Owner and to the rights of any subsequent licensee. Distributor acknowledges and admits that there is no adequate remedy at law for such failure and agrees that, in the event of such failure, Trademark Owner shall be entitled to equitable relief by way of temporary and permanent injunctions and such other and further relief as any court with jurisdiction may deem just and proper.
- 3.5 Distributor shall report to Trademark Owner and Manufacturer, in writing, any infringement or imitation of the Trademarks of which Distributor becomes aware. Trademark Owner shall have the sole right to determine whether to institute litigation upon such infringements as well as the selection of counsel. Trademark Owner may commence or prosecute any claims or suits for infringement of the Trademarks in its own name or in the name of Manufacturer or the Distributor or may join Distributor and/or Manufacturer as a party thereto. If Trademark Owner brings an action against any infringer of the Trademark, Distributor and Manufacturer shall cooperate with Trademark Owner and lend whatever assistance is necessary in the prosecution of such litigation. If Trademark Owner decides not to institute such litigation, it may authorize, within its sole discretion, in writing, Distributor or Manufacturer to institute such litigation.
- 3.6 Distributor shall not contest or deny the validity or enforceability of the Trademark or oppose or seek to cancel any registration thereof by Trademark Owner, or aid or abet others in doing so, either during the term of this Agreement or at any time thereafter.
- 3.7 Distributor acknowledges that any use of the Trademark in violation of the provisions of this Article will cause irreparable damage to Trademark Owner and its licensees, constitutes an incurable default of this Agreement, and is grounds for immediate termination of this Agreement.

DISTRIBUTORSHIP AGREEMENT**ARTICLE IV: REGISTRATION OF PRODUCT**

- 4.1 Distributor shall register the Product with the regulatory authorities of [COUNTRY].
- 4.2 Manufacturer will provide a technical dossier for registration and assist in responding to specific questions that may arise during registration. Registration documents supplied to Distributor shall be in English. Any translation of the registration documents shall be the responsibility of Distributor.
- 4.3 If the law and/or regulations of [COUNTRY] require that Distributor be named as sole or joint owner of the subject registration, Distributor agrees that upon termination or expiration of this Agreement, Distributor will promptly assign to Trademark Owner all right, title, and interest that the Distributor may have in the subject registration and will terminate Distributor's own interest therein.
- 4.4 The technical dossier provided hereunder contains technical and proprietary information supplied by the Manufacturer and shall be deemed to have been provided in confidence for the sole purpose herein set forth. Distributor undertakes not to use any of the information for any purpose other than the registration in [COUNTRY] of the Product manufactured by Manufacturer and not to disclose any information to any third party, other than government regulatory authorities, without the written consent of Manufacturer.
- 4.5 Distributor will use all possible care and diligence to obtain the prompt issuance of the registration for the Product.
- 4.6 All expenses incurred relating to the registration of Product, including but not limited to taxes, official fees, and clinical trials that might be required by the government authorities of [COUNTRY], shall be borne by the Distributor.

ARTICLE V: SUPPLY TERMS

- 5.1 Distributor agrees that Manufacturer shall be Distributor's sole supplier of Product and agrees that it will distribute only Product purchased from manufacturer except that Distributor may receive and distribute in the Public Sector, Product supplied to Distributor by international donor agencies for such distribution regardless of where the donor agency obtained such Product. All Product sold to Distributor hereunder shall be manufactured by Manufacturer in accordance with Good Manufacturing Practices.
- 5.2 Since Manufacturer has made, or is making, distribution arrangements for Product with representatives in other countries, Distributor agrees that it shall not knowingly allow Product to be distributed for use in countries outside of [COUNTRY] without prior approval from Manufacturer.
- 5.3 All orders submitted by Distributor to Manufacturer are subject to acceptance by Manufacturer, to government restrictions and approval, and to allocations that may be necessary due to production capacity restrictions.
- 5.4 To assure a constant supply of the Product, Distributor shall stock a sufficient quantity of the Product to satisfy without delay the demands for it, and Distributor undertakes to

DISTRIBUTORSHIP AGREEMENT

keep at all times ____-months' (__) stock of the Product for the Private and Public Sectors in [COUNTRY]. However, Distributor is not required to carry a stock of Product in the expectation of sales to entities of the Public Sector who purchase through public bidding. To this end, Distributor shall place with Manufacturer timely and sufficient orders for the Product, taking into account the market demand, shipping time, and filling of the order by Manufacturer. Manufacturer shall supply and ship to Distributor as quickly as possible and always within ninety (90) days of receiving its purchase order with the amount of Product specified therein.

- 5.5 Distributor shall at all times remain in close contact with those entities of the Public Sector that purchase through public bidding and with those of their officers whose responsibilities have a bearing on these purchases; assure that it is immediately advised whenever a tender for [PRODUCT TYPE] is being solicited; and whenever such is the case, relay the information to the Manufacturer within forty-eight (48) hours.
- 5.6 Distributor shall clear the Products from the airport or other port of entry at its own expense within fifteen (15) days after their arrival in [COUNTRY]. Distributor shall be responsible for the clearance of customs of Product and local transport to its facilities.
- 5.7 Distributor agrees to inspect the Product immediately upon delivery and to give notice by fax to the manufacturer within fifteen (15) days of such delivery of any matter of thing by reason whereof it alleges that the Product is not in good condition. If no such notice is served by the Distributor upon the Manufacturer, the Product shall be deemed to be in accordance with this Agreement in all respects and the Distributor shall be deemed to have accepted the Product. If Distributor, having served notice on the Manufacturer, demonstrates that the Product is not in good condition, Manufacturer shall at its option either replace the defective goods with Product complying with this Agreement or refund to the Distributor the price paid for defective Product.
- 5.8 Distributor agrees to inform Manufacturer in writing three (3) months before the end of each calendar year of its estimated requirements of the Product for the following year.
- 5.9 Manufacturer shall be free to accept or not the return of expired Product.

ARTICLE VI: PRICING AND PAYMENTS

- 6.1 Prices charged to Distributor will, unless otherwise negotiated, be in accord with the Manufacturer's prices for Public Sector and Private Sector distribution prevailing at the time of shipment. After the initial order, two (2) months' notice will be given for any price increase. Manufacturer will endeavor to keep Distributor supplied with current information regarding pricing. The price for the Public Sector shall be preferential and set at the lowest possible reasonable level permitting a commercially reasonable return; however, nothing herein shall be interpreted as requiring the sale of Product below fully allocable costs plus a mark up of _____ percent (__%). Price shall be FOB [PLACE].
- 6.2 Distributor guarantees payment of all orders placed or approved by Distributor. Orders will provide for payment terms of thirty (30) days from date of order in [CURRENCY], except that in the event of unsatisfactory payment history, Manufacturer reserves the right to provide Product to Distributor on a COD basis.

DISTRIBUTORSHIP AGREEMENT**ARTICLE VII: PACKAGING**

- 7.1 Distributor shall package the Product under the supervision of its own technicians, in its own factory or in another qualified factory, and shall oversee the process with all necessary care, strictly following good pharmaceutical manufacturing practices.
- 7.2 Should Distributor need to have the Product packaged by a third party, said party must first have been approved by the Manufacturer and must commit itself in writing to comply with the articles of this Agreement relevant to the Product.
- 7.3 Distributor agrees to mark all packaging for Product in accordance with the applicable laws in [COUNTRY]. Said packaging shall be submitted to Manufacturer for approval before it is made up or printed.
- 7.4 All packaging costs and expenses shall be borne entirely by the Distributor.

ARTICLE VIII: ADVERTISING AND PROMOTION

- 8.1 Distributor undertakes at its own expense to actively promote the Product in [COUNTRY] by the best legal and appropriate means and to retain a trained sales force of [TYPE] representatives and detailers to assure an effective promotion of the Product with the [TYPE] community and with other professional [TYPE] personnel. Distributor shall further place, at its own expense, promotional advertisement and writings on the Product in [TYPE] and other suitable publications covering [COUNTRY].
- 8.2 Each year by September 30, Distributor shall submit to Manufacturer for approval Distributor's promotional plan for the following year detailing promotional visits to health professionals and to others, distribution of samples of the Products and promotional materials and to whom, advertisements and writings of the Product to be placed in publications in [COUNTRY], and planned participation and contributions to [TYPE] reunions and function. Said promotional plan to be reviewed jointly by the Distributor and the Manufacturer each six (6) months for the eventual modifications by mutual agreement. Special educational or promotional activities not included in the promotional plan require the approval of the Manufacturer, and the apportionment of their cost, if there be any, will be decided by mutual consent of the parties.
- 8.3 Distributor shall submit to Manufacturer quarterly marketing reports listing the promotional activities carried out during each month of the last period.
- 8.4 Manufacturer shall provide to Distributor free of charge, save customs duties, a certain quantity of free samples of the Product and dummies of the scientific, technical, commercial, and training materials required to carry out promotional programs for the Product. Should the laws of [COUNTRY] not recognize the distribution of free samples, in no event shall Distributor be allowed to claim any discount on the price of Product. Distributor shall provide, at its own cost, to the Public Sector agencies that use or may use Product, the needed scientific, technical, educative, and training material for this purpose and previously approved by the Manufacturer.
- 8.5 In promoting the Product, Distributor shall refrain from making any claims regarding its therapeutic action or effectiveness different or greater than those specified by the Manufacturer and by the Sanitary Authorities of [COUNTRY].

DISTRIBUTORSHIP AGREEMENT

- 8.6 All advertisements and promotional materials, including text and graphics, used by Distributor shall be subject to prior written approval of Manufacturer, which approval shall not be unreasonably withheld.

ARTICLE IX: REPORTING

- 9.1 Distributor will provide to Manufacturer monthly sales reports containing such information regarding sales of Product as Manufacturer shall specify, and including nonbinding, good-faith forecasts of its anticipated requirements and shipping dates for the three (3) month periods following such reports.
- 9.2 On or before February 1 of each year, Distributor shall supply Manufacturer with a report for the preceding calendar year or part thereof showing separately the quantity of Product purchased from Manufacturer and sold to the Private Sector and Public Sector in [COUNTRY], the average selling price of the Product purchased from Manufacturer, the quantity of Product supplied to Distributor by international donor agencies, and the selling price, if any, of the Product supplied by the international donor agencies. Manufacturer shall promptly provide a copy of the report to Trademark Owner.
- 9.3 Distributor shall, upon request by Manufacturer or Trademark Owner provide supporting documentation adequately justifying the pricing structure for the Public Sector. The rights created by this paragraph are directly enforceable by Manufacturer on behalf of any Public Sector agency wishing to purchase Product. To the extent possible under [COUNTRY] law, the rights created by this paragraph are directly enforceable by any Public-Sector agency on its own behalf. In addition to any other rights possessed by Manufacturer, a breach of any of the provisions of this paragraph shall be sufficient basis for termination of this Agreement by Manufacturer upon thirty (30) days' written notice.

ARTICLE X: COVENANTS AND REPRESENTATIONS OF DISTRIBUTOR

- 10.1 Distributor is a corporation duly formed, validly existing, and in good standing under the laws of [COUNTRY] and is duly qualified to transact business.
- 10.2 Distributor agrees that it shall not use or distribute Product in any manner inconsistent with the terms and intent of this Agreement.
- 10.3 Distributor agrees to use its best efforts to successfully market and distribute Product from Manufacturer in [COUNTRY] on a continuing basis during the term of this Agreement and to comply with good business practices and all laws and regulations relevant to this Agreement or the subject matter hereof.
- 10.4 Distributor agrees to keep Manufacturer informed as to any problems encountered with the Products and any resolutions arrived at for those problems and to communicate promptly to Manufacturer any and all suggested modifications, design changes or improvements of the Products. Manufacturer agrees to promptly pass this information on to Trademark Owner. Distributor and Manufacturer further agree that Trademark Owner shall have all right, title, and interest in and to any such suggested modifications, design changes, or improvements of the Products, without the payment of any additional consideration thereof.

DISTRIBUTORSHIP AGREEMENT

ARTICLE XI: CONFIDENTIALITY

All technical, corporate, business, and other proprietary information furnished by Trademark Owner of Manufacturer hereunder, or which results from the joint efforts of Trademark Owner and/or Manufacturer's and Distributor's personnel, shall be deemed to have been furnished to Distributor in confidence for the sole purposes herein set forth, and Distributor undertakes not to use any of this information for any purpose not connected with the orders accepted under this Agreement. Distributor shall also take all reasonable precautions to prevent communication, without the written consent of Trademark Owner or Manufacturer, of any such technical or other proprietary information to any third party, except as may be necessary to carry out the purposes of this Agreement.

ARTICLE XII: TERM AND TERMINATION

12.1 This Agreement is effective as of the Effective Date and will expire _____ () years thereafter, provided the following minimum volumes have been purchased by Distributor:

Year	Amount
------	--------

The above minimum volume for [YEAR] assumes approval for product registration by the government in [COUNTRY] by [DATE], and will be reduced or expanded pro rata using the quantity specified for [YEAR] in case of delayed or expedited approval. If Distributor does not purchase the minimum volume specified for any year, Manufacturer may terminate this Agreement by giving thirty (30) days' written notice, provided that if Distributor during the thirty (30)-day period orders sufficient Product for immediate delivery to make up the deficiency, the notice will be revoked.

12.2 This Agreement may also be terminated in the event Manufacturer determines that a change in management or effective financial control of Distributor has or will adversely affect the distribution of Product in accordance with this Agreement.

12.3 Distributor may terminate this Agreement any time by giving six (6) months' written notice to Manufacturer. During this six (6)-month period, Distributor will continue to use its best efforts to promote the sale and use of Product.

12.4 Extensions and renewals of this Agreement will be subject to agreement between the parties made at least six (6) months prior to its expiration.

ARTICLE XIII: RIGHTS AND OBLIGATIONS ON TERMINATION

Upon termination or expiration of this Agreement, Distributor shall return unused inventory to Manufacturer. Distributor shall dispose of all advertising material relating to the Product or the Trademark and shall discontinue immediately any use of the Trademark. Distributor shall maintain as confidential all proprietary information supplied to Distributor hereunder.

ARTICLE XIV: RELATIONSHIP OF PARTIES

The parties hereto expressly understand and agree that Distributor is an independent contractor in the performance of each and every part of this Agreement and is solely responsible for the actions of all of its employees and agents. Neither Trademark Owner nor Manufacturer shall be obligated by any agreements, representations, or warranties made by Distributor, its employees, or its agents nor with respect to any other action of Distributor, its employees, or its agents, nor

DISTRIBUTORSHIP AGREEMENT

shall Trademark Owner or Manufacturer be obligated for any claims, liabilities, damages, debts, settlements, costs, expenses, and liabilities that may arise on account of Distributor's activities, or those of its employees or its agents.

ARTICLE XV: HOLD HARMLESS

15.1 Distributor agrees to use its best efforts to ensure that Product is transported, stored, and distributed in accordance with handling instructions provided by Manufacturer. Distributor further agrees to use its best efforts to ensure that Product is provided to customers in a manner which facilitates its safe and proper use. Manufacturer shall have the right to enter and inspect any premises or facilities used by Distributor for or in connection with the preparation, promotion, marketing, and distribution of the Product, at any time during normal business hours and shall further have the right to take a reasonable number of samples of the Product at no charge in order to determine Distributor's compliance with the terms and condition of this Agreement.

The Distributor shall sell the Product on its own account and in no event shall the Manufacturer be deemed liable for credits the Distributor may grant or for any other obligations the Distributor may have to fulfill for its sales or other types of transaction in [COUNTRY]. It is understood and agreed that the Distributor has no right or authority whatsoever to accept any financial obligation on the Manufacturer's name or account without the Manufacturer's prior written approval.

15.2 Distributor shall, in respect of Product distributed by it, indemnify and hold harmless Trademark Owner, and its employees and agents against any and all claims that might arise, and liabilities and related fees and expenses that might be incurred, on account of any injury, illness, suffering, disease, or death to any person or unborn offspring of any such person by reason of the distribution, sale, or use of the Product distributed by Distributor.

ARTICLE XVI: NOTICES

Any report, accounting, objection, notice, or consent required or provided for by the terms of this Agreement shall be in writing, and all accounting, obligations, notices, consents, and reports provided for hereunder shall be sent by registered mail, prepaid, or by facsimile to the business address of the party to be served therewith. It is agreed that the business addresses of the parties shall be as follows:

If to Manufacturer: _____

If to Distributor: _____

ARTICLE XVII: PROHIBITION AGAINST ASSIGNMENT

This Agreement is entered into in reliance upon and in consideration of the experience, knowledge, skills, and qualifications of and trust and confidence placed in Distributor by Manufacturer. Therefore, neither Distributor's interest in this Agreement nor any of its rights or privileges hereunder shall be assigned, transferred, shared, or divided voluntarily or involuntarily, by operation of law or otherwise, in any manner, without the prior written consent of Manufacturer and Trademark Owner. In the event of any change in management or effective financial control of Distributor, Distributor shall inform Manufacturer immediately. If, in the opinion of Manufacturer, this change adversely affects the management of Distributor or the business or general best

DISTRIBUTORSHIP AGREEMENT

interest of either party, Manufacturer may, within sixty (60) days of Distributor's notice, terminate this Agreement and cancel any or all pending orders by giving Distributor ninety (90) days' written notice, such termination and/or cancellation to be effective at the end of such ninety (90)-day period.

ARTICLE XVIII: FORCE MAJEURE

No failure or omission by any party in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement nor create any liability if the same shall arise from any cause or causes beyond the control of such party, including, but not restricted to, the following, which for the purposes of this Agreement shall be regarded as beyond the control of the party concerned:

Government regulations, acts of God, strikes or other acts of workers, fire, storm, explosions, riots, war, rebellion, transportation embargoes, or failures or delays in transportation.

ARTICLE XIV: AMENDMENTS

No amendment or other modification of this Agreement shall be valid or binding on any party hereto unless reduced to writing and executed by the parties hereto.

ARTICLE XX: WAIVER

No waiver by any party of any provision hereof shall be deemed a waiver of any other provision hereof or of any subsequent breach by any party of the same or any other provision. None of the terms of this Agreement will be held to have been waived or altered unless such waiver or alteration is in writing and signed by all of the parties hereto.

ARTICLE XXI: GOVERNING LAW AND ARBITRATION

- 21.1 This Agreement shall be governed by the law of _____.
- 21.2 The parties hereto undertake to settle any dispute, controversy, or claim arising under, out of, or in connection with this Agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach, or termination, as well as noncontractual claims, in an amicable manner. If an amicable settlement cannot be reached within 30 days for any reason, the dispute shall be referred to and finally settled by arbitration in accordance with the UNCITRAL Arbitration Rules then obtaining. The appointing authority shall be the Secretary-General of the Permanent Court of Arbitration, the number of arbitrators shall be three, and the language to be used in the arbitral proceedings shall be English. The place of arbitration shall be determined by mutual agreement, but if agreement cannot be reached the proceedings shall take place in _____.
- 21.3 Either party to this Agreement may request any judicial authority to order any interim measures of protection for the preservation of its rights and interests to the extent permitted by law, including, without limitation, injunctions and measures for the conservation of such property and information that form part of the subject matter in dispute. Such requests shall not be deemed incompatible with, or as a waiver of, this agreement to arbitrate. In respect of any requests for interim measures of protection, and without limitation to proceeding in any other forum, the parties hereby consent to the exercise of jurisdiction by the judicial authorities of _____.
- 21.4 In the event a party fails to proceed with arbitration, unsuccessfully challenges the arbitrator's award, fails to comply with the arbitrator's award, or fails to comply with any

DISTRIBUTORSHIP AGREEMENT

interim measure of protection issued by any competent authority, the other party shall be entitled to costs of suit, including reasonable attorney's fees, for having to compel arbitration or defend or enforce the award or interim measure.

IN WITNESS WHEREOF the parties hereto have caused these presents to be executed in triplicate by their duly authorized officers.

For Manufacturer:

For Distributor:

By: _____

By: _____

Date: _____

Date: _____