

GLAXOSMITHKLINE TERMS AND CONDITIONS OF PURCHASE

(GOODS & SERVICES) Egypt

1. DEFINITIONS

“**Affiliate**” means an organisation which is directly or indirectly controlled by, in Control of, or under common Control with, either Supplier or GSK as appropriate, in each case for the time being and from time to time.

“**Agreement**” means the agreement between GSK and Supplier consisting of the Purchase Order, these Terms and Conditions, the Specification, and any other documents (or parts thereof) specified in the Purchase Order or otherwise expressly incorporating these Terms and Conditions.

“**Control**” means the ownership of more than 50% of the shares of any organisation or the legal power to direct or cause the direction of the general management of either Supplier or GSK as appropriate.

“**Goods**” means all (or any) of the goods specified in the Purchase Order.

“**Incoterms**” means the Year 2000 edition of the official International Chamber of Commerce Rules for the interpretation of trade terms.

“**Intellectual Property Rights**” means any and all rights in and/or to; (a) patents; (b) inventions, discoveries, utility models and improvements whether or not capable of protection by patent or registration; (c) **formulas**, processes, compositions of matter, formulations, methods of use or delivery, data, reports, specifications and computer programs or models; (d) copyright and related rights; (e) moral rights; (f) design rights; (g) trademarks and service marks; (h) business or trade names, domain names, rights in get-up, rights to goodwill or to sue for passing off or unfair competition; (i) database rights; (j) confidential information, know-how, trade secrets; and (k) other intellectual property rights; in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

“**Losses**” means all losses, claims, liabilities, costs, awards, fines, penalties, expenses (including legal fees and other professional expenses) and damages of any nature whatsoever and whether or not reasonably foreseeable or avoidable.

“**Packaging**” means all packaging for or relating to the Goods, including, without limitation, all bags, cases, carboys, cylinders, drums, pallets and other containers.

“**GSK**” means GlaxoSmithKline Services Unlimited, but shall, where rights or benefits are granted or Services provided, also include its Affiliates.

“**Purchase Order**” means GSK’s purchase order issued to Supplier setting out GSK’s requirements for Goods or Services.

“**Services**” means the services specified in the Purchase Order.

“**Specification**” means the written specification for the Goods or Services that is supplied by GSK to Supplier or produced by Supplier and agreed in writing by GSK.

“**Supplier**” means the person, company or other legal entity to whom the Purchase Order is addressed.

“**Terms and Conditions**” means the terms and conditions set out in this document.

“**Territory**” Egypt.

"Sanction Country" means Egypt, Libya, Yemen, Iraq, Lebanon and Afghanistan

2. STATUS OF THESE TERMS AND CONDITIONS

- 2.1. These Terms and Conditions and other matters appearing on the Purchase Order shall apply to the purchase by GSK from Supplier of all Goods or Services set out on the Purchase Order to the exclusion of all other terms and conditions, including any terms or conditions which are implied by trade, custom, practice or course of dealing or which Supplier may purport to apply or which are endorsed upon any correspondence or documents issued by Supplier irrespective of their date of communication to GSK. However, the terms and conditions in any separately negotiated and signed written contract entered into by the parties in respect of the Goods or Services identified in the Purchase Order shall overrule these Terms and Conditions.
- 2.2. The Purchase Order constitutes an offer by GSK to purchase the Goods or Services specified therein in accordance with these Terms and Conditions. The Purchase Order and these Terms and Conditions shall be deemed to be accepted by Supplier on the earlier of: (a) Supplier issuing a written acceptance of the Purchase Order; or (b) Supplier doing any act consistent with fulfilling the Purchase Order, at which point the Agreement shall come into existence.
- 2.3. GSK will not be liable in respect of any Purchase Order(s) or instructions other than those issued or confirmed on its official Purchase Order documents, whether issued in hard copy or by facsimile (in which case such documents shall be valid only when duly signed), or issued electronically in accordance with these Terms and Conditions.

3. SERVICES & DELIVERABLES

- 3.1. Supplier agrees to provide to GSK (or its affiliate, if such affiliate are designated as the contracting parties in the purchase order) (hereinafter referred to as "GSK") the services ("Services") and/or goods ("Goods"), described in any purchase order, in accordance with these Terms and Conditions ("Agreement"). Upon acceptance of a purchase order, shipment of Goods or commencement of a Service, Supplier shall be bound by the provisions of this Agreement, including all provisions set forth on the face of any applicable purchase order, whether Supplier acknowledges or otherwise signs this Agreement or the purchase order, unless Supplier objects to such terms in writing prior to shipping Goods or commencing Services.
- 3.2. This writing does not constitute a firm offer, and may be revoked at any time prior to acceptance. This Agreement may not be added to, modified, superseded, or otherwise altered, except by writing signed by an authorized GSK representative. Any terms or conditions contained in any acknowledgment, invoice, or other communication of Supplier, which are inconsistent with the terms and conditions herein, are hereby rejected. To the extent that this Agreement might be treated as an acceptance of Supplier's prior offer, such acceptance is expressly made on condition of assent by Supplier to the terms hereof and shipment of the Goods or beginning performance of any Services by Supplier shall constitute such assent. GSK hereby reserves the right to reschedule any delivery or cancel any purchase order issued at any time prior to shipment of the Goods or prior to commencement of any Services. GSK shall not be subject to any charges or other fees as a result of such cancellation.

4. DELIVERY

- 4.1. Time is of the essence. Delivery of Goods and Services shall be made pursuant to the schedule, via the carrier, and to the place specified on the face of the applicable purchase order. GSK reserves the right to return, shipping charges collect, all Goods received in advance of the delivery schedule. If no delivery schedule is specified, the order shall be filled promptly and delivery will be made by the most expeditious form of land transportation. If no method of shipment is specified in the purchase order, Supplier shall use the least expensive carrier. In

the event Supplier fails to deliver the Goods or Services within the time specified, GSK may, at its option, decline to accept performance and terminate the Agreement or may demand its allocable fair share of Supplier's available Goods and terminate the balance of the Agreement. Supplier shall package all items in suitable containers to permit safe transportation and handling. Each delivered container must be labeled and marked to identify contents without opening and all boxes and packages must contain packing sheets listing contents. GSK's purchase order number must appear on all shipping containers, packing sheets, delivery tickets, and bills of lading.

- 4.2. Unless otherwise instructed in writing by GSK's nominated representative, all Goods must be delivered and all Services must be performed at the time and place specified in the Agreement. Supplier shall supply GSK with details of the anticipated lead times between placing a Purchase Order and delivery of any Goods and Supplier shall keep GSK informed of progress. All deliveries of Goods must be accompanied by a delivery note (and any other delivery documentation specified in the Purchase Order or otherwise in the Agreement) showing the date of the Purchase Order, the Purchase Order number, the type and quantity of Goods being delivered, special storage instructions (if any) and, if the Goods are being delivered by instalment, the outstanding balance remaining to be delivered. If Goods or Services are incorrectly delivered Supplier shall be responsible for additional expenses incurred in delivering them to the correct point specified in the Agreement or subsequently advised in writing by GSK. The quantity of Goods or Services specified in the Agreement may not be changed without GSK's prior written consent. Quantities of Goods or Services delivered in excess of those stated in the Agreement may not be accepted.
- 4.3. Time shall be of the essence in relation to the performance of any and all of Supplier's obligations pursuant to the Agreement.

5. IDENTIFICATION, RISK OF LOSS, & DESTRUCTION OF GOODS

- 5.1. Supplier assumes all risk of loss until receipt by GSK. Title to Goods shall pass to GSK upon receipt by it of the Goods at the designated destination. If the Goods ordered are destroyed prior to title passing to GSK, GSK may at its option cancel the Agreement or require delivery of substitute Goods of equal quantity and quality. Such delivery will be made as soon as commercially practicable. If loss of Goods is partial, GSK shall have the right to require delivery of the Goods not destroyed.
- 5.2. Unless Incoterms are agreed (in which risk shall pass to GSK in accordance with the agreed Incoterms), title and risk in the Goods shall pass to GSK on completion of delivery at the place specified in the Agreement.
- 5.3. Neither payment by, nor passing of title or risk in the Goods or the Services to, GSK shall be deemed to constitute acceptance of the Goods or the Services.

6. PAYMENT

- 6.1. As full consideration for the performance of the Services, delivery of the Goods and the assignment of rights to GSK as provided herein, GSK shall pay Supplier (i) the amount agreed upon and specified in the applicable purchase order, or (ii) Supplier's quoted price on date of shipment (for Goods), or the date Services were started (for Services), whichever is lower. Applicable taxes and other charges such as shipping costs, duties, customs, tariffs, imposts, and government imposed surcharges shall be stated separately on Supplier's invoice. Payment is made when GSK's check is mailed. Payment shall not constitute acceptance. All personal property taxes assessable upon the Goods prior to receipt by GSK of Goods conforming to the purchase order shall be borne by Supplier. Supplier shall invoice GSK for all Goods delivered and all Services actually performed. Each invoice submitted by Supplier must be provided to GSK within ninety (90) days of completion of the Services or delivery of Goods and must reference the applicable purchase order, and GSK reserves the right to

return all incorrect invoices. GSK will receive a 2% discount of the invoiced amount for all invoices that are submitted more than ninety (90) days after completion of the Services or delivery of the Goods. Unless otherwise specified on the face of a purchase order, GSK shall pay the invoiced amount within sixty (60) days after receipt of a correct invoice. Supplier will receive no royalty or other remuneration on the production or distribution of any products developed by GSK or Supplier in connection with or based on the Goods or Services provided.

- 6.2. The correct Purchase Order number must be quoted on all invoices, and GSK will accept no liability whatsoever for invoices, delivery notes or other communications which do not bear such Purchase Order numbers.

7. WARRANTIES

- 7.1. **Services:** Supplier represents and warrants that all Services shall be completed in a professional, workmanlike manner, with the degree of skill and care that is required by current, good, and sound professional procedures. Further, Supplier represents and warrants that the Services shall be completed in accordance with applicable specifications and shall be correct and appropriate for the purposes contemplated in this Agreement. Supplier represents and warrants that the performance of Services under this Agreement will not conflict with, or be prohibited in any way by, any other agreement or statutory restriction to which Supplier is bound.
- 7.2. **Goods:** Supplier warrants that all Goods provided will be new and will not be used or refurbished. Supplier warrants that all Goods delivered shall be free from defects in materials and workmanship and shall conform to all applicable specifications for a period of fifteen (15) months from the date of delivery to GSK or for the period provided in Supplier's standard warranty covering the Goods, whichever is longer. Supplier hereby agrees that it will make spare parts available to GSK for a period of five (5) years from the date of shipment at Suppliers then current price, less applicable discounts. Additionally, Goods purchased shall be subject to all written and oral express warranties made by Supplier's agents, and to all warranties provided for by the English Commercial Code and applicable Commercial Code in the territory. All warranties shall be construed as conditions as well as warranties and shall not be exclusive. Supplier shall furnish to GSK Supplier's standard warranty and service guaranty applicable to the Goods. All warranties and Service guaranties shall run both to GSK and to its customers.
- 7.3. If GSK identifies a warranty problem with the Goods during the warranty period, GSK will promptly notify Supplier of such problems and will return the Goods to Supplier, at Supplier's expense. Within five (5) business days of receipt of the returned Goods, Supplier shall, at GSK's option, either repair or replace such Goods, or credit GSK's account for the same. Replacement and repaired Goods shall be warranted for the remainder of the warranty period or six (6) months, whichever is longer.
- 7.4. Supplier shall ensure that the Goods comply with all applicable statutory and regulatory requirements relating to the manufacture, labelling, Packaging, storage, handling and delivery of the Goods.
- 7.5. Supplier shall ensure that all of its personnel and sub-contractors are suitably qualified to perform the Services and that all necessary licences, work permits or other authorisations have been obtained.
- 7.6. GSK shall have the right exercisable during the performance of the Services to suspend any payment obligation in respect of the Services if the performance does not conform in quality with any stipulations in the Agreement or if the performance is delayed.
- 7.7. If the Services do not conform with the Agreement, GSK shall have the right to purchase Services from elsewhere which nearly as practicable conform to the Agreement and any extra expense incurred in doing so shall be paid by Supplier to GSK. Before exercising such right to purchase the Services from an alternative

supplier GSK shall give Supplier an opportunity to replace the Services in respect of which payment was cancelled with Services which conform with the Agreement.

8. REJECTION, REPAIR AND REPLACEMENT OF GOODS

- 8.1. In the case of Goods not conforming with the Agreement and without limiting any of its other rights or remedies, GSK may, at its discretion:
 - 8.1.1 reject the Goods (in whole or in part) and return them to Supplier at Supplier's own risk and expense; and/or
 - 8.1.2 require Supplier as soon as reasonably practicable to either repair or replace the Goods at the site of delivery or Supplier's premises, whichever GSK shall so determine, or to refund to GSK any amounts paid in respect of any Goods which do not correspond with the Agreement (and repaired or replacement Goods shall themselves be subject to the obligations in the Agreement); and/or
 - 8.1.3 in the case of incorrect delivery, require Supplier to promptly reimburse GSK in respect of any cost (including but not limited to freight, clearance, duty and storage charges) incurred by GSK; and/or
 - 8.1.4 claim damages for any other costs, losses or expenses incurred by GSK which are in any way attributable to Supplier's failure to carry out its obligations under the Agreement.
- 8.2. the event of a rejection (in whole or in part) in accordance with Section 8.1 above GSK shall notify Supplier in writing, and the payment obligation in relation to any such delivery shall be suspended immediately.
- 8.3. If the expert finds that any delivery of the Goods has not complied with the Agreement, GSK shall have the rights stated in Section 8.1.
- 8.4. If the expert finds that the Goods comply with the Agreement, GSK shall pay for such Goods in accordance with the payment provisions contained in the Agreement.

9. PACKAGING

- 9.1. At no cost to GSK, Supplier will package and label the Goods in a manner suitable for transit and storage so as to enable them to reach their destination in good condition. GSK will not pay for or return Packaging materials unless previously agreed between the parties and confirmed in writing. Supplier shall ensure that Packaging complies with all relevant legislative requirements, including those pertaining to environmental, and occupational health and safety standards. Supplier will investigate potential environmental improvements to Packaging and will, where practicable, use minimal Packaging, recyclable Packaging and recycled Packaging materials.

10. INTELLECTUAL PROPERTY RIGHTS

- 10.1. Supplier shall indemnify GSK and its Affiliates, and keep them indemnified, on demand from and against all Losses incurred or suffered as a result of or in connection with any claim that the Goods or the provision of the Services by Supplier, or the use by or on behalf of GSK of the Goods or of any assets used or provided by Supplier in connection with the performance of the Services, infringes the Intellectual Property Rights or any other rights of any third party.
- 10.2. Supplier shall, at its expense, defend any and all claims or legal proceedings arising from infringements or alleged infringements of its Intellectual Property Rights in connection with the Goods or Services, provided that GSK gives Supplier all reasonable assistance and the sole authority to defend or settle any legal proceedings at Supplier's expense.
- 10.3. GSK retains Intellectual Property Rights in, and ownership of all materials, plans, drawings, tools, data, the Specification, patterns and/or designs provided by GSK to Supplier, and they shall all be returned at any time in good condition to GSK at GSK's request.

- 10.4. Where Goods are made to GSK's Specification, model, or plans, the Intellectual Property Rights in the Goods in so far as they relate to the Specification, model, or plans, and any improvements or developments thereof shall be the absolute property of GSK, and Supplier will assign all such Intellectual Property Rights to GSK on demand.
- 10.5. Intellectual Property Rights arising during or out of the provision of Services ("**Arising IP**") shall be and remain the property of GSK. Supplier assigns to GSK (with full title guarantee and free of all encumbrances) all of the Arising IP. This assignment shall take effect on the date of the Agreement in respect of any Arising IP then in existence, or as a present assignment of future rights that will take effect immediately on the coming into existence of the Arising IP, as appropriate. At its cost, Supplier shall do all such further acts and things, and execute all such other documents, as GSK may reasonably request to vest the Arising IP in GSK and/or to enable GSK to protect, perfect, enforce or enjoy the full benefit of the rights assigned under the Agreement.
- 10.6. In the event that any Intellectual Property Rights relating to the Goods and/or Services are held by the courts to infringe a third party's rights, and their use is enjoined by that third party, Supplier shall have the option and at its expense to procure for GSK the right to continue using the Goods or Services, or replace the Goods with non-infringing Goods or Services, or modify the Goods or Services so that they become non-infringing without detracting from their overall performance and functionality.

11. CONFIDENTIALITY AND PUBLICITY

- 11.1. Supplier shall, and shall procure that its employees and sub-contractors shall, keep confidential all information of a commercial or technical nature disclosed to Supplier by or on behalf of GSK for the purpose of the Agreement, and shall not disclose such information to any third party without GSK's prior written consent. Supplier shall not without GSK's prior written consent disclose, copy, publicise or publish, the existence of the Agreement or any information related to the Agreement including the name of GSK, any GSK Affiliate, the Goods, Services, or the place of delivery or performance.
- 11.2. Supplier will acquire knowledge of GSK Confidential Information (as defined below) in connection with its performance hereunder and agrees to keep such GSK Confidential Information in confidence during and following termination or expiration of this Agreement. "GSK Confidential Information" includes but is not limited to all information, whether written or oral, in any form, including without limitation, information relating to the research, development, products, methods of manufacture, trade secrets, business plans, customers, vendors, finances, personnel data, Work Product (as defined herein), and other material or information considered proprietary by GSK relating to the current or anticipated business or affairs of GSK which is disclosed directly or indirectly to Supplier. In addition, GSK Confidential Information means any third party's proprietary or confidential information disclosed to Supplier in the course of providing Services or Goods to GSK. GSK Confidential Information does not include any information (i) which Supplier lawfully knew without restriction on disclosure before GSK disclosed it to Supplier, (ii) which is now or becomes publicly known through no wrongful act or failure to act of Supplier, (iii) which Supplier developed independently without use of the GSK Confidential Information, as evidenced by appropriate documentation, or (iv) which is hereafter lawfully furnished to Supplier by a third party as a matter of right and without restriction on disclosure. In addition, Supplier may disclose Confidential Information which is required to be disclosed pursuant to a requirement of a government agency or law so long as Supplier provides prompt notice to GSK of such requirement prior to disclosure.
- 11.3. Supplier agrees not to copy, alter, or directly or indirectly disclose any GSK Confidential Information. Additionally, Supplier agrees to limit its internal

distribution of GSK Confidential Information to Supplier's Assistants who have a need to know, and to take steps to ensure that the dissemination is so limited, including the execution by Supplier's Assistants of nondisclosure agreements with provisions substantially similar to those set forth herein. In no event will Supplier use less than the degree of care and means that it uses to protect its own information of like kind, but in any event not less than reasonable care to prevent the unauthorized use of GSK Confidential Information.

- 11.4. Supplier further agrees not to use the GSK Confidential Information except in the course of performing hereunder and will not use such GSK Confidential Information for its own benefit or for the benefit of any third party. The mingling of the GSK Confidential Information with information of Supplier shall not affect the confidential nature or ownership of the same as stated hereunder. Supplier agrees not to design or manufacture any products which incorporate GSK Confidential Information. All GSK Confidential Information is and shall remain the property of GSK. Upon GSK's written request or the termination of this Agreement, Supplier shall return, transfer, or assign to GSK all GSK Confidential Information, including all Work Product, as defined herein, and all copies thereof.

12. FORCE MAJEURE

- 12.1. Neither party shall be liable for, nor be deemed to be in default of the Agreement, on account of any delay in completion or the performance of any other act under the Agreement due to circumstances which could not have been contemplated by the parties and which are beyond the party's reasonable control ("**Force Majeure**"), provided that the party claiming hereunder shall notify the other as soon as possible specifying the cause and probable duration of the delay or non-performance and shall minimise the effects of such delay or non-performance.
- 12.2. If the performance by either party of any of its obligations under the Agreement is prevented or delayed by Force Majeure:
- 12.3. for a consecutive period in excess of 5 working days, the parties shall enter into bona fide discussions with a view to alleviating its effects, or to agreeing upon such alternative arrangements as may be fair and reasonable in the circumstances; and
- 12.4. for a period in excess of 60 days cumulatively or consecutively, then the other party shall in its discretion have the right to immediately terminate the Agreement upon written notice.
- 12.5. In the event of Force Majeure arising, GSK may, by notice in writing to Supplier, cancel any deliveries of Goods or Services (and the applicable Purchase Orders or parts thereof) which in GSK's opinion cannot be made within a reasonable time after the due date without incurring any liability on the part of GSK.
- 12.6. GSK shall not be liable for any failure to perform including failure to (i) accept performance of Services or, (ii) take delivery of the Goods as provided caused by circumstances beyond its control which make such performance commercially impractical including, but not limited to, acts of God, fire, flood, acts of war, government action, accident, labor difficulties or shortage, inability to obtain materials, equipment, or transportation. In the event GSK is so excused, either party may terminate the Agreement and GSK shall at its expense and risk, return any Goods received to the place of shipment.

13. LICENCES AND COMPLIANCE WITH LAWS AND REGULATIONS

- 13.1. Supplier shall ensure that at all times it has and maintains all the licences, permissions, consents and permits that it needs to lawfully carry out its obligations under the Agreement and to grant the rights set out in the Agreement.
- 13.2. Supplier warrants that the Goods and Services shall comply with the Agreement, relevant laws, regulations and other legal requirements.

14. INSPECTION

- 14.1. GSK, and any third party it appoints on its behalf, shall have the right upon prior notice to inspect and carry out any tests, or batch sampling, it wishes on all

Goods at Supplier's premises (and Supplier shall procure equivalent rights for GSK in relation to the premises of any sub-contractors and on any premises where the Services are provided). Where pre-shipped inspection is specified, Supplier must, at its expense, facilitate the same and provide any or all relevant certificates of analysis. If, following any such inspection or testing, GSK considers that the Goods or Services are unlikely to comply with the Agreement, GSK shall inform Supplier and Supplier shall immediately take such remedial action as is necessary to ensure compliance. GSK shall have the right to conduct further inspections and tests after Supplier has carried out its remedial actions.

- 14.2. Any inspections, tests, approvals or acceptance given on behalf of GSK in relation to the Goods or Services shall not relieve Supplier from its obligations or liabilities under the Agreement.
- 14.3. Supplier shall, and shall ensure that its sub-contractors shall, grant a right of access to GSK and any third party it appoints in order to inspect and test the Goods for compliance with relevant environmental, occupational health and safety legislation and other requirements such as GSK standards or any requirements set out in the Specification.

15. DATA PROTECTION

- 15.1. To the extent that Supplier, in providing any Services under the Agreement, "processes" (where "processes" is as defined in the Data Protection Act 1998 and includes, without limitation, obtaining, organising, storing, accessing, using, disclosing or adapting, and "processed" and "processing" shall be construed accordingly) any GSK information that constitutes "personal data" within the meaning of the Data Protection Act 1998, Supplier shall ensure that all such personal data is kept secure, and in accordance with all relevant legislation, and shall:
 - 15.1.1 ensure, before processing any such personal data, that adequate technical and organisational controls are in place to:
 - a) prevent unauthorised or unlawful processing of any such personal data it may hold; and
 - b) protect any such personal data from accidental loss, damage or destruction; and
 - 15.1.2 act only on the instructions of GSK when processing such personal data, including ensuring that such personal data is used only as authorised by GSK, or by the Agreement.
- 15.2. Supplier shall not process or transfer any personal data outside the European Economic Area, or transfer any personal data to any third party, without the prior written consent of GSK, which consent may be subject to Supplier (or the relevant third party) entering into a data transfer agreement with GSK, where GSK so requires, in a form substantially similar to the Standard Contractual Clauses issued from time to time by the European Commission, and entering into such other arrangements as GSK may reasonably require to satisfy its requirements as a data controller under the Data Protection Act 1998, as amended from time to time.
- 15.3. Supplier shall indemnify GSK and its Affiliates, and keep them indemnified, on demand from and against all Losses incurred or suffered as a result of or in connection with Supplier's breach of this Section 15.

16. HAZARDS

- 16.1. Supplier shall, and shall ensure that its staff and those of any sub-contractor shall, when working on any site in connection with the Agreement, comply with all relevant environmental, occupational health and safety legislation and any other appropriate standards, policies and procedures notified by GSK from time to time.
- 16.2. Supplier will provide applicable hazard information such as material safety data sheets and will inform GSK of all regulations and guidance (statutory or

otherwise) which Supplier knows or believes to be associated with the Goods and any combination of the Goods with another product.

- 16.3. Supplier shall indemnify GSK and its Affiliates, and keep them indemnified, on demand from and against all Losses incurred or suffered as a result of or in connection with any third party claim arising from Supplier's or Supplier's sub-contractors' actions resulting in alleged release of any waste, hazardous substance or other pollutant.
- 16.4. Supplier will endeavour to exceed any statutory minimum environmental, occupational health and safety requirements in accordance with generally accepted best working practices and any specific standards or other requirements of GSK.

17. RESPONSIBILITY FOR INFORMATION

- 17.1. Supplier shall be responsible for any errors or omissions in any drawings, calculations, Packaging details or other particulars supplied by Supplier, whether such information has been approved by GSK or not, provided that such errors or omissions are not due to inaccurate information furnished in writing by GSK.

18. SUPPLIER'S EMPLOYEES

- 18.1. For the duration of the period that any Services are being provided, the employment of any employee of Supplier shall remain with Supplier and shall not pass or otherwise transfer to GSK or its Affiliates and nothing in the Agreement shall be construed or have effect as constituting any relationship of employer and employee between GSK (or its Affiliates) and the employees and/or sub-contractors of Supplier. Supplier agrees that it is performing the Services as an independent contractor and will retain all responsibility for payment of any income tax, national insurance contributions, and any other taxation that may arise from the provision of the Services, and shall indemnify GSK and its Affiliates, and keep them indemnified, on demand from and against all Losses incurred or suffered as a result of or in connection with GSK or its Affiliates having to pay any tax, income tax or national insurance contributions and/or make any deductions at source in respect of the Services.
- 18.2. Notwithstanding the provisions of Section 18.1, if and to the extent that the Transfer of Undertakings (Protection of Employment) Regulations 2006 or any other equivalent laws apply, such that GSK or its Affiliates (or a successor supplier to Supplier) incurs Employment Liabilities arising in relation to any Supplier personnel whose employment (or any claim arising out of such employment, or arising as a result of its termination) transfers to GSK (or its Affiliate) or to such successor supplier, Supplier shall indemnify GSK, its Affiliates and any replacement supplier, and keep them indemnified, on demand from and against all such Employment Liabilities. For the purposes of this Section 18.2, "**Employment Liabilities**" means any costs, claims, demands, fines, or expenses (including reasonable legal and other professional expenses) and all losses, damages, compensation and other liabilities incurred by, or attributed to, GSK or its Affiliates (and including those incurred by or attributed to any successor supplier or sub-contractor of GSK), and shall include any incurred as a result of an indemnity or warranty given, or to be given, by GSK or its Affiliates to, or any claim made by, a successor supplier or sub-contractor, in each case relating to the employment contracts of such Supplier personnel, or any claim under the Employment Rights Act 2003 or similar.

19. SOFTWARE DEFECTS

- 19.1. Supplier warrants that any Goods comprising computer hardware or software, and supplied by Supplier to GSK (the "**Products**"):
- 19.1.1 are free from viruses, defects, disabling codes, software routines or hardware components designed to permit (either automatically or through externally applied controls) unauthorised access or allow the Products to be disabled, have content erased, or otherwise be harmed (collectively, "**Contaminants**"),

- have been duly tested to ensure that there are no such Contaminants, and are subject to recognised and appropriate release procedures including the latest version of a proprietary virus detection software package approved by GSK, and Supplier shall procure that corresponding obligations are imposed with its sub-contractors or agents;
- 19.1.2 have been obtained from a reputable and reliable software developer and not through any interest group or multi-organisational software sharing scheme, and do not include any open source, freeware or shareware (unless otherwise agreed in writing in advance by GSK); and
 - 19.1.3 will comply and function substantially in accordance with any related user documentation.
- 19.2. Supplier warrants that neither the performance nor the functionality of the Products will be adversely affected by any changes caused by the advent of the a particular calendar date.
- 19.3. Supplier shall indemnify GSK and its Affiliates, and keep them indemnified, on demand from and against all Losses incurred or suffered as a result of or in connection with Supplier's breach of the warranties set out in Sections 19.1 and 19.2 above.

20. INDEMNITY AND INSURANCE

- 20.1. Supplier shall indemnify, hold harmless, and at GSK's request, defend GSK, its officers, directors, customers, agents and employees, against all claims, liabilities, damages, losses, and expenses, including attorneys' fees and cost of suit arising out of or in any way connected with the Goods or Services provided under this Agreement, including, without limitation, (i) any claim based on the death or bodily injury to any person, destruction or damage to property, or contamination of the environment and any associated clean up costs, (ii) Supplier failing to satisfy the Internal Revenue Service's guidelines for an independent contractor, (iii) any claim based on the negligence, omissions, or willful misconduct of Supplier or any Supplier's Assistants, and (iv) any claim by a third party against GSK alleging that the Goods or Services, the results of such Services, or any other products or processes provided under this Agreement, infringe a patent, copyright, trademark, trade secret, or other proprietary right of a third party, whether such are provided alone or in combination with other products, software, or processes. Supplier shall not settle any such suit or claim without GSK's prior written approval. Supplier agrees to pay or reimburse all costs that may be incurred by GSK in enforcing this indemnity, including attorneys' fees.
- 20.2. Should GSK's use, or use by its distributors, subcontractors, or customers, of any Goods or Services purchased from Supplier be enjoined, be threatened by injunction, or be the subject of any legal proceeding, Supplier shall, at its sole cost and expense, either (a) substitute fully equivalent non-infringing Goods or Services; (b) modify the Goods or Services so that they no longer infringe but remain fully equivalent in functionality; (c) obtain for GSK, its distributors, subcontractors, or customers the right to continue using the Goods or Services; or (d) if none of the foregoing is possible, refund all amounts paid for the infringing Goods or Services.
- 20.3. Supplier shall indemnify GSK and its Affiliates, and keep them indemnified, on demand from and against all Losses incurred or suffered as a result of or in connection with any defect in the Goods or Services or any breach by Supplier of its obligations hereunder or of any statutory duty or from any act or omission of Supplier's employees, agents or sub-contractors.
- 20.4. Supplier shall be solely responsible for maintaining and requiring Supplier's Assistants to maintain such adequate health, auto, workers' compensation, unemployment compensation, disability, liability, and other insurance, as is required by law or as is the common practice in Supplier's and Supplier's

Assistants' trades or businesses, whichever affords greater coverage. Upon request, Supplier shall provide GSK with certificates of insurance or evidence of coverage before commencing performance under this Agreement. Supplier shall provide adequate coverage for any GSK property under the care, custody or, control of Supplier or Supplier's Assistants.

21. ETHICAL STANDARDS AND HUMAN RIGHTS

- 21.1. Unless otherwise required or prohibited by law, Supplier warrants, to the best of its knowledge, that in relation to the supply of Goods or Services under the terms of the Agreement:
- 21.1.1 it does not employ engage or otherwise use any child labour in circumstances such that the tasks performed by any such child labour could reasonably be foreseen to cause either physical or emotional impairment to the development of such child;
 - 21.1.2 it does not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work;
 - 21.1.3 it provides a safe and healthy workplace, presenting no immediate hazards to its employees, any housing provided by Supplier to its employees is safe for habitation, and it provides access to clean water, food, and emergency healthcare to its employees in the event of accidents or incidents at Supplier's workplace;
 - 21.1.4 it does not discriminate against any employees on any ground (including race, religion, disability or gender);
 - 21.1.5 it does not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and does not use cruel or abusive disciplinary practices in the workplace;
 - 21.1.6 it pays each employee at least the minimum wage, or a fair representation of the prevailing industry wage (whichever is the higher), and provides each employee with all legally mandated benefits;
 - 21.1.7 it complies with the laws on working hours and employment rights in the countries in which it operates;
 - 21.1.8 it is respectful of its employees right to join and form independent trade unions and freedom of association; and
 - 21.1.9 it complies with the GSK Anti-Bribery and Corruption Requirements set out in Annex A.
- 21.2. Supplier agrees that it is responsible for controlling its own supply chain and that it shall encourage compliance with ethical standards and human rights by any subsequent supplier of goods and services that are used by Supplier when performing its obligations under the Agreement.
- 21.3. Supplier shall ensure that it has ethical and human rights policies and an appropriate complaints procedure to deal with any breaches of such policies.
- 21.4. GSK reserves the right upon reasonable notice (unless inspection is for cause, in which case no notice shall be necessary) to enter upon Supplier's premises to monitor compliance by Supplier of the warranties set out in Section 21.1 above and Supplier shall, subject to compliance with law, furnish GSK with any relevant documents requested by GSK in relation thereto.

22. OWNERSHIP OF WORK PRODUCT

- 22.1. For purposes of this Agreement, "Work Product" shall include, without limitation, all designs, discoveries, creations, works, devices, masks, models, work in progress, Service deliverables, inventions, products, computer programs, procedures, improvements, developments, drawings, notes, documents, information and materials made, conceived, or developed by Supplier, alone or with others, which result from or relate to the Services performed hereunder. Standard Goods manufactured by Supplier and sold to GSK without having been designed, customized, or modified for GSK do not constitute Work Product. All

Work Product shall at all times be and remain the sole and exclusive property of GSK. Supplier hereby agrees to irrevocably assign and transfer to GSK and does hereby assign and transfer to GSK all of its worldwide right, title, and interest in and to the Work Product including all associated intellectual property rights. GSK will have the sole right to determine the treatment of any Work Product, including the right to keep it as trade secret, execute and file patent applications on it, to use and disclose it without prior patent application, to file registrations for copyright or trademark in its own name, or to follow any other procedure that GSK deems appropriate. Supplier agrees: (a) to disclose promptly in writing to GSK all Work Product in its possession; (b) to assist GSK in every reasonable way, at GSK's expense, to secure, perfect, register, apply for, maintain, and defend for GSK's benefit all copyrights, patent rights, mask work rights, trade secret rights, and all other proprietary rights or statutory protections in and to the Work Product in GSK's name as it deems appropriate; and (c) to otherwise treat all Work Product as GSK Confidential Information as described above. These obligations to disclose, assist, execute, and keep confidential survive the expiration or termination of this Agreement. All tools and equipment supplied by GSK to Supplier shall remain the sole property of GSK.

- 22.2. Supplier will ensure that Supplier's Assistants appropriately waive any and all claims and assign to GSK any and all rights or any interests in any Work Product or original works created in connection with this Agreement. Supplier irrevocably agrees not to assert against GSK or its direct or indirect customers, assignees, or licensees any claim of any intellectual property rights of Supplier affecting the Work Product.
- 22.3. GSK will not have rights to any works conceived or reduced to practice by Supplier which were developed entirely on Supplier's own time without using equipment, supplies, facilities, or trade secret or GSK Confidential Information, unless (i) such works relate to GSK's business, or GSK's actual or demonstrably anticipated research or development, or (ii) such works result from any Services performed by Supplier for GSK.

23. TERMINATION

- 23.1. Subject to Section 23.4, if either party to the Agreement is in breach of the Agreement and does not remedy the breach within 30 days of notice from the other party so to do (if capable of remedy) the other party may terminate the Agreement immediately by notice to the party in breach.
- 23.2. If either party becomes bankrupt, dissolved, wound up, or makes any arrangement with its creditors or has a receiver, administrative receiver, liquidator or provisional liquidator appointed over all or any part of its assets or goes into liquidation (whether voluntary or otherwise) save as part of a bona fide reconstruction not involving insolvency or takes or suffers any similar action as a result of its liability to pay its debts or its insolvency it shall promptly so notify the other party in writing providing particulars of the circumstances whereupon the other party may terminate the Agreement immediately by notice.
- 23.3. If at any time during the term of the Agreement there shall be any change in the legal or beneficial ownership or Control of Supplier:
- 23.3.1 Supplier shall immediately so notify GSK in writing; and
- 23.3.2 GSK may, upon receiving notice or otherwise becoming aware of a change in the legal or beneficial ownership or Control of Supplier, terminate the Agreement immediately by notice in writing to Supplier if it considers in its sole discretion that such change of ownership or Control is prejudicial to its interests.
- 23.4. The Agreement may be cancelled at any time by GSK for any reason whatsoever, by giving Supplier notice in writing.

24. CONSEQUENCES OF TERMINATION

- 24.1. Within 7 days after termination of the Agreement for any reason, Supplier shall:

- 24.1.1 at GSK's option and cost, deliver to GSK (or as GSK shall direct) all quantities of the Goods in its possession which comply with the Agreement;
 - 24.1.2 at Supplier's cost, return to GSK all documents provided to Supplier by GSK; and
 - 24.1.3 at Supplier's cost, ensure that all documents containing Intellectual Property Rights and/or any information of a technical nature relating to the Goods, the manufacture of the Goods and the provision of Services, or of a confidential nature and supplied by GSK to Supplier, are returned to GSK or destroyed by Supplier at GSK's option.
- 24.2. With effect from termination of the Agreement Supplier shall not make any use for any purpose whatsoever of any Intellectual Property Right which is the property of GSK.
- 24.3. Termination of the Agreement or withdrawal of any Goods or Services from the Agreement shall be without prejudice to the continuation in force of Sections 1, 2, 7, 10, 11, 15, 18, 19, 24, 25, 26.9 and 26.10. Supplier agrees to provide GSK with all reasonable support with respect to any investigation required by GSK or any regulator with respect to the Goods or Services carried out prior or after such termination or withdrawal. GSK will reimburse Supplier's reasonable costs in providing such assistance.
- 24.4. Termination or expiry shall not relieve either party from any liability or action accrued prior to such termination or expiry. A fair and reasonable price will be paid for all Services in progress that have been delivered to GSK and which comply with the Agreement. GSK's liability is limited to Services in progress, and no further loss or liability will accrue on their account.

25. ASSIGNMENT

- 25.1. Supplier's rights and obligations under the Agreement may not be assigned in whole or in part without the prior written consent of GSK (acting in its sole discretion) and any such consent shall not be deemed to relieve Supplier of any of its obligations and liability to GSK pursuant to the Agreement.
- 25.2. GSK shall be entitled at any time by notice in writing to Supplier to assign the whole or any part of its rights and obligations under the Agreement to any Affiliate or to any successor in title to the whole or part of that part of GSK's business which relates to the Goods or Services.
- 25.3. If another company is created or a third party acquires GSK's assets through a divestiture or reorganisation of GSK's business or any part of it (such company or such third party acquirer being the "**Divested Entity**") such Divested Entity may use any portion of the Products provided under the Agreement for up to twelve months, on notice to Supplier, provided that the Divested Entity agrees to the terms and conditions of the Agreement. During this period, the Divested Entity may use the Products for either its business operations or GSK's business operations. If the Divested Entity wishes to continue to use any Product at the end of the time period specified above, the Divested Entity must execute a mutually agreeable contract with Supplier which will govern its subsequent use of the relevant Product.

26. GENERAL

- 26.1. Supplier shall not, without the prior written consent of GSK, appoint any sub-contractor or any person or persons to carry out its obligations under the Agreement. In the event that Supplier appoints a sub-contractor or other person to perform its obligations it shall remain liable to GSK for the performance of all its obligations and shall ensure that any such sub-contractor or other person agrees to be bound by terms equivalent to those in the Agreement.
- 26.2. The Agreement contains the whole agreement between the parties in respect of the subject matter of the Agreement and supersedes all prior written or oral

agreements, arrangements and understandings between them relating to that subject matter.

- 26.3. Each party acknowledges that, in entering into the Agreement, it has not relied on, and shall have no right or remedy (other than for breach of contract) in respect of, any statement, representation, assurance or warranty made or given, or purportedly made or given, by or on behalf of the other party (whether made negligently or innocently) other than as expressly set out in the Agreement.
- 26.4. Nothing in the Agreement shall create, or be deemed to create a partnership, joint venture or other relationship between the parties other than the contractual relationship expressly provided for in the Agreement.
- 26.5. No failure or delay by a party to exercise any right or remedy provided under the Agreement or by law shall constitute a waiver of that (or any other) right or remedy and nor shall it preclude or restrict its further exercise. In addition, no single or partial exercise of any such right or remedy shall preclude or restrict the further exercise of that (or any other) right or remedy.
- 26.6. If any provision of the Agreement is held by any court or other competent authority to be invalid or unenforceable in whole or in part, the Agreement shall continue to be valid as to its other provisions and the remainder of the affected provision.
- 26.7. The Agreement may not be modified except by an instrument in writing signed by the duly authorised representatives of both parties.
- 26.8. Except for any rights granted to GSK Affiliates, which the parties hereby designate as intended third party beneficiaries to the Agreement, no person who is not a party to the Agreement shall have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term. The rights of the parties to terminate rescind or agree any variation, waiver or settlement under the Agreement is not subject to the consent of any person that is not a party to the Agreement.
- 26.9. The Agreement and any dispute or claim arising out of or in connection with it or its subject matter (including non-contractual disputes or claims) is governed by and shall be construed in accordance with English law.
- 26.10. The parties irrevocably agree that the English courts shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with the Agreement or its subject matter (including non-contractual disputes or claims).

27. SANCTIONS

- 27.1. The Parties acknowledge that a number of organisations and countries including the United Nations, the United States, the United Kingdom and the European Union have adopted sanctions legislation relating to the Sanction Country and/or entities and individuals which or who are resident or operate in the Sanction Country and that such sanctions are varied or amended from time to time (the "Sanctions").
- 27.2. Supplier represents and warrants to GSK that:
 - A. neither it nor any of its Affiliates nor any of its or their respective directors, officers, agents, employees (I) is currently the target of any sanctions programme administered by U.S. Treasury Department's Office of Foreign Assets Control ("OFAC"), the United Nations Security Council, the European Union, Her Majesty's Treasury or other relevant sanctions authority (collectively, "Sanctions"); (ii) is or in the preceding 12 months has been in violation of or subject to an investigation relating to Sanctions (iii) is listed on, or majority-owned or otherwise controlled by any parties identified on OFAC's List ("SDN List") of Specially Designated Nationals and Blocked Persons or any list of parties designated by the European Union, the United Kingdom or other relevant sanctions authority (a "Sanctions Target"),

- B. so far as Supplier is aware, performance by both Parties of this Agreement will not breach any Sanctions.
- 27.3. Supplier has provided to GSK complete and accurate details of the identities of the following parties:
- I. its legal owners;
 - II. its ultimate beneficial owners;
 - III. its directors;
 - IV. its senior managers;
 - V. its bankers;
 - VI. its sub- Suppliers;
 - VII. its subcontractors
 - VIII. its customers
- 27.4. Supplier will promptly notify GSK in writing of any changes in the information provided pursuant to Clauses 27.2 (B) and/or 27.3.
- 27.5. In the event that either Party (such party being a "Restricted Party") is or becomes unable to perform its obligations pursuant to this Agreement, because to do so would (or might) in the opinion of the Restricted Party breach any Sanctions, any applicable export control regime or other similar applicable laws of any jurisdiction (whether or not such Sanctions, controls or laws were in existence at the date of this Agreement and whether or not there have been any other changes in circumstance from those that existed at the date of this Agreement), the Restricted Party shall be entitled, in its sole discretion:
- I. to suspend the performance of such provisions of the Agreement (including any payment or supply provisions) which require performance by either or both parties where, in the sole opinion of the Restricted Party, such performance would result in a breach of any such Sanctions, controls or laws until, in the sole discretion of the Restricted Party, such time as all necessary approvals or licences have been obtained to enable the Agreement to continue in a lawful and compliant manner; and/or
 - II. to terminate the Agreement with immediate effect (at any time following the Restricted Party learning of such restrictions, including following a period of suspension of the Agreement pursuant to Clause 27.5 (I); and/or
 - III. where the restriction only affects the supply of a particular Product or Products, to remove such Product(s) from the scope of the Agreement with immediate effect,
 - IV. and, notwithstanding any provision of this Agreement, the Restricted Party shall not be obliged to pay any compensation to the other party or otherwise indemnify the other party in respect of any losses or costs which that other party may suffer or incur as a result of such suspension and/or termination.
- 27.6. Supplier further agrees that it shall:
- A. Familiarize itself with the Sanctions and ensure that it remains up to date regarding the identities of the entities and individuals which are Sanctions Targets for the purposes of the provision of the services hereunder;
 - B. not engage, in connection with the performance of the Services, (whether as a sub- Supplier , a supplier, a Supplier , a member of the team or otherwise) any person or entity which is a Sanctions Target or which is directly or indirectly, majority-owned or otherwise controlled by, under common control with, or acting for the benefit of or on behalf of any Sanctions Target;
 - C. not make, directly or indirectly, any payments or make any other benefit available to any person or entity which is a Sanctions Target or which is, directly or indirectly, majority-owned or otherwise controlled by, under

- common control with, or acting for the benefit of or on behalf of any Sanctions Target in connection with the performance of the Services;
- D. not sell, directly or indirectly, any Products to any person or entity which is a Sanctions Target or which is, directly or indirectly, owned or otherwise controlled by, under common control with, or acting for the benefit of or on behalf of, any Sanctions Target; and
- 27.7. immediately notify GSK if any person or entity which is engaged in connection with its performance of Services (whether as a sub- Supplier, a sub contractor, a supplier, a Supplier, a member of the Team or otherwise) or any of its customers becomes a Sanctions Target (whether directly or indirectly through being controlled by a person or entity that is a Sanctions Target).

28. NONEXCLUSIVE AGREEMENT

- 28.1. This is not an exclusive agreement. GSK is free to engage others to perform Services or provide Goods the same as or similar to Supplier's. Supplier is free to, and is encouraged to, advertise, offer, and provide Supplier's Services and/or Goods to others; provided however, that Supplier does not breach this Agreement.

29. SURVIVAL OF OBLIGATIONS

- 29.1. Any obligations and duties which by their nature extend beyond the expiration or termination of this Agreement shall survive the expiration or termination of this Agreement.

30. INJUNCTIVE RELIEF

- 30.1. Supplier acknowledges and agrees that the obligations and promises of Supplier under this Agreement are of a unique, intellectual nature giving them particular value. Supplier's breach of any of the promises contained in this Agreement will result in irreparable and continuing damage to GSK for which there will be no adequate remedy at law and, in the event of such breach, GSK will be entitled to seek injunctive relief, or a decree of specific performance

ANNEX A GSK ANTI BRIBERY AND CORRUPTION REQUIREMENTS

GSK requires compliance with the highest ethical standards and all anti-corruption laws applicable in the countries in which GSK (whether through a third party or otherwise) conducts business. All GSK employees and any third party acting for or on behalf of GSK must ensure that all dealings with third parties, both in the private and government sectors, are carried out in compliance with all relevant laws and regulations and with the standards of integrity required for all GSK business. GSK values integrity and transparency and has zero tolerance for corrupt activities of any kind, whether committed by GSK employees, officers, or third-parties acting for or on behalf of the GSK.

It is a material term of this Agreement that Supplier shall comply with the following:

1. Supplier shall comply fully at all times with all applicable laws and regulations, including but not limited to applicable anti-corruption laws, of the territory in which the Supplier conducts business with GSK.
2. Supplier agrees that it has not, and covenants and that it will not, in connection with the performance of this Agreement, directly or indirectly, promise, authorise, ratify or offer to make or make any “payments” of “anything of value” (as defined in the glossary section) to any individual (or at the request of any individual) including a “government official” (as defined in the glossary section) for the improper purpose of influencing or inducing or as a reward for any act, omission or decision to secure an improper advantage or to improperly assist the Supplier or GSK in obtaining or retaining business.
3. Supplier agrees that it has not, and covenants and that it will not, in connection with the performance of this Agreement, directly or indirectly, promise, authorise, ratify or offer to make or make any “facilitating payments” (as defined in the glossary section) to any individual (or at the request of any individual) including a “government official” (as defined in the glossary section).

GLOSSARY

The terms defined herein should be construed broadly to give effect to the letter and spirit of GSK’s ethical standards.

Anything of Value: this term includes cash or cash equivalents, gifts, services, employment offers, loans, travel expenses, entertainment, political contributions, charitable donations, subsidies, per diem payments, sponsorships, honoraria or provision of any other asset, even if nominal in value.

Facilitating Payments: otherwise known as “greasing payments” shall mean a payment to an individual to secure or expedite the performance of a routine government action by government officials.

Government Official shall mean: (i) Any officer or employee of a government or any department, agency or instrument of a government; (ii) Any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (iii) Any officer or employee of a company or business owned in whole or part by a government; (iv) Any officer or employee of a public international organisation such as the World Bank or United Nations; (v) Any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or (vi) Any candidate for political office.

Payments: this term refers to and includes any direct or indirect offers to pay, promises to pay, authorisations of or payments of anything of value.

ANNEX B
For Market Research Agreements and Patient Support Programs

Adverse Event (“AE”) Reporting obligations

The purpose of this document is to provide template contract provisions for inclusion in Market Research, Patient Access Programs and Interactive Digital Media Services agreements.

The language may need to be adjusted to fit the facts of the services. For example, a flow down provision must be included in the contract if there is a possibility that the vendor may engage a subcontractor. Any other amendments must be agreed with Safety and Legal.

A. Definitions

Insert the following into the Definitions section of your agreement

“**Adverse Event**” or “**AE**” shall mean any untoward medical occurrence in a patient, clinical investigation subject or consumer, temporally associated with the use of a GSK Product, whether or not considered drug-related. An Adverse Event and other Human Safety Information (HSI) can include:

- a) any unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated);
- b) failure to produce expected benefits (i.e. lack of efficacy);
- c) reports of medication errors or misuse, including drug overdose, whether accidental or intentional;
- d) reports of drug abuse or effects of drug withdrawal;
- e) reports of occupational exposure;
- f) reports of patients taking GSK Products whilst pregnant or breastfeeding;
- g) reports of drug interaction;
- h) reports of paternal exposure to a GSK Product;

- i) reports of suspicion that an infectious agent has been transmitted via a GSK product
- j) information received as part of a product quality complaint;
- k) unexpected therapeutic benefits – an unexpected improvement in a concurrent condition other than the one being treated.

“**GSK Product**” shall mean an investigational or licensed medicinal product, consumer healthcare product, vaccine, biological product or device whether under development by, or manufactured, marketed, supplied or distributed by or on behalf of, any division or operating company of GSK, whether in the Territory or in any other country.

B. Applicable Law Provision

Insert this clause or amend your existing clause as appropriate.

1.1 GSK and the [**Agency/Supplier/Vendor**] or its contractors shall comply with applicable local laws, regulations, industry codes of practice or other guidelines in relation to the reporting of Adverse Events (“AE”)(as defined below), in the provision of the Services. In the event of conflict, the more stringent requirements of such laws, regulations, codes and guidelines, or of this Section [X] shall take precedence.

C. Adverse Event Reporting Language

Insert this clause

1.2 The [Agency/Supplier/Vendor] shall ensure that all personnel, whether [Agency/Supplier/Vendor]’s employees or contractors, involved in the provision of the Services and who could become aware of an AE receive annual training in recognising and reporting AEs. The [Agency/Supplier/Vendor] will keep records of such training for not less than five (5) years and permit GSK to audit these records on request.

1.3 If in the course of providing the Services, the [**Agency/Supplier/Vendor**] or any of its contractors is informed or becomes aware of any AE (whether the information relates to the GSK Product by reference to its generic name or by reference to its trade mark) it shall forward such information to GSK. All AEs must be reported using the most up to date AE reporting form. This form must

19/9

- carry the project no./activity ID...**[Agency/Supplier/Vendor]** must request the most up to date AE reporting form from the GSK contact
- 1.4 **[Agency/Supplier/Vendor]** or its contractors shall verify that the AE relates to a GSK Product and if it fails to establish the product's manufacturer, **[Agency/Supplier/Vendor]** will verify this with GSK. The **[Agency/Supplier/Vendor]** or its contractors shall provide the AE to GSK within 24 hours of initial receipt (or next working day if over a weekend).
 - 1.5 The **[Agency/Supplier/Vendor]** or its contractors shall provide this information in the format set out in, and to the contacts shown on, the form in Schedule **XXX** of this Agreement and in accordance with such other procedures as GSK may notify to the **[Agency/Supplier/Vendor]** from time to time.
 - 1.6 In the event that the Services involve research subjects, the **[Agency/Supplier/Vendor]** or its contractors shall inform each research subject prior to the start of any research interview that if that research subject reports an AE, details will be forwarded to GSK and (i) if the subject is a healthcare professional, GSK may ask to contact them for further information or (ii) if the subject is a patient, they may be asked for contact details of their doctor so that GSK may follow-up any AEs. Refusal of any research subject to provide such contact details will not prevent their participation in the research.
 - 1.7 Where research is conducted via the internet, the **[Agency/Supplier/Vendor]** or its contractors shall monitor regularly the responses received for any reports of AEs. The regularity must be agreed with the GSK contact prior to the start of the activity and documented in the project documentation.
 - 1.8 The **[Agency/Supplier/Vendor]** or its contractors shall ensure that any information sent to GSK relating to AEs is sent only by e-mail or fax on the form outlined in **[Schedule XXX]**.
 - 1.9 GSK or its Affiliate will provide the **[Agency/Supplier/Vendor]** or its Affiliate access to a list of GSK Products.
 - 1.10 Failure to comply with this **[Section X]** shall constitute a material breach of this Agreement.

FOR PATIENT SUPPORT PROGRAM AND MARKET RESEARCH AGREEMENTS

- 1.11 Every three (3) months or at the end of the **[Service/Study/Activity]** if less than three (3) months duration the **[Agency/Supplier/Vendor]** will provide to GSK a completed listing of AEs received including AEs from its contractors in the reconciliation form set out in **Schedule YYY**. The most up to date version of this form must be used. This form must carry the project no./activity ID.
- 1.12 GSK will verify correctness of these listings and respond to **[Agency/Supplier/Vendor]** within seven (7) days requesting further information if any AE reports are found not to have been previously reported. **[Agency/Supplier/Vendor]** will provide corrective actions for any deviations from the requirements of this Agreement. This includes evidence from contractors that required corrective actions are complete

FOR INTERACTIVE DIGITAL MEDIA AGREEMENTS

- 1.12 **[Agency/Supplier/Vendor]** or its contractors shall conduct appropriate checks (e.g. e-mail, or fax notification) to confirm that the AEs that it sends GSK were sent without error. If a failure notification is received, **[Agency/Supplier/Vendor]** or its contractors shall immediately re-send the AE and take reasonable steps to ensure the same does not occur again.

D. DATA PRIVACY

Incorporate the following if not already covered in the agreement's Data Privacy Section. Use appropriate definitions already used within your agreement.

2. Data Protection

- 2.1 In no event will personally identifiable information of any patient be provided to GSK in connection with any AE without consent from the respondent.
- 2.2 Personal data of a healthcare professional who has reported an AE under this Agreement may be disclosed to GSK only where that healthcare professional has given their consent for such disclosure.

Schedule XXX

	GSK Global Adverse Event Reporting Form for Market Research / Patient Support Programme / Interactive Digital Media
	To be completed in English
	Please send completed form to GSK within 24 hours of identifying the safety information via fax or e-mail to:
	E-mail: ae.egypt@gsk.com Fax: +2 02 261850001

Agency/Project details		
Activity type: Market Research <input type="checkbox"/> , Patient Support Programme <input type="checkbox"/> , Digital Media <input type="checkbox"/>		
Project no./Activity ID:	Project title:	
Agency name:	Contact name:	
Address:		
Country:		
Tel. no:	Fax no:	E-mail:

Safety information		
Event no:	Respondent ID:	
When did the agency identify the safety information (day:month:year)?		
What GSK product is the safety information about?		
What indication (condition) was the product used for?		
Dose used:	Lot/Batch no:	Expiry date:
Describe the safety information disclosed during the research (include any verbatim text):		

Information about the reporter (respondent) who disclosed the safety information	
Reporter: Consumer <input type="checkbox"/> Doctor <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other (specify): _____	
Which country does the reporter live in?	
Did the reporter consider the event was possibly related to the product use? Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	
Is the reporter willing for GSK's safety team to contact them to discuss further? Yes <input type="checkbox"/> No <input type="checkbox"/> If <u>No</u> , please complete just the reporter fields above. If <u>Yes</u> , please provide contact details below. For an HCP it is their contact details; for a patient it is their doctor's contact details:	
<p><i>SAMPLE ONLY – PLEASE ENSURE YOU USE THE MOST UP TO DATE VERSION</i></p>	
Name:	
Address:	
Tel. no / E-mail:	

Information about the patient (person) or groups who used the product (may be the reporter or someone else)	
Gender: Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown <input type="checkbox"/>	Individual/Multiple Patients: Individual <input type="checkbox"/> Multiple <input type="checkbox"/>
Age:	If Multiple state no. if known:
Initials:	Other (date/year of birth, patient ID, etc):
Was the patient pregnant when using the product? Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	

Agency signature and date:	
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Schedule YYY

GSK Global Adverse Event Reconciliation Report for Market Research/Patient Support Programme



To be completed in English

Please send completed form to the GSK Project Lead and GSK Safety at the end of the project via fax or e-mail to:

E-mail: ae.egypt@gsk.com

Fax: +2 02 261850001

Agency/Project details		
Project no/Activity ID:	Project title:	
Agency name:	Contact name:	
Address:		
Country:		
Tel. no:	Fax no:	E-mail:

The following is a summary of adverse event reports submitted to GSK's safety department:

Safety information received (<i>please state timeframe</i>)			
Event no.	Respondent ID	Product	Event details
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			

**SAMPLE ONLY – PLEASE
ENSURE YOU USE THE
MOST UP TO DATE
VERSION**

16			
17			
18			
19			
20			

Total number of adverse events reported for the project: If no adverse events are reported please indicate Zero(0)	
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For any additional events please continue on an additional form – thank you

Agency signature and date:	
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