

General Terms and Conditions of Purchase of TEVA

PART I: GENERAL PROVISIONS FOR GOODS AND SERVICES

1. APPLICABILITY

- 1.1 These General Terms and Conditions of Purchase ("**Conditions**") apply to the purchase by TEVA of (i) any services ("**Services**") and/or (ii) any goods and materials, including, without limitation, products, equipment, and parts or components specifically developed or customized for TEVA, and deliverables resulting from a Service ("**Goods**"). "**TEVA**" means the legal entity of the TEVA Group issuing a Purchase Order for Goods and/or Services to the Supplier of such Goods and/or Services ("**Supplier**"), as set forth in the Purchase Order into which these Conditions are incorporated by reference. "**The TEVA Group**" is an international group of companies headed by Teva Pharmaceutical Industries Limited, Israel (www.tevapharm.com). "**Purchase Order**" means a request (in whatever form) of TEVA to the Supplier for the supply of Goods and/or Services, which is deemed to always include the Conditions.
- 1.2 Standard terms of the Supplier (including any pre-printed standard terms and conditions on the reverse of, or attached to, any offer, invoice, delivery note or any other correspondence issued by the Supplier in connection with the Contract (as defined below) shall not apply unless TEVA expressly consents thereto in writing.

2. PURCHASE ORDERS, CONFIRMED PURCHASE ORDERS

- 2.1 Within 5 days (or any other period specified in the Purchase Order) of receiving a Purchase Order ("**Confirmation Period**"), the Supplier shall confirm acceptance of such Purchase Order in writing ("**Confirmed Purchase Order**") and such Confirmed Purchase Order, shall form a binding contract between Supplier and TEVA for the supply of the Goods and/or Services so ordered ("**Contract**").
- 2.2 Any comments and/or changes to the Contract by the Supplier after the acceptance require TEVA's written acceptance. Until a Purchase Order has been duly accepted by the Supplier, TEVA may revoke, modify or change the Purchase Order at any time. Fulfillment by Supplier of the Purchase Order shall be deemed as acceptance by Supplier of the Purchase Order.
- 2.3 Any specifications for the Goods and/or Services contained in or incorporated in the Contract by reference, or any other specifications agreed in writing between TEVA and the Supplier from time to time are referred to as "**Specifications**".

3. DELIVERY OF GOODS AND PERFORMANCE OF SERVICES

- 3.1 The Supplier shall supply the Goods and perform the Services within regular business hours on the Delivery Date at the Delivery Point and in accordance with the Specifications, good industry practice, cGMP (as applicable), the terms of the Contract, the Applicable Law (as defined in Section 22.1) and any reasonable direction given by TEVA in writing from time to time. Unless otherwise agreed in writing, delivery of the Goods shall be according to FCA (Incoterms 2020) or the delivery terms specified in the Purchase Order.
- 3.2 **Delivery Date** means the date(s), and **Delivery Point** means the location(s) for the delivery of the Goods and/or the performance of the Services, as specified in the Purchase Order under: "Deliver To/Ship To" or as otherwise reasonably notified by TEVA in writing from time to time.
- 3.3 Time shall be of the essence in relation to the delivery of the Goods and the performance of the Services. The Supplier shall inform TEVA in writing as soon as it is aware of any events or circumstances which may, or have, adversely affect(ed) the supply of the Goods and/or performance of the Services. The Supplier shall use best efforts to minimize any adverse effects that could arise from any actual or potential delay, including the use of the fastest possible method of delivery or performance of the Goods and/or Services at the Supplier's sole cost and expense.
- 3.4 If the Supplier fails to deliver the Goods or fails to perform the Services as ordered and on the Delivery Date, TEVA may, after the

expiry of a reasonable extension granted to the Supplier, and without prejudice to any other rights and remedies of TEVA and without liability to the Supplier: (i) immediately terminate the Contract for cause by giving written notice to the Supplier, (ii) request a refund of the purchase price, if already paid by TEVA, and (iii) claim compensation for all costs, expenses, damages and other direct losses suffered by TEVA due to the Supplier's failure to properly perform. Acceptance by TEVA of portions of Goods or Services under the Contract shall not oblige TEVA to accept later delivery of Goods / Services, nor affect TEVA's right to return Goods / Services already accepted.

- 3.5 TEVA shall not be obligated to receive deliveries in excess of the quantity ordered or before the specified delivery date. TEVA reserves the right, at its sole discretion, to return any such excess, or to receive the same and charge Supplier with all storage charges incurred by TEVA. All expenses of transportation and storage, if any, resulting therefrom shall be applied against Supplier's account. Partial shipments of Goods, or deliveries of Goods prior to the Delivery Date, require TEVA's prior written approval. In the event of a delivery prior to the Delivery Date, TEVA may, at its discretion, at the Supplier's risk and expense, either return the Goods to the Supplier or store the Goods until the Delivery Date.
- 3.6 If, for any reason, TEVA is unable to accept the Goods on the Delivery Date, the Supplier shall, if requested by TEVA, delay the delivery for a reasonable period of time and store and maintain the Goods in good order and condition. TEVA shall reimburse the Supplier for the reasonable, actual and documented costs of such storage and maintenance.
- 3.7 All Goods must be packaged (i) securely so as to prevent damage during loading, transportation and off-loading and (ii) in compliance with Supplier's Warranties and the Specifications.
- 3.8 The Supplier shall provide to TEVA, upon request, with certificates of origin, certificates of analysis, certificates of conformance (as applicable), declarations, documents and data pertaining to trade requirements and, inform TEVA in detail and in writing of any potential export restrictions or approval obligations in the country of origin of the Goods, and/or Services or their destination. Supplier shall provide to TEVA all information related to the safety, safe handling, environmental impact, and disposal of the Goods including, without limitation, material safety data sheets (as applicable). Supplier shall promptly deliver to TEVA, as it becomes available to Supplier, any updates or amendments to the information, including those made to address the United Nations Globally Harmonized System of Classification and Labeling of Chemicals' requirements, provided pursuant to this Section and any new information relating to the safety, safe handling, environmental impact, or disposal of the Goods.

4. TRANSFER OF RISK AND TITLE

- 4.1 Unless otherwise specified in the Contract or agreed in writing, the risk of loss and damage to the Goods passes to TEVA at the time of receipt of the Goods at the Delivery Point.
- 4.2 Unless otherwise specified in the Contract or agreed in writing, title to the Goods passes to TEVA on the delivery of such Goods at the Delivery Point. Where title to all or any part of the Goods has passed to TEVA but the Goods remain in the possession of the Supplier, the Supplier shall clearly label the Goods as the property of TEVA and store such Goods separately from all other goods.

5. PRICE AND PAYMENT

- 5.1 Unless otherwise specified in the Contract or agreed in writing, the price(s) for the Goods and/or Services specified in the Purchase Order remain fixed for the term of the Contract.
- 5.2 TEVA shall pay, in addition to the price(s) for the Goods and Services, for the Supplier's expenses (e.g. for accommodation, travel and subsistence), only if TEVA has agreed in writing in advance to pay the expense(s) and reimbursement shall be made in accordance with TEVA's expense reimbursement policy.

5.3 Unless otherwise agreed in the Contract, the price(s) payable for the Goods and/or Services are:

5.3.1 exclusive of value added tax ("VAT") or other sales tax; and

5.3.2 inclusive of all charges for packaging, packing, shipping, carriage, insurance and delivery of the Goods, all travel expenses, food and beverage, accommodation and other costs related to the Goods and/or Services and all duties, licenses, permits and taxes (other than VAT or other sales tax) as may be payable for the Goods and/or Services from time to time.

5.3.3 The applicable VAT or other sales tax rate (if any) shall be paid to Supplier only if Supplier provided TEVA with a valid VAT or other sales tax invoice (applicable in accordance with the relevant VAT or other sales tax legislation) in relation to that amount.

5.4 Unless otherwise agreed in writing, and subject to the Supplier complying with its obligations under the Contract, TEVA shall pay for the Goods and/or the Services within the number of days specified in the Purchase Order from the date of receipt of the valid Supplier's invoice and required documentation, at the "send invoice to" address stated on the Purchase Order. The Supplier may not issue the invoice until the relevant Goods have been shipped to TEVA or the relevant Services have been completed. Invoices shall include TEVA's Purchase Order number and comply with all Applicable Laws and any specifications reasonably requested in writing by TEVA.

5.5 Payments shall be made by wire transfer (Automated Clearing House) transfers to Supplier's bank account as designated by Supplier in writing in advance, Supplier is responsible to communicate to TEVA any changes thereto, accompanied by supporting documentation (such as a letter from the bank or a copy of a bank account statement). TEVA may call the Supplier and ask for a verbal confirmation thereof, and Supplier shall cooperate with such request.

5.6 TEVA may withhold payment of any disputed or insufficiently documented amounts included in any invoice. TEVA may set-off any sum due from the Supplier to TEVA, against any amount due from TEVA to the Supplier under the Contract, or to recover such sums as a debt.

5.7 Payment of an invoice by TEVA does not constitute acceptance of the Goods and/or Services and is without prejudice to any other rights or remedies of TEVA.

6. QUALITY REQUIREMENTS

6.1 The Supplier (i) shall provide Goods of the highest quality and in accordance with the Supplier's Warranties, Specifications, all Applicable Law, and good industry practice and standards and (ii) shall develop, manufacture and test the Goods prior to their delivery to ensure they comply with the requirements set forth in the Contract (collectively "**Quality Requirements**").

6.2 The Supplier shall not make any changes to or modifications of the Goods in relation to Specifications as set forth in Sec. 2.3 and Quality Requirements without TEVA's prior written approval.

6.3 If the Supplier becomes aware or has reasons to believe that the Goods or Services do not or may not comply with the Quality Requirements, the Supplier shall promptly notify TEVA thereof in writing and shall advise TEVA on the further steps to be taken. Receipt and handling of such information by TEVA is without prejudice to any rights and remedies of TEVA.

7. INSPECTION, TESTING

7.1 The statutory provisions of §§ 377, 381 of the German Commercial Code [Handelsgesetzbuch] and the provisions in this Section 7 shall apply to TEVA's commercial obligation to inspect and complain. TEVA's obligation to inspect shall be limited to the following: (i) TEVA shall only be required to visually inspect the Goods for variations in identity and quantity and obvious transport damage as well as by means of a quality control in random sampling procedure and (ii) TEVA shall notify the Supplier of any such discrepancies and damages within a reasonable period of time (not to exceed 8 days) after receipt of the Goods at the Delivery Point. With regard to latent defects of the Goods, TEVA shall notifi-

fy the Supplier within 8 business days after TEVA becomes aware of a latent defect. TEVA reserves the right to reject, or refuse acceptance of, Goods or Services which do not comply with the Quality Requirements. Acceptance of all or part of the Goods or Services, use thereof and payment therefore, or failure to notify the Supplier promptly, shall not waive, nor affect TEVA's right to cancel, all or part of the Contract, or to return all or part of the Goods, recover damages, or pursue any other remedy TEVA may have.

7.2 If, according to the Contract or under the Applicable Law, TEVA is allowed or required to test and approve the Goods and/or Services to confirm their compliance with the Quality Requirements, the Supplier shall request TEVA in writing to carry out such acceptance test ("**Acceptance Procedure**"). The Supplier shall make such request in accordance with the dates as specified in the Contract or, if no dates are specified, as soon as practicable after delivery of the Goods or completion of the Services. Upon request by TEVA, the Supplier shall provide suitable Supplier Personnel (as defined in Section 20.1) to attend any such tests at its own cost. TEVA may reject the Goods and/or Services in whole or in part if they are not proven by the Supplier to comply with the Quality Requirements and/or any acceptance criteria. If TEVA does not accept the Goods and/or Services in whole or in part, the Supplier shall promptly investigate the non-conformity, correct such non-conformity and repeat the Acceptance Procedure. If the Goods or Services fail to pass the repeated Acceptance Procedure, TEVA may at its discretion choose whether to repeat the Acceptance Procedure or to claim the remedies as set forth in Section 9 hereof.

8. SUPPLIER WARRANTIES AND OBLIGATIONS

8.1 The Supplier warrants that the Goods and the Services and any parts or materials used in the manufacture or performance of any work related to the Goods and/or Services will:

8.1.1 be free from any defects in design, materials, and workmanship ;

8.1.2 be fit for any special purpose required by TEVA as reasonably known by or notified to the Supplier;

8.1.3 be of the highest quality and professional standards and be performed with a degree of high professional skill, sound practices and good judgment normally exercised by recognized professional firms providing goods and/or services of a similar nature;

8.1.4 conform to the Specifications in all respects and, where applicable, to any samples or drawings . In particular, the weights, measures, signs, legends, words, particulars, or descriptions (if any) stamped, printed, or otherwise attached to the Goods or their packaging (including any required country of origin markings) or referring to the Goods will be true and correct and comply with all Applicable Law;

8.1.5 be – in relation to Goods – new and unused;

8.1.6 be – in relation to pharmaceutical goods – not adulterated or misbranded within the meaning of any relevant Applicable Law;

8.1.7 conform to all Applicable Law and standards (including International Standards Organization (ISO) standards as applicable);

8.1.8 be accompanied by all information, warnings, instructions and documentation relevant and appropriate for the use, storage, operation, consumption, transportation and disposal of such Goods and/or Services;

8.1.9 not infringe any third party rights (including intellectual property rights);

8.1.10 conform to the representations and warranties in the Supplier's literature and advertising materials; and

8.1.11 be delivered free of liens and encumbrances, and with clear transfer of title to the Goods.

8.2 The Supplier's warranties as set forth in Section 8.1 and any other warranty of the Supplier under the Contract, under Applicable Law and otherwise (collectively, the "**Supplier's Warranties**") shall apply through and until shelf life expiration or re-test date applicable to

- the Goods/Services, or, if no expiration date is applicable, then for a period of 24 months commencing with the latest of (as applicable to the Goods/Services): (i) the delivery of the Goods to the Delivery Point, (ii) completion of the Services, (iii) final acceptance of the Goods and/or Services by TEVA according to Section 7.2, or (iv) any longer period provided by Applicable Law or in the Contract, including in Section 8.3 below ("**Warranty Period**").
- 8.3 The Warranty Period shall be extended by a period equal to the period that any Goods and/or Services or portions thereof cannot reasonably be used by reason of a breach of the Supplier's Warranties.
- 8.4 Any repaired, corrected, replaced or re-performed Goods and/or Services (as applicable) are subject to a warranty on the same terms as the Supplier's Warranties and to a new Warranty Period.
- 8.5 This Section is without prejudice to any other rights and remedies TEVA may have under the Contract, Applicable Law or otherwise.
- 9. REMEDIES**
- 9.1 If the Goods fail to comply with the Quality Requirements ("**Defective Goods**") within the Warranty Period, TEVA may, without prejudice to any other rights and remedies of TEVA, at its discretion, elect to:
- 9.1.1 refuse to accept the Defective Goods; and/or
- 9.1.2 require the Supplier to repair, correct or replace the Defective Goods at the Supplier's expense, within 14 days of receipt of TEVA's request or any other (longer or shorter) period reasonably specified by TEVA; and/or
- 9.1.3 in case of imminent danger or urgency, carry out (or have carried out by a third party) the repair instead of the Supplier, at the Supplier's sole cost and expense; and/or
- 9.1.4 require the Supplier to reimburse TEVA for all costs and expenses associated with the repair or replacement, including, without limitation, costs for investigation and analysis of the defect, for installation/de-installation, for the use of its own or external personnel, costs for parts, attorneys' fees, accommodation, travel or transportation costs; and/or
- 9.1.5 claim compensation for all costs, expenses, damages and other losses incurred by TEVA due to the Defective Goods.
- 9.2 If the Supplier fails to provide a remedy with respect to the Defective Goods within the period according to Section 9.1.2, or if the Supplier is not able to or rejects the repair or replacement of the Defective Goods, TEVA may, without prejudice to any other rights and remedies of TEVA and in addition to the remedies as set forth in Section 9.1, at its discretion:
- 9.2.1 terminate the Contract and request a refund of the purchase price, if already paid, in which case TEVA shall return the Defective Goods to the Supplier at the Supplier's sole cost and expense; or
- 9.2.2 claim a reduction or refund (as the case may be) of the purchase price in the amount of the reduced value of the Defective Goods; or
- 9.2.3 return the Defective Goods to the Supplier at the Supplier's risk and expense and obtain identical or similar goods from an alternative supplier and claim reimbursement from the Supplier for any additional costs and expenses reasonably incurred by TEVA;
- 9.2.4 carry out the repair instead of the Supplier, or may have it carried out by a third party at the Supplier's sole cost; and
- 9.2.5 claim compensation for all costs, expenses, damages and other losses incurred by TEVA due to the Defective Goods.
- 9.3 If the Services performed fail to comply with the Quality Requirements ("**Defective Services**") within the Warranty Period, TEVA may, without prejudice to any other rights and remedies of TEVA, at its option elect to:
- 9.3.1 require the Supplier to re-perform the Services within any reasonable period specified by TEVA; and/or
- 9.3.2 require the Supplier to provide such additional Services as are necessary to remedy the failure of the Services to comply with the Quality Requirements; and/or
- 9.3.3 require the Supplier to reduce the purchase price for the Services pro-rata based on the amount of the purchase price allocable to the Defective Services; and/or
- 9.3.4 obtain the Services from a third party and require the Supplier to reimburse TEVA for all reasonable costs and expenses incurred by TEVA in connection therewith; and/or
- 9.3.5 terminate the Contract and refuse to accept any further performance of Services under the Contract; and/or
- 9.3.6 claim compensation for all costs, expenses, damages and other losses incurred by TEVA due to the Defective Services.
- 10. LIABILITY, INDEMNIFICATION**
- 10.1 Except for damages caused by (i) TEVA's willful misconduct or gross negligence, (ii) are based on injury to life, body or health, or (iii) result from the breach of essential contractual obligations, i.e. such obligations the fulfilment of which is essential for the proper performance of the contract and on the observance of which the customer regularly relies and may rely, TEVA's aggregate liability for damages arising from or in relation to the Contract, whether in contract, tort or otherwise, is limited to the total amounts paid by TEVA for the Goods and/or the Services under the Contract, and TEVA's liability for indirect, punitive, or consequential damages, which include (without limitation) loss of revenues, profits, anticipated savings and goodwill, howsoever arising, are excluded entirely. In the event of a breach of material contractual obligations, TEVA's liability shall be limited in amount to the damage typical for the contract and foreseeable at the time of conclusion of the contract. The limitations of liability in this clause shall not apply if TEVA has fraudulently concealed a defect, given a guarantee for the quality of the goods or assumed a procurement risk. In addition, any mandatory legal liability, in particular under the Product Liability Act [Produkthaftungsgesetz], shall remain unaffected.
- 10.2 The Supplier shall indemnify and hold harmless TEVA and its affiliates, and its and their employees, officers, directors, agents, advisors, customers, suppliers, consultants, contractors, and successors and assigns against any liability, loss, costs (including legal fees, costs for recalls, and costs for its own employees), damages and injury in consequence of:
- 10.2.1 any Defective Goods or Defective Services;
- 10.2.2 any breach by the Supplier or its suppliers or subcontractors of the Contract (including any late delivery of Goods or failure to complete the Services by the Delivery Date),
- 10.2.3 any negligence, willful default or wrongful act or omission of the Supplier or its suppliers or subcontractors; and
- 10.2.4 an infringement or alleged infringement of any third party right (including intellectual property rights and know-how) made by any person as a result of the manufacture, provision, receipt, importation, export, distribution, offer for sale, sale, use or possession of any Goods and/or Services provided by or on behalf of the Supplier.
- 10.3 In case of Section 10.2.4, the Supplier shall inform TEVA promptly thereof and Supplier shall at its own cost and expense (including any royalty) and at TEVA's option:
- 10.3.1 procure for TEVA an unconditional, irrevocable, perpetual license to use the Goods and/or Services and to exercise its other rights granted with regard to the Goods and/or Services under the Contract; or
- 10.3.2 modify or replace the Goods and/or Services so that they comply with the Quality Requirements and do not infringe any third party rights without impairing in any material respect the functionality or performance of the Goods and/or Services. Any such replacement or modification shall be approved in writing by TEVA in advance (TEVA will not unreasonably withhold the approval).
- 10.4 In the event none of the options specified in Section 10.3 is implemented, TEVA may, at its sole discretion cancel all outstanding

Purchase Orders and Confirmed Purchase Orders for each such Goods and/or Services that is subject to the claim and have any infringing or possibly infringing Goods returned to the Supplier at the Supplier's expense; the Supplier shall repay to TEVA the full price paid by TEVA for any affected Goods and/or Services, plus VAT or other sales taxes (if applicable), that is returned or is, in TEVA's opinion, not useable by TEVA and/or its customer.

- 10.5 TEVA's rights under this Section 10 shall be without prejudice to any other rights and remedies of TEVA.

11. INTELLECTUAL PROPERTY RIGHTS OWNERSHIP

- 11.1 "Intellectual Property Right" ("IPR") means any patent, copyright, database right, design right, registered design, trade mark, service mark, domain name, know-how (including without limitation the Know-How), utility model, unregistered design or, where relevant, any application for such right, or other industrial or intellectual property right. "Know-How" means all technology, data, processes, formulae, information and methods, whether patentable or not, owned or used by the Supplier and incorporated into Goods and/or necessary to obtain and maintain regulatory approvals and/or any other knowledge relating to the manufacture, importation, distribution, marketing and sales of the Goods.

- 11.2 All right, title and interest and/or control in a party's Background IPR shall remain vested in the respective party and nothing in the Contract shall operate to assign any right, title or interest in such Background IPR to the other party (save as otherwise provided below). **Background IPR** means any IPR (as defined above) owned and/or controlled by a party prior to the date of the Purchase Order.

- 11.3 TEVA hereby grants to the Supplier a non-exclusive right to use Background IPR of TEVA solely to the extent necessary or useful, if at all, for Supplier to supply, the Goods or perform the Services, as applicable, and such grant shall terminate upon the earlier of (i) the Supplier satisfying its obligations under the Contract and (ii) termination of the Contract.

- 11.4 Supplier hereby grants to TEVA a royalty free, non-exclusive, worldwide, perpetual and irrevocable (except for breach by TEVA) sub licensable and transferable right and license to use the Supplier's Background IPR:

11.4.1 for use of any Goods and/or Services in a manner that is consistent with TEVA's intended purpose; and/or

11.4.2 to commercially exploit such Goods and/or Services.

- 11.5 All Foreground IPR, whenever created at any stage and in its actual state, shall become the sole and exclusive property of TEVA with the right to use and exploit the Foreground IPR in any desired way and is covered by the payment of the purchase price for the Goods and/or Services. **Foreground IPR** means any IPR, conceived, discovered, created, produced, developed or reduced to practice by the Supplier specifically for TEVA in connection with the Goods and/or Services.

- 11.6 In the event that, for legal reasons, exclusive right, title and interest in and to the Foreground IPR does become vested in TEVA pursuant to the Contract, the Supplier agrees to do, or procure to be done, all such things, and execute, or procure to be executed, all such documents, as TEVA may require to vest in TEVA all Foreground IPR.

- 11.7 If the Foreground IPR consist of copyrights, know-how or other proprietary rights and if for legal reasons TEVA cannot become the owner of such copyrights or other proprietary rights, the Supplier shall irrevocably grant to TEVA and hereby irrevocably grants to TEVA the - with regard to location and time - unrestricted, exclusive, world-wide, royalty free, perpetual, sublicense able, transferable right to use such Foreground IPR in their original or in any modified form and in any known or unknown way in connection with the Goods and/or Services.

12. PHARMACOVIGILANCE

The Supplier undertakes to comply with the Specific Provisions on Pharmacovigilance regulated in Part III.

13. INSURANCE

The Supplier shall arrange and maintain, at its own cost, all insurance customary and on terms common in the industry and not less than \$5M or the equivalent amount in local currency, or other amount as agreed with TEVA, per occurrence and in the annual aggregate per insurance policy, in particular a professional, public, cyber, workman compensation/employer liability and product liability insurances. The Supplier shall produce evidence of such insurance to TEVA upon request and will include TEVA as additional insured for any act and/or omission of the Supplier. Should any required insurance be written on a claims made policy form, the first named insured shall ensure continuity of cover for claims which might be presented following the term of the insurance. The insurance coverage or the failure to maintain insurance shall not waive nor limit in any way the Supplier's responsibility and liability for its Goods delivered and Services performed to TEVA.

14. CONFIDENTIALITY

- 14.1 The Supplier shall keep confidential all information and documents that TEVA makes or has made available to the Supplier, or that it otherwise acquires relating to TEVA's business, or that Supplier creates or produces, or has created or produced, in connection with the supply of the Goods and/or the performance of the Services, provided that the Supplier may disclose such confidential information to its employees and subcontractors (together, "**Supplier's Representatives**") solely on a need to know basis in order for the Supplier to satisfy its obligations under the Contract. The Supplier shall not use or cause to be used such information or documents other than for the purpose of performing its obligations under the Contract. Such confidentiality obligation will continue in force notwithstanding delivery of the Goods, completion of the Services or termination of the Contract, although such provisions do not apply to any information or document in the public domain or coming into the public domain other than through the Supplier's or the Supplier's Representatives violation of its confidentiality obligations.

- 14.2 The Supplier shall not make any reference to the TEVA Group in its advertising, literature or correspondence without TEVA's prior written consent. Nothing in the Contract shall entitle the Supplier to use any name, trademark or logo of the TEVA Group.

- 14.3 In the event that the Parties have concluded or hereafter conclude a separate confidentiality agreement with respect to the subject matter of the Contract, the provisions of this confidentiality agreement shall take precedence over the confidentiality provisions in Sections 13.1 and 13.2.

15. DATA PROTECTION

- 15.1 When the parties process personal data in connection with their management of, or performance of their obligations under, the Contract, they do so as separate controllers. Each party shall comply with all Applicable Law, including, without limitation, applicable data protection regulations. At the reasonable request of a party, the other party shall demonstrate to it that it has complied with its obligations under this clause. In the event that either party reasonably considers that longer form data protection provisions are needed (for example, if the relationship between the parties is no longer that of separate controllers), then the parties agree to negotiate such longer form terms in good faith. For information as to how will process personal data about Supplier's Personnel, as required by Applicable Law, or information about Supplier's rights in regards to personal data, Supplier may reach out to the contact person in TEVA. In the event Personal Data of Supplier's employees is made available to TEVA in the course of fulfilling the Contract, Supplier shall inform its affected employees accordingly and make TEVA's data protection declaration available to them.

16. SPARE PARTS

The Supplier shall, for a period of at least 10 years after discontinuation of the production of each of the Goods, have available compatible spare parts substantially equivalent in terms of function and quality to the parts contained in the Goods, or shall provide equivalent solutions on commercially reasonable terms to TEVA, for repairing or replacing the Good.

17. TOOLS

- 17.1 Any material, software, equipment or tools (i) provided by TEVA to the Supplier or (ii) purchased or manufactured or used by the Sup-

plier in connection with this Contract and paid for by TEVA ("Tools") shall remain or become, as the case may be, the property of TEVA, and may only be used by the Supplier for the sole purpose of performing the Supplier's obligations under the Contract.

17.2 The ownership of all Tools described in (ii) of Section 16.1 above is transferred to TEVA by the Supplier on the date of the acquisition of the Tool by the Supplier, or in the case of Tools manufactured by the Supplier, on the date of the completion of the manufacturing by the Supplier. No further action by any party is required to make such transfer effective.

17.3 The Supplier shall mark all Tools as being TEVA's property. Upon request, the Supplier shall provide reasonable evidence of such marking to TEVA. The Supplier shall, at its own expense, insure the Tools belonging to TEVA at the replacement value on appropriate terms. The Supplier shall carry out timely inspection, servicing, maintenance and repair work at its own expense. Upon request of TEVA, the Supplier shall, at TEVA's option, deliver the Tools to TEVA or provide representatives of TEVA access to the Supplier's premises to permit the removal of the Tools by such representatives.

18. SUBCONTRACTORS

The Supplier shall not engage subcontractors without TEVA's prior written consent. To the extent TEVA consents to the use of a subcontractor, the Supplier shall require the subcontractor to comply with all obligations under this Contract. The Supplier shall at all times remain liable to TEVA for any acts or omissions of any subcontractors to the same extent as if the Supplier were performing such activities.

19. ENVIRONMENTAL, SAFETY AND INDUSTRIAL HYGIENE MATTERS

19.1 With respect to all environmental, safety and industrial hygiene matters related to Supplier's (including Supplier Personnel, as defined in Section 20.1.) activities in providing Goods and/or Services to TEVA, Supplier shall: (a) inform TEVA promptly of any significant adverse event (e.g., fires, explosions, accidental discharges) that have affected or could affect (i) the quality, quantity and delivery/completion schedule of the Goods and/or Services to be delivered/performed and/or (ii) any TEVA facility, property or asset and any individual located at those locations; (b) inform TEVA promptly of any allegations or findings of violations of Applicable Law that have affected or could affect (i) the quality of the Goods and/or Services to be delivered/performed and/or (ii) any TEVA facility, property or asset and any individual located at those locations; and (c) implement promptly any corrective action which may be reasonably requested by TEVA, including, without limitation, adhering to reasonable and significant elements of the environmental, safety and industrial hygiene program adhered to by TEVA in its own operations.

19.2 Supplier shall have and implement a documented, comprehensive health and safety policy which addresses, among other things, elimination of workplace injuries. Supplier shall be responsible for the health and safety of Supplier Personnel, including providing necessary training and other requirements of Applicable Law, while present at a TEVA facility, property or asset. Supplier shall immediately notify TEVA of any health and safety incidents or any non-compliance with health and safety Laws while performing Services at a TEVA facility, property or asset. All Goods and Services shall be subject to environmental, safety and industrial hygiene inspections at all times by TEVA.

19.3 Hazardous materials and substances: Unless otherwise specified in the Contract or agreed in writing by the parties, hazardous materials and substances must be correctly classified and marked by Supplier with international danger pictograms (s) and display the proper shipping name of the material in English and/or any other language which is required by the Applicable Law independently of the mode of transport. Transport and other documents must include a declaration of the hazard and name of the material in English and/or any other language which is required by the applicable laws and rules. Hazardous materials and substances must be accompanied by all mandatory documents such as, but not limited to, emergency information in English and/or any other language, which is required by the Applicable Law in the form of written instructions, labels and markings. The Supplier shall observe

the requirements of International Agreements relating to the packing, labelling and carriage of hazardous materials and substances.

20. TEVA SUPPLIER CODE

20.1 The Supplier represents and warrants that it will:

20.1.1 familiarize itself with the requirements of the Teva Supplier Code of Conduct found at: <http://www.tevapharm.com/?catid=%7B734AE5F2-5FEE-4A5E-9F54-CAE2438818C9%7D>

(the "Teva Supplier Code");

20.1.2 answer any reasonable inquiry regarding the Supplier's compliance with the Teva Supplier Code;

20.1.3 allow reasonable audits during regular business hours to assess the Supplier's compliance with the Teva Supplier Code;

20.1.4 train any representative of the Supplier who is involved with the performance of Services and/or delivery of Goods on Anti-Corruption Laws, and the standards set out in TEVA's Ethical Business Provisions and the Teva Supplier Code;

20.1.5 provide TEVA with prompt written notice of any facts or circumstances (whether occurring prior to or after the date of the Purchase Order) which cause or could cause the Supplier or any of its subcontractors to be in violation of any Anti-Corruption Laws or in non-compliance with TEVA's Ethical Business Provisions or the Teva Supplier Code; and

20.1.6 acknowledge that failure to adhere to these standards might be considered as a material breach of the Contract and thus shall entitle TEVA to terminate the Contract.

21. WORK ON TEVA'S PREMISES

21.1 The Supplier shall be solely responsible for its personnel, including its employees, officers, directors, subcontractors, suppliers, agents, consultants and representatives performing or assigned to perform any activities in connection with the Goods and/or Services (collectively, "Supplier Personnel"), and in particular for obtaining, at its expense, any and all visas, permits or other authorizations required for Supplier Personnel to travel to and work at premises owned or controlled by TEVA ("TEVA Premises").

21.2 Employee Compensation: Supplier represents, warrants and covenants that Supplier is responsible for the payment of compensation to Supplier's Personnel, federal and state income tax withholding, social security taxes, and unemployment insurance applicable to such personnel as employees of Supplier.

21.3 The Supplier shall ensure that no Supplier Personnel, in particular when working on TEVA's premises, is considered to enter into, or be entitled to enter into, an employment relationship with TEVA; and no Supplier Personnel will hold any right, title or interest whatsoever in or to the premises of TEVA. The Supplier shall indemnify TEVA for all related costs, expenses, damages and other losses arising to TEVA from Supplier Personnel working at any TEVA Premises.

21.4 TEVA may refuse to allow any Supplier Personnel to access TEVA Premises at any time, for reasons of security or on any other reasonable grounds. While accessing any TEVA Premises, the Supplier shall ensure that neither it nor any Supplier Personnel unnecessarily interferes with TEVA's business activities.

21.5 While accessing any TEVA Premises, the Supplier shall comply with, and procure that all of Supplier Personnel comply with, Applicable Law, including health and safety legislation, TEVA's health and safety policies, and any instructions provided to the Supplier. While accessing any TEVA Premises, Supplier Personnel shall not engage in an any inappropriate conduct, such as (i) use or possession of alcohol, illegal drugs or any other controlled substance, except for approved medical purposes; (ii) use or possession of a weapon of any sort; (iii) harassment, threats or disorderly, disruptive or violent behavior, or (iv) any other behavior which may reflect adversely on TEVA's business or reputation.

- 21.6 TEVA may require Supplier to conduct one or more criminal or other background checks, drug tests and similar tests of Supplier Personnel, to the extent permitted under Applicable Law.
- 22. TERMINATION**
- 22.1 TEVA may terminate the Contract, without liability to the Supplier and while preserving to itself any accrued rights or remedies, by giving written notice to the Supplier with effect from the date specified in the termination notice, if:
- 22.1.1 the Supplier commits a material breach of any provision of the Contract and, in the case of a breach capable of remedy, fails to remedy the breach within a reasonable time but in no case longer than within 30 days of being notified by TEVA of such breach (the Supplier acknowledges that a series of minor breaches may together constitute a material breach);
- 22.1.2 the Supplier files a petition in bankruptcy or has such a petition filed against it or is subject to an insolvency proceeding or a proceeding giving protection against creditors, or if an order is issued appointing a receiver or trustee or a levy or attachment is made against a substantial portion of its assets, or if any assignment for the benefit of its creditors is made; or
- 22.1.3 the Supplier suspends or ceases, or threatens to suspend or cease, to carry on all or a substantial part of its business.
- 22.2 In the event that any exercise by TEVA of any right to terminate the Contract for cause is found to be a wrongful termination, any notice of termination issued by TEVA will be deemed to be a notice of termination for convenience under Section 22.3.
- 22.3 Termination for convenience
- 22.3.1 TEVA may, at any time and without cause, terminate the Contract in whole or in part by giving the Supplier at least one week written notice whereupon all work on the Contract shall be discontinued and TEVA shall pay to the Supplier for all compensation accruing to the Supplier under the Contract as of the termination date, including, but subject to the remainder of this Section 21, a fair and reasonable compensation for work-in-progress at the time of termination.
- 22.3.2 Such compensation of the Supplier shall not include any indirect, punitive, or consequential damages (including (without limitation) loss of revenues, profits, anticipated savings and goodwill) howsoever arising, and shall not exceed the purchase price paid by TEVA for the Goods and/or Services.
- 22.3.3 If the Supplier claims compensation for work-in-progress as per Section 22.3.1, the Supplier shall provide reasonable evidence to TEVA that such work-in-progress cannot be used by the Supplier in fulfilling the Supplier's obligations under any other contract, or reasonably anticipated contract, issued or to be issued by TEVA or by other customers of the Supplier. TEVA may request that any work-in-progress which is subject to a payment of compensation by TEVA shall be delivered to TEVA in its then current state.
- 22.4 Any rights and obligations that have an effect beyond fulfillment, expiration or termination of the Contract, including the provisions regarding confidential information, insurance, warranty, indemnifications, governing law, payment due and owed, shall survive such fulfillment, expiration or termination.
- 23. GOVERNING LAW, APPLICABLE LAW AND JURISDICTION**
- 23.1 The Contract, and any supply of Goods and/or performance of Services thereunder shall be governed by the laws of the country in which TEVA has its registered office, without regard to principles of conflicts of laws and excluding the application of the UN-Convention on Contracts for the International Sale of Goods ("**Governing Law**"). **Applicable Law** when used in these Conditions, shall mean Governing Law, the laws and regulations in the country of manufacture of Goods or provision of Services and any other laws and regulations applicable under the circumstances.
- 23.2 The Parties shall submit any dispute, controversy or claim arising out of or in connection with the Contract, including any dispute as to the validity of the Contract, exclusively to an appropriate court in the country or jurisdiction in which TEVA has its registered office and at the place of such registered office, save that TEVA may always initiate court action against the Supplier at the court of general jurisdiction at the place of the registered office of the Supplier.
- 24. MISCELLANEOUS**
- 24.1 **Modification.** The Contract may only be amended, modified or supplemented by an instrument in writing signed for and on behalf of each of the parties. Such writing requirement may only be waived through an instrument in writing signed for and on behalf of each of the parties.
- 24.2 **Form.** If the Contract requires a notice or document to be "written", "in writing" or "in written form", such notice or document shall be duly signed by a person or persons duly authorized to legally bind the respective party. Electronic communication shall qualify as a written notice or document, unless otherwise explicitly specified by written agreement or prohibited by the Governing Law.
- 24.3 **Order of contractual components.** In case of contradictions in the Contract, the hierarchy of the parts of the Contract shall, unless expressly agreed otherwise, correspond to the following order priority: first, the Confirmed Purchase Order before these Conditions in the version valid at the conclusion of the Contract.
- 24.4 **Set-Off.** The Supplier may not set-off any claims it may have under the Contract against any other claims TEVA may have against Supplier or refuse to perform any obligation on the grounds that it has a right of retention, unless the rights or claims of the Supplier are not disputed by TEVA or have been confirmed by a final decision of a court of competent jurisdiction.
- 24.5 **Independent Contractor Status.** Supplier is an independent contractor under the Contract, and nothing herein shall be construed to create a partnership, joint venture or agency relationship between Supplier and TEVA. Neither party shall have the authority to enter into agreements of any kind on behalf of the other party and shall have no power or authority to bind or obligate the other party in any manner to any third party. Supplier has the sole right and obligation to supervise, manage, contract, direct, procure, perform or cause to be performed all work to be carried out by Supplier and its personnel hereunder, unless otherwise provided herein.
- 24.6 **Waiver.** No failure or delay on the part of TEVA to exercise any right or remedy under the Contract shall be deemed as a waiver thereof nor shall any single or partial exercise by TEVA of any right or remedy preclude any other or further exercise thereof or the exercise of any other power, right or remedy. No waiver by TEVA of any breach of any of the terms or conditions of the Contract shall be construed as a waiver of any subsequent breach whether of the same or of any other term or condition thereof. No waiver by TEVA is validly made unless made in writing and signed by TEVA.
- 24.7 **Without Prejudice.** The rights and remedies available to TEVA under this Contract are without prejudice to any and all other rights and remedies available to TEVA at law or in equity.
- 24.8 **Assignment.** The Contract is personal to the Supplier and the Supplier shall not, without the prior written consent of TEVA, assign, transfer or sub-contract any rights or obligations under the Contract to any third party. TEVA may at any time assign the Contract or any rights or obligations under the Contract to any affiliate of TEVA or to any third party without the prior written consent of the Supplier.
- 24.9 **Severability.** If any term or provision of the Contract is void or unenforceable, the remainder of the provisions of the Contract shall remain in full force and effect to the fullest extent permitted by Governing Law. In place of the invalid or unenforceable provision, or to fill a contractual lacuna, such valid and enforceable provision shall apply which reflects as closely as possible the commercial intention of the parties as regards the invalid, unenforceable or missing provision.

PART II: SPECIFIC PROVISIONS FOR SOFTWARE

25. APPLICABILITY

- 25.1 The provisions of this Part II apply to the delivery of Software and supplement the provisions of Part I and, if there is an inconsistency, take precedence over the provisions of Part I.
- 25.2 **Software** means any computer program developed and/or licensed by the Supplier, together with any software which has been produced primarily to overcome defects in that program ("**Update**") or software which has been provided primarily to provide an extension, alteration, improvement or additional functionality to that program ("**New Release**"), and in particular Standard Software and Specific Software.
- 25.3 **Standard Software** means the Software (excluding Specific Software) being the Supplier's or a third party's standard Software that is or could be offered by the Supplier or the third party to customers generally. **Specific Software** means Software that has been customized, developed or otherwise created by the Supplier to specific requirements of TEVA, as specified by the Parties in the Contract or elsewhere.

26. STANDARD SOFTWARE

- 26.1 The Supplier shall and hereby grants (or procure the grant) to TEVA a license to use, copy and distribute the Standard Software and any related documentation in the course of its business and the business of any entity of the TEVA Group and for purposes reasonably incidental thereto, on the following terms:
- 26.1.1 non-exclusive, worldwide, irrevocable, sub licensable and transferable; and
- 26.1.2 except for the license fee, royalty-free and fully paid up.
- 26.2 TEVA may make such copies of the Standard Software and related documentation as are reasonably required for operational use, backup and security and in-house educational and training purposes.
- 26.3 TEVA shall be entitled to appoint a third party to run or host the Software for the benefit of TEVA or any entity of the TEVA Group under the terms and conditions of this Section 26.
- 26.4 The license commences on the Delivery Date and shall, as specified by the Parties, either (i) continue in effect for the duration of the license term or (ii) be for perpetual use by TEVA.
- 26.5 Unless the Parties have specified a maximum number of permitted users of the Standard Software, the Standard Software shall be licensed to TEVA on the basis of an enterprise license, i.e. allowing TEVA an unlimited use of the Standard Software through-out its organization.

27. SPECIFIC SOFTWARE

- 27.1 The Supplier will provide TEVA with detailed specifications of the Specific Software. TEVA will review the specifications and, after its review, either approve each of the specifications, if satisfied that each is consistent with TEVA's requirements, or notify the Supplier in writing of its reasons for rejecting any part of the specifications. The Supplier will accommodate any request for alteration reasonably made by TEVA in writing.
- 27.2 The Supplier shall strictly adhere to the agreed timeframes and milestones dates for the Specific Software. Each development stage shall be subject to a successful acceptance testing by TEVA. TEVA may at any time request the Supplier to provide interim reports in writing, stating the present status of development of the Specific Software.
- 27.3 Specific Software shall be delivered by the Supplier in source code and object code form and the Supplier will ensure that both source code and object code form of the Specific Software is written and documented in a way which would enable future modifications by a competent developer without further reference to the Supplier or its personnel.
- 27.4 The intellectual property rights in the Specific Software shall follow Section 11 of Part I. In any event, TEVA shall be granted, at a minimum, the license rights pursuant to Section 26 for Standard Software.

28. DELIVERY, INSTALLATION

- 28.1 Unless otherwise agreed in writing, the Supplier shall deliver to TEVA the Software in its latest release on a magnet medium in machine-readable object-code form, and/or source code form, if licensed, or in any other format as agreed by the Parties, e.g. by download.
- 28.2 If so agreed, the Supplier shall install the Software on the designated equipment on the date or period for the assembling, erection, control and test of the Software or any component thereof as specified by the parties. For the avoidance of doubt, TEVA may, at no additional charge to TEVA and without consent of the Supplier, change the designated equipment, i.e. the hardware configuration, operating system, network structure, or transfer the Software from the designated equipment to any new equipment.

29. UPDATES AND NEW RELEASES

- 29.1 Unless otherwise agreed in writing, the Supplier will offer to TEVA all Updates and New Releases immediately after becoming available.
- 29.2 Unless otherwise agreed in writing between TEVA and Supplier, TEVA may require that the Update or New Release be implemented by the Supplier at no additional charge to TEVA and without increase of the license fee. Notwithstanding the foregoing, TEVA shall not be obligated to accept an Update or New Release, and a refusal by TEVA to acquire an Update or New Release shall not affect its right to receive ongoing support services relating to the Software which are to be performed by the Supplier as specified by the parties and shall not relieve the Supplier from the Quality Requirements.

30. SUPPORT SERVICES

- 30.1 If the parties have agreed on the provision of support services, the support services shall commence on the day following expiry of the Warranty Period, unless otherwise specified by the Parties, and shall continue in effect for the duration of the support term.
- 30.2 The Supplier shall provide the support services in response to a report by TEVA of a suspected malfunction, defect or error in the Software or at such frequency and duration as are reasonably necessary to ensure:
- 30.2.1 malfunction, defects or errors in the Software identified by TEVA or which otherwise come to the attention of the Supplier are rectified; and
- 30.2.2 the Software remains in conformity with the Quality Requirements and continues to comply with the minimum performance level(s) of the Goods and Services to be achieved by the Supplier as specified by the parties ("**Key Performance Indicator(s)**").
- 30.3 The support services include provision of the following services:
- 30.3.1 telephone, remote and online support in the form of consultations, assistance and advice;
- 30.3.2 if such telephone, remote and online support fails to remedy any defect or error notified by TEVA, on-site correction of errors or defects in the Software;
- 30.3.3 such services as the Supplier considers more effectively provided off-site; and
- 30.3.4 training necessitated by such advice or corrections.
- 30.4 Upon receipt of a request for support services, the Supplier shall provide such services within the time within which the Supplier must respond to a request and successfully complete the support services as specified by the parties in writing ("**Support Response Time**" and "**Remedial Time**").
- 30.5 The Supplier shall ensure that Supplier Personnel will use work-around solutions and similar measures to the maximum extent

possible to enable TEVA to continue to use the Software during the performance of any support services.

31. KEY PERFORMANCE INDICATORS

- 31.1 Where the parties have agreed on Key Performance Indicators for the support services (including the Support Response Times and Remedial Times), the Supplier shall provide the support services so as to meet or exceed the Key Performance Indicators, and time shall be of the essence.
- 31.2 Where the Supplier fails to meet any Key Performance Indicator, the Supplier shall:
 - 31.2.1 correct the failure as soon as possible and resume the performance of the support services in accordance with the Key Performance Indicators; and
 - 31.2.2 credit the service credits (if any) or at the request of TEVA pay the service credits (if any) in order to reflect the reduced level of Service provided to TEVA. Where a sum is expressed to be payable as a service credit, the parties agree that (i) such sums are a price adjustment and do not represent an estimate of the loss or damage that may be suffered by TEVA in respect of the breach of the Key Performance Indicators; and (ii) the crediting of such sums is without prejudice to TEVA's other rights and remedies, and such service credits are not to be taken into account for the purposes of any limitation of liability of the Supplier (if any).
- 31.3 Without prejudice to any other rights and remedies available to TEVA, TEVA may terminate the Contract if the Supplier fails to achieve the minimum standard for any specific Key Performance Indicator (i) in two consecutive months or (ii) in three or more months during any 12 month period.

32. TRAINING

If so agreed, the Supplier shall provide TEVA's personnel with such training as TEVA considers necessary or useful to enable operation of the Software in the manner contemplated by the TEVA.

33. WARRANTIES

- 33.1 In addition to any specific warranties, in particular in addition to the Supplier's Warranties, the Supplier represents and warrants it is the owner or authorized distributor of the Software and has the right and authority to grant the license granted under the Contract to TEVA. Without limiting the foregoing, the Supplier represents and warrants that there are no existing restrictions or constraints on its right and authority to supply, install and license the Software.
- 33.2 The Supplier represents and warrants that the Software will (i) be free from viruses, defects and errors and free from any built-in, automatic and/or random expiry dates; (ii) be properly installed; (iii) be compatible with the designated equipment; and (iv) perform in accordance with the Quality Requirements.

34. ESCROW OF SOURCE CODE

- 34.1 Unless it is agreed in writing that the Supplier is not required to deposit the Standard Software into escrow (in which case this entire clause will not apply), the Supplier shall within 14 days upon the written request of TEVA deposit a complete copy of the source code of the Standard Software, together with any additional items agreed by the parties (if any), into escrow with an independent escrow agent and on terms and conditions reasonably acceptable to TEVA.
- 34.2 The escrow agreement shall be in a form approved by TEVA and shall provide for the release of the source code by the escrow agent to TEVA in the event, inter alia, that TEVA has a right to terminate the Contract pursuant to Section 21 of Part I.

PART III: SPECIFIC PROVISIONS ON PHARMACOVIGILANCE

1. SCOPE

1.1 The following specific provisions on pharmacovigilance apply in particular to services in the field of consulting, marketing, market research services, medical information, studies and programs (e.g. Patient Support Program) as well as services in the field of pharmacovigilance, security and postal services. The following provisions are also to be fulfilled by subcontractors.

1.2 The Supplier warrants that to the extent applicable, the relevant provisions and regulations, such as the EFPIA Code of Practice for the Promotion of Medicinal Products, the Code of Conduct of the European Pharmaceutical Market Research Association (EphMRA) and the Good Pharmacovigilance Practice Guidelines of the European Medicines Agency (EMA) shall be complied with.

2. SUPPLIER'S PHARMACOVIGILANCE OBLIGATIONS

2.1 The Supplier acknowledges that TEVA must comply with the strict legal and safety requirements for its products and in particular, fully and promptly comply with all related reporting obligations.

2.2 The Supplier agrees that he shall forward to TEVA information about medical risks and pharmaceutical technical complaints that he receives regarding products of the TEVA Group in connection with the provision of the Services.

2.3 HOW SHOULD BE REPORTED?

In order to enable TEVA to fulfill its regulatory reporting obligations, the Supplier (including any subcontractors) is obliged to record all information received on medical risks or pharmaceutical-technical complaints and to forward it in writing via email to safety.germany@teva.de or complaints@ratiopharm.de within 1 (one) working day (reports on weekends or public holidays, the following working day) after becoming aware of it. The Supplier shall forward all information, including the date of receipt, of the items listed under **What should be reported**, to safety.germany@teva.de without further verification, filtering or preparation (only permitted if a secure/encrypted email transmission, e.g. TLS connection or as a password-protected PDF) is possible. If the Supplier does not receive an acknowledgement of receipt within two working days, the Supplier is obliged to contact TEVA in order to clarify receipt of the notification.

2.4 WHAT SHOULD BE REPORTED?

Any suspected case of a medical risk or a pharmaceutical-technical complaint spontaneously expressed or reported in the course of a study or investigation must be reported to TEVA.

These include in particular:

- **Medical Risks:**

- Adverse events (AEs): any adverse medical event in a patient who has been given a drug, regardless of whether it is causally related to that treatment. In this context, the term AE also covers undesirable effects attributed to the use of cosmetics, medical devices or food supplements.
- Side effects, interactions with other medicines or foods/stimulants
- Overdose/underdose (administration of an amount of a medicinal product per single dose or cumulatively more than the maximum recommended dose/below the minimum recommended dose according to the authorized product information).
- Abuse (persistent or sporadic, deliberate excessive use of medicinal products resulting in harmful physical or psychological effects) or misuse (situations in which the medicinal product is intentionally and improperly used not in accordance with the authorized product information) of medicinal products.

- Medication error related to a product: An unintentional error in the drug treatment process that leads or may result in harm to the patient.

- Habituation to medication and, as a result, possible dependence

- Resistance to antibiotics

- Insufficient or unexpected therapeutic efficacy of medicinal products

- Transmission of infectious particles by a drug

- Reports relating to pregnancy (maternal or paternal exposure) and breastfeeding, with or without Adverse events, where the fetus or infant, respectively, may have been exposed.

- Unintentional exposure to a medicinal product/active substance in the course of professional or non-occupational activity (this does not include exposure to any of the ingredients during the manufacturing process prior to release as a finished product).

- Off-label use: use of the drug outside the indication

- Adverse events related to a quality defect or a counterfeit medicine/product.

- **Pharmaceutical-technical complaint (PTC)**

Any message indicating a possible deviation from the specification. In particular, defects in the quality of a drug/product (i.e. changes or deterioration of physical and/or chemical properties)

- Defects in the containers

- Inadequate labeling (e.g. label)

- Deficiencies in the Summary of Product Characteristics and Package Leaflet

- Counterfeit products and medicines

2.5 MINIMAL CRITERIA

For suspected medical risks, the Supplier shall provide at least the following information:

2.5.1 Patient Identifiers (initials, gender, date of birth and/or age) and the medicinal product/product concerned with product name, dosage form, strength, and batch (possibly also other additional medicines taken).

2.5.2 the medical risk experienced, as detailed as possible.

2.5.3 the details of the medication/non-medicinal product taken (all of the following: product name, active ingredient, dose strengths and batch number)

2.5.4 Reporter identifiers: Name, initials, qualification (e.g. physician, pharmacist, other healthcare professional, lawyer, consumer, or other non-healthcare professional), or address (e.g. reporter's organization, department, street, city, state or province, post-code, country, email, phone number).

Incomplete reports regarding medical risks or pharmaceutical-technical complaints that fulfill not all of the aforementioned minimal criteria must also be forwarded by the Supplier to TEVA.

3. RECONCILIATION

In order to ensure that the data exchange works and that relevant reports have been completely transmitted, the Supplier will provide a listing or screenshots of the case reports sent to TEVA at least quarterly (the exact frequency is to be determined on a project-by-project basis), by e-mail to safety.germany@teva.de. In the case of market research, the market research institute sends a listing of the case reports to safe-

ty.germany@teva.de within two weeks (14 calendar days) after the end of the field work and at least quarterly in the case of long-term projects. If no medical risks or PTCs have been reported, this must also be communicated by e-mail to safety.germany@teva.de. Pharmacovigilance TEVA checks the forwarded data and confirms its correctness or points out any discrepancies.

4. FOLLOW-UP OBLIGATIONS

The Supplier and/ or the subcontractor, at TEVA's request, shall obtain further information on the relevant medical risk or pharmaceutical-technical complaint report and shall forward such information to TEVA. Records of contact attempts must be archived by the Supplier and made available to safety.germany@teva.de upon request.

5. PHARMACOVIGILANCE TRAINING

5.1 For all services related to drugs or diseases and with direct or indirect contact (e.g. social media screening) with patients or healthcare professionals, all employees of the Supplier, as well as the employees of the subcontractor involved in the implementation or analysis of the services in question, must complete the pharmacovigilance training (hereinafter referred to as "Training") before initiating such contacts and repeat it annually.

5.2 The Supplier is responsible for providing sufficient information and training to its employees, as well as subcontractors, to comply with the obligations imposed in the previous paragraphs. Completion of the training must be documented by the Supplier or subcontractor. The training certificates must be forwarded to TEVA (safety.germany@teva.de).

6. INSPECTIONS AND AUDITS

6.1 In the event of inspections and audits of an affiliate of the TEVA Group, the Supplier will immediately assist TEVA with regard to project-related document requirements and queries. In the event that an inspection of the supplier is required by an authority, the Supplier agrees to undergo this inspection with TEVA's assistance.

6.2 Within the framework of the cooperation and for a period of two (2) years thereafter, TEVA may audit the Supplier within normal business hours with regard to compliance with pharmacovigilance obligations, subject to appropriate prior notice.

7. ARCHIVING AND RETENTION REQUIREMENTS

7.1 The Supplier will comply with all archiving and retention requirements in accordance with accepted industry standards and applicable law. With regard to data retention, the Supplier applies its internal processes and systems.

7.2 As soon as the reconciliation has been successfully completed and the complete information and documents received (e.g. report forms, physician's letters, other written notes, photos, etc.) have been forwarded to TEVA Pharmacovigilance, there are no further archiving and storage obligations for the Supplier.

7.3 The completion of training courses must be documented and archived at the Supplier's premises. The copy or scan of the training certificate must be forwarded to TEVA.

8. OBLIGATIONS UNDER DATA PROTECTION LAW

To the extent that the report of a medical risk contains personal data, the Supplier will comply with the relevant legal provisions, in particular the General Data Protection Regulation (GDPR), with regard to personal data in connection with a report on a medical risk. Such personal data will be collected, stored, processed and used by the Supplier if, to the extent and for as long as this is necessary for compliance with the reporting obligation under this Agreement. Further processing of this personal data will only take place to the extent that this is expressly required or permitted by law. The Supplier's compliance with the legal provisions requires, in particular, that the persons authorized to process the personal data have committed themselves to confidentiality with the Supplier, that the Supplier takes all technical and organizational measures required in accordance with Article 32 of the GDPR in relation to such data, and that the Supplier, after completion of the provision of the processing services, discloses all personal data at the Controller's discretion either erases or returns, unless there is an obligation under Union or Member State law to retain the personal data.

9. PROJECTS IN DIGITAL MEDIA

9.1 In the case of projects in which the Supplier analyses, manages or checks websites or social media channels/accounts, or in which social media campaigns are carried out by TEVA, the Supplier is obliged to check all incoming information on a working day and to ensure that identified medical risks and pharmaceutical-technical complaints are forwarded to TEVA (safety.germany@teva.de) within one working day. Before forwarding the information/medical risk or pharmaceutical-technical complaint, the Supplier checks whether contact details of the reporting party (e.g. user data of the social media channels, participants in social media campaigns (e-mail address/direct message via social media platform)) are available and informs safety.germany@teva.de whether contact options exist. This also applies if potential medical risks or pharmaceutical-technical complaints are identified by other means, e.g. via the account on the platform/website from which a message can be sent, again the Supplier must attempt to contact the reporter.

9.2 Follow-Up Obligations in Digital Media Projects:

The regulations under point 3 FOLLOW-UP OBLIGATIONS are to be applied to projects in social media.

9.3 Reconciliation In Digital Media Projects

For projects in digital media, the regulations under point 2 Reconciliation are to be applied.

9.4 Data Privacy in Digital Media in Digital Media Projects

For projects in which the Supplier analyses, manages or checks platforms/websites or social media channels/accounts, the Supplier undertakes to place the following notice on the platforms/websites or social media channels/accounts regarding side effects:

For reasons of patient safety, the companies of the TEVA Group with registered office in Germany have the legal obligation to collect information in connection with a side effect that you provide to us, for example, in the context of your interaction (e.g. comment, contact form or direct message) in relation to the post (post). This information may be shared with other companies of the TEVA Group and contractual partners as well as national and European authorities for the purpose of evaluation and comparison with other adverse reaction reports recorded for this product (including in connection with quality complaints) in order to assess the benefit-risk ratio of the product used and, if necessary, to update the Summary of Product Characteristics.

Should TEVA's Pharmacovigilance require more information about any adverse events/quality complaints/use during pregnancy, we would contact you again to request it, subject to your consent, without disclosing your personal information to TEVA. The manufacturer will use this information solely for the purpose of following up and assessing any adverse reactions or events reported. Please be assured that you will not be mentioned by name in this report.

The data you provide will be treated confidentially in accordance with applicable data protection law and the TEVA Data Protection Directive and may also be processed and stored outside the EU on the basis of a legally approved transfer mechanism. In doing so, TEVA takes measures to ensure the security of personal data. Your personal information will be passed in a pseudonymized form, so that it cannot be easily traced back to you. Please notify us if you do not agree to the use of your data and wish to object to its further processing or if you wish to access your personal data.

You can find more detailed information on data protection for side effect reports at the following link: <https://www.ratiopharm.de/nebenwirkungsanzeigen/>. If you do not report about yourself, please ensure that the person concerned is aware of your report and the possible transfer of their personal data.

If you have any questions or concerns about pharmacovigilance, you are welcome to contact Pharmacovigilance TEVA at any time via the e-mail address safety.germany@teva.de. Everything necessary will be done to answer your questions promptly or to solve your problem.