

ARTICLE 1 - Application of General Terms and Conditions of Purchase

These General Terms and Conditions of Purchase apply to any relationship with any supplier or service provider (hereinafter called the Supplier) and the company issuing the purchase order shown on the opposite page (hereinafter called Opella Healthcare Egypt) except when overridden by other provisions.

The Supplier's acceptance of the purchase order means that it agrees to these General Terms and Conditions of Purchase.

Should these General Terms and Conditions of Purchase contradict the Supplementary Conditions which appear on the reverse side of the purchase order, the Supplementary Conditions shall take precedence.

If the purchase order was issued to perform under a contract, the contract's provisions shall take precedence in case of a contradiction with these General Terms and Conditions of Purchase.

ARTICLE 2 - Acceptance - Modification of the Order

The Supplier must acknowledge receipt of the order within a maximum of eight (8) calendar days after receiving the order "for unqualified acceptance".

Any modification, addition or substitution that could be made to the terms and conditions of the order may only be deemed to be approved by Opella Healthcare Egypt when both parties have agreed to it in writing.

ARTICLE 3 - Billing and Payment Terms

Prices are inclusive of tax if delivered to Opella Site; in case it is with a different incoterm i.e. CIF or CIP or Exwork then it will be excluding Tax; Prices mentioned in the Purchase Order are contracted prices and may not be revised.

The Supplier's invoices to Opella Healthcare Egypt must be made out to Opella Healthcare Egypt who placed the order and sent to the address which appears on the purchase order.

All invoices shall be drawn up in accordance with article L 441-3 of the French Commercial Code in two copies, and shall bear the order's reference number. It is essential that separate invoices be drawn up for each order when several orders are delivered together.

Each and every invoice must show the amount of taxes that are recoverable or non-recoverable. When a purchase is made within the European Community, the invoice must show the VAT identification number for both the Supplier and Opella Healthcare Egypt. Any incomplete or erroneous invoice will be returned to the Supplier.

Opella Healthcare Egypt shall pay the Supplier by electronic funds transfer sixty (60) days following the invoice date. This deadline does not negate the thirty (30) day deadline that applies to the transport sector. Should payment not be received by the required deadline, a late penalty rate equal to three times the legal interest rate shall be applied.

Generally speaking, Opella Healthcare Egypt does not make any down payment to the Supplier. However, in the case where down payments are granted, the Supplier must provide a deposit refund bank guarantee.

When payment is made in instalments, the Supplier will require a holdback of at least 5% of the pre-tax invoice amount. This holdback shall be paid twelve (12) months following the final acceptance of the Goods/Services or of the service.

However, this holdback may be paid to the Supplier in exchange for a holdback bank guarantee equal to the holdback amount and issued by a world-class banking institution. This bank guarantee shall be releasable twelve (12) months from the time the Goods/Services or service is finally accepted.

ARTICLE 4 - Delay - Penalties

Opella Healthcare Egypt must notify the Supplier in writing at the address shown on the purchase order of any delay that occurs while filling the order, no matter what the cause. Opella Healthcare Egypt reserves the right to cancel the order should the Supplier fail to deliver the Goods/Services or perform the service on the delivery date.

Should there be a delay in delivering the Goods/Services or in performing the service and, unless the Supplementary Conditions stipulate otherwise, Opella Healthcare Egypt shall bill the Supplier for penalties of two (2) percent for each week of delay, computed on the total pre-tax amount of the order and capped at ten (10) percent of this amount.

These penalties shall be paid by offsetting against the amount of the Supplier's invoices.

In addition, when there is a partial payment, Opella Healthcare Egypt reserves the right to cancel the order while withholding the Goods/Services already delivered or the portion of the service already performed against payment of the portion of the corresponding price.

ARTICLE 5 - INCOTERM

All orders must specify the Incoterm used. Failing this, the delivery shall be deemed to be "Delivered Duty Paid" to the agreed destination (Incoterm ICC, 2000).

ARTICLE 6 - Delivery - Transfer of Ownership and Risk

The Supplier shall deliver within the deadlines and to the address shown on the purchase order. Failing this, Opella Healthcare Egypt reserves the right to refuse the Goods/Services or the service.

The Goods/Services must be sent with sufficient protection under current norms and practices. The Supplier shall draw up the various documents necessary, particularly for clearing export customs, and include them with the shipment.

Notwithstanding the provisions of the Incoterm used, ownership is transferred to the extent the order is filled while risk is transferred once the Goods/Services or the service is finally accepted.

ARTICLE 7 - Transport Insurance

At the time of shipment, the Supplier shall take out insurance sufficient to cover the value of the order at its own expense unless the Incoterm provides otherwise pursuant to article 5 above.

ARTICLE 8 - Receiving and Accepting Supplies - Surpluses

Opella Healthcare Egypt will issue a provisional and/or a final acceptance upon any delivery of supplies or provision of services. In the event of a final acceptance, the provisional acceptance, which verifies that the order has been correctly filled, marks the starting point of the contractual warranty period. The final acceptance presumes that the exceptions have been closed out.

Any surplus over the quantities stated on the purchase order and delivered to Opella Healthcare Egypt shall be held at the Supplier's expense and liability for a period not to exceed ten (10) days starting from the delivery date. If, at the end of this period, the Supplier has not taken back the aforesaid supplies or sent instructions for shipment at its expense, Opella Healthcare Egypt shall return the aforesaid supply to the Supplier at the latter's expense and liability.

ARTICLE 9 - Warranties

The Supplier warrants the reliable performance and proper functioning of the supplies for a period of twelve (12) months from the time of acceptance and for a period of six (6) months in the case of computer applications (software, etc.) unless otherwise specified in the Supplementary Conditions. The Supplier shall provide any and all spare parts needed for reliable performance and proper functioning for a period of ten (10) years after delivery. The price of these parts may not exceed their market price.

The Supplier guarantees to Opella Healthcare Egypt that it will register chemical substances under the terms stipulated by the REACH Regulation no. 1907/2006/EC dated 18 December 2006. The Supplier must submit proof of this registration to Opella Healthcare Egypt together with the documentation stipulated by the REACH Regulation.

The Supplier is aware of Opella group's commitment, through its accession to the United Nations Global Compact, to support and apply the fundamental principles in the area of human rights, working conditions, the environment and the fight against corruption. It is committed to act likewise in its relationship with Opella Healthcare Egypt with respect to this order.

ARTICLE 10 - Applicable Rules in the Event of Intervention on Opella Healthcare Egypt's Premises

When the Supplier's personnel intervene on Opella Healthcare Egypt's premises, the Supplier is bound to apply all of the rules and regulations that apply to the premises in which it is operating to its own personnel, for whom it remains responsible.

ARTICLE 11 - Illegal Employment Practices

The Supplier must satisfy its obligations under the Egyptian Labour Code relating to manpower movements, illegal employment and the employment of foreign workers. Consequently, the Supplier is bound to submit to Opella Healthcare Egypt, together with its acknowledgment of receipt of the order, and every six (6) months until its expiry: 1) the documents and certifications which establish, under the terms of the Egyptian Labour Code, that it satisfies all of the legislative and regulatory provisions relating to the fight against illegal employment; and 2) a sworn certificate stating, as provided under the Egyptian Labour Code, whether or not it intends to employ foreign nationals to perform the services and, if so, certifying that these employees are or are not authorized to work in France. The Supplier is expressly bound to satisfy the aforementioned legislative and regulatory provisions for the entire term of the order.

ARTICLE 12 - Liability

The Supplier shall respond to any direct and/or indirect damages caused to Opella Healthcare Egypt owing to the Supplier's negligence in filling the order. At Opella Healthcare Egypt's first request, the Supplier is bound to send a certificate of insurance to Opella Healthcare Egypt stating the amounts of its civil liability coverage and proof that the corresponding insurance premiums have been paid. Additionally, the Supplier shall inform Opella Healthcare Egypt of any modification that may occur to the content thereof, and also in the event of any suspension or cessation of guarantees.

ARTICLE 13 - Termination

This order may be terminated at any time by either party, should the other party fail to perform any one of its obligations, fifteen (15) days after a demand of performance sent by the injured party by registered mail with acknowledgement of receipt to the defaulting party remains without effect. This does not prevent the injured party from claiming money damages of the defaulting party for any possible harm that it may have suffered. This order may be terminated immediately and without advance notice by a simple registered letter with acknowledgement of receipt in the event of a breach of the last two sections of article 9, of a proven or repeated delay, transfer or sub-contracting of all or part of this order without Opella Healthcare Egypt's previous written permission. It may also be terminated in the event of the breach of safety precautions and of the in-house rules at Opella Healthcare Egypt's premises in which the order may be filled, or in the event of the Supplier's court-ordered restructuring owing to bankruptcy in accordance with the French Commercial Code.

ARTICLE 14 - Repudiation

Should the Supplier breach any one of its obligations, Opella Healthcare Egypt may repudiate this order at any time fifteen (15) days after a demand of performance sent by Opella Healthcare Egypt to the Supplier by registered letter with acknowledgement of receipt remains without effect. As a result, the Supplier shall refund to Opella Healthcare Egypt all of the amounts of money received under this order on the repudiation date without prejudice to any money damages which might be claimed of it.

ARTICLE 15 - Confidentiality

The Supplier is bound to hold confidential and not to divulge any technical, commercial or scientific information relating to the order and to Opella Healthcare Egypt's activity which it may become partial to while filling the order. The Supplier must never, without Opella Healthcare Egypt's written agreement, state Opella Healthcare Egypt's name in its lists of references, nor publish technical notes, photos and images pertaining to the merchandise and services covered by the order.

ARTICLE 16 - Force Majeure

When the Supplier intends to rely on a case of force majeure, it must notify Opella Healthcare Egypt immediately in writing of all the factors justifying the unforeseeable, insurmountable and extraneous nature of the event which makes it impossible for it to honor its commitments and the consequences it expects were it to fill the order. Opella Healthcare Egypt reserves the right to then take all measures that it deems useful to protect its interests. A company strike does not constitute a case of force majeure in the meaning of this article.

ARTICLE 17 - Intellectual Property

The Supplier transfers all of the rights to use, operate, reproduce, represent and adapt all of the supplies listed in the order and documents drawn up to fill this order with all of the related guarantees in law or in fact. This transfer, which applies to all countries, will be operable for the entire term these rights are protected as set forth under current law, particularly the Intellectual Property Code. By the terms of this transfer, the Supplier acknowledges that it no longer has any property right on any and all of the documents drawn up while filling this order. The cost of transferring all of the aforesaid rights is included in the amount appearing on the reverse side of the order. It is definitive. The provisions of this article shall remain in force after this order expires for any reason whatsoever. The Supplier guarantees the quiet enjoyment of the rights transferred to Opella Healthcare Egypt. To this end, the Supplier shall be bound to compensate Opella Healthcare Egypt for all of the expenses and money damages incurred owing to a sentence on this account, including attorneys' and advisors' fees, expenses, fringe expenses plus money damages relating to any eventual operating loss.

ARTICLE 18 - Provisions Relating to the Order

The merchandise and/or services are defined by all of the documents that make up the order, i.e. a letter of purchase, a specifications sheet, technical specifications, etc. These merchandise and/or services must be delivered as stipulated in the order, according to good trade practice and current regulations. The plans and documents which the Supplier must submit form an integral part of the order. Hence, they may be freely used by Opella Healthcare Egypt.

ARTICLE 19 - Sub-contracting -Transfer

The Supplier may neither transfer nor sub-contract, in whole or in part, the rights and obligations of this order without Opella Healthcare Egypt's previous permission in writing. Opella Healthcare Egypt may freely transfer the rights and obligations of this order to any affiliated company. An affiliated company is understood to be any company controlled by Opella Healthcare Egypt, controlling it, or subject to the same control as the latter either directly or indirectly in all cases. For the purposes of this definition, "control" means the holding (directly or indirectly through an affiliate) of over 50% of the share capital or voting rights of the company in question. The affiliate's status is determined at the date on which this definition must be used.

ARTICLE 20 - Applicable Law and Competent Jurisdiction

This order is governed by Egyptian law. Any dispute between Opella Healthcare Egypt and the Supplier which cannot be resolved out of court shall be the exclusive competence of the Commercial Court of Cairo.

ARTICLE 21 - United Nations Convention on Contracts for the International Sale of Goods

The United Nations Convention on Contracts for the International Sale of Goods signed in Vienna on 11 April 1980 does not apply to this order. However the Sale of Goods Act and Supply of Goods and Services Act in the UK applies to this Purchase Order.

ARTICLE 22 - Pharmacovigilance requirements

Service Providers who perform Good Practices or Health Regulated Activities on behalf of Opella must comply with International and Local Regulatory Requirements and Opella Global Quality Documents: Appropriate pharmacovigilance system must be in place in order to comply with the safety reporting obligations as provided in the Applicable Regulations. The Service Providers shall ensure that all relevant members of their staff performing tasks for Opella are adequately trained on the processes relating to their responsibilities in pharmacovigilance. A copy of the training documentation can be provided upon request from Opella. Basic pharmacovigilance training is mandatory for all staff upon joining the company and annually thereafter. If during the agreed fieldwork timelines, the service provider becomes aware of any PV Data it shall report this to Opella Pharmacovigilance Department ("Opella PV") within one (1) business day from the date of the service provider becoming aware of such PV Data to Pharmacovigilance.eg@sanofi.com. The service provider agrees to inform OPELLA promptly of any Emerging Safety Issue (i.e. leading to changes in the known risk-benefit balance of the Product(s) and / or impact on public health), regulatory inquiries or regulatory action, alert or crisis linked to the safety of the Product(s) and to collaborate with OPELLA to manage the situation and to protect public health.

ARTICLE 23 - Quality Article

Service Provider who perform Good Practices or Health Regulated Activities on behalf of Opella must comply with International and Local Regulatory Requirements and Opella Global Quality Documents :

Quality Management System must be in place , all the members of the personnel must receive an initial training for the assigned jobs and should follow strictly the Data Integrity Rules in data handling in order to avoid any Data Integrity Breach. The computerized systems must be validated, protected from any intrusion or deterioration. The data must be backed up and of measurements of replacement in the event of breakdown must be envisaged.

The complaints on the quality of Opella products must be recorded and transmitted to Opella within 24 hours to the following Contacts : Country Quality , e-mail Address : EG.Quality@sanofi.com. Opella shall be entitled to perform a Quality Audit at Service Provider premises and in case of critical audit findings and/or other findings , they must be promptly documented in a corrective& preventive action by Service Provider and communicated to Opella for approval & follow up .

Service Provider must notify Opella of all Regulatory Inspection with potential impact on the contracted Good Practices and/or Health Regulated Activities and all relevant Findings or Regulatory Actions in a timely manner & must notify Opella immediately and without delay about any Quality or Product Events and/or Alerts related to Opella or any of its products that may come to be aware of , and must cooperate with Opella in their management e.g. recalls .