

**ARTICLE 1 - SCOPE**

These General Conditions of Purchase (hereinafter "GCP") apply to all orders placed by ELANCO FRANCE SAS hereinafter "ELANCO"), as well as to any amendments relating to such orders, according to the following modalities: (a) In the absence of General Conditions of Sale of the supplier (hereinafter the "Supplier"), the acceptance of the order imply full acceptance of these GCP; (b) in case the Supplier has General Conditions of Sale: (i) If after negotiation with ELANCO, the Supplier accepts, without reservations, by signing the Acceptance form, the application of the GCP, the Supplier will be deemed to have accepted the application of the GCP over its General Conditions of Sale in case of contradiction with the latter; (ii) If after negotiation, the Parties decide to amend certain provisions of the GCP on the basis of the Supplier's General Conditions of Sale (basis of their negotiation), such amendments shall be formalized by the signature of Special Conditions of Purchase between the Parties. In this case, the provisions contained in the Special Conditions of Purchase shall prevail over the provisions contained in the CGP where there is contradiction with the latter.

ELANCO reserves the right to modify the content of the GCP at any time, and shall notify the Supplier the amendments made by email or by any other suitable means. Where there is substantial modification of the signed GCP, a new Acceptance form shall be provided to the Supplier for signature. In case the Supplier refuses to apply the new version of the GCP, the business relationship between the Parties will be terminated of right without the requirement of any additional formality, subject to compliance with sufficient notice under the provisions of article L 442-6 5° of the French Commercial Code. The Parties agree that any order already in progress on the date of the notification of the modifications of the GCP by ELANCO, will be completed according to the GCP in force on the day the order was issued.

**ARTICLE 2 - ACCEPTANCE OF THE GCP AND ORDERS**

The Supplier shall prepare its offer in the form of a quote in accordance with the "call for tenders", "brief", "technical specifications" (collectively "Request for Quotation") communicated by ELANCO prior to the order. The Supplier's offer shall take into consideration all legal, administrative and technical constraint due to the execution of the order and, where necessary, or due to the facilities where the goods will be installed and/or the services performed. The offer shall include all the necessary supplies.

The issuance of an order by ELANCO shall be interpreted as an acceptance of the offer. Only an order may be deemed as binding between the Parties. Any reservation expressed by the Supplier after the order shall only be binding after ELANCO's acceptance and the placement of a new Order.

In certain cases, a budget allowance will be estimated as an indication for the set of supplies that ELANCO may entrust to the Supplier over a reference period of time. It is specified that an "open" order does not bind ELANCO with respect to the amount indicated in the order. Where ELANCO issues an open order, only delivery calls issued by ELANCO shall be interpreted as being an agreement to contract with the Supplier. Any open order issued by ELANCO shall be accepted by the Supplier in order to bind the latter. In the case where the Supplier does not confirm the order, or express no rejection regarding the conditions of the order within seventy-two (72) hours of the issuance of the order, the order shall be deemed accepted and binding on the Supplier.

**ARTICLE 3 - PRICING**

Unless otherwise provided for between the Parties, the price contained in the order, set in accordance with the quote or the negotiated fees, shall be firm and nonrevisable. The price includes the transfer of intellectual property rights to ELANCO under Article 10 and 11 hereinafter. The Supplier shall be deemed to have a perfect knowledge of the documents and information necessary to assess the scope of the commitments it has undertaken, of the site, season and dates of its intervention. The Supplier may not claim for any additional expenses, reimbursement or allowances to the price or the fee negotiated in the quote.

Subject to the proper execution of the order, and unless otherwise provided for by the regulations or expressly agreed between the Parties, the price shall be payable within sixty (60) days date of the invoicing.

Unless otherwise provided for, no deposit shall be paid upon order placement. Any unjustified late payment by ELANCO shall give rise to the payment of penalties to the amount equal to three times the French legal interest rate on the date on which the amount falls due. This penalty shall accrue following the due date until the date of actual payment. Furthermore, ELANCO shall also owe to the Supplier a lump sum of forty (40) euros in recovery cost.

Where a guarantee deduction is stipulated in the order, it shall only be released after the completion by the Supplier of any reservation issued by ELANCO.

Invoices and delivery receipt issued by the Supplier shall include all statutory compulsory mentions and shall indicate the number of the order previously notified by ELANCO, and where applicable, the EU customs codes related to the delivered products, the mode of transport and the destination of the goods. Invoices shall be sent to Service Comptabilité Fournisseurs, ELANCO FRANCE; SAS, Crisco Uno, Bâtiment C, 3-5 avenue de la Cristallerie, CS 80022 - 92317 Sèvres CEDEX.

**ARTICLE 4 - SUPPLIER'S OBLIGATIONS**

4.1. Compliance of the goods or services: The Supplier shall deliver the goods and/or perform the services in compliance with the professional standards and

practices, with the most suitable methods and means in accordance with the contractual documents. The goods and/or services shall be delivered in full state of completion, with all the documentation required for their proper use and maintenance as well as any instructions and recommendations needed to be used properly in appropriate safety conditions. The goods delivered and/or services provided by the Supplier shall (i) be fit for purpose; (ii) comply with the usual quality criteria; (iii) perform quantitatively and qualitatively as per the contractual documents or, where there are no contractual specifications, perform as ELANCO is entitled to expect from goods and/or services of the same type; and (iv) shall comply with the national and/or European regulations in force. Any goods and/or services that do not fulfil such requirements shall be deemed non-compliant.

4.2. Deadlines: The order shall specify the deadlines at which the Supplier shall deliver the goods or is expected to have reached an identified situation in the performances of the services. In case of delay with respect to the contractual deadlines, except where such delay is exclusively attributable to ELANCO, the Supplier shall be liable for delay penalties without the need for ELANCO to send prior formal notice. Save as otherwise provided, the amount of such penalties for delays will be equal to 2% of the total amount of the order per week of delay, without prejudice to any damages that ELANCO may claim in addition.

4.3. Information: Given its field of expertise the Supplier is required with regard to ELANCO to a duty to provide advice and information, including in the case where ELANCO imposes certain types of materials, brands or suppliers. It shall check the indications on all the documents that are disclosed to it, and highlight in writing any anomalies, non-compliance and other issues that may appear. Furthermore, if necessary, it shall make any appropriate proposals to achieve the best possible results.

4.4. On-site Intervention: In case where the Supplier is operating on a ELANCO site, it shall take on all the obligations assigned to it under Decree No 92-158 of 20 February 1992. Pursuant to the Decree and where required under the provisions of the Decree, the Parties undertake to establish a prevention plan and to comply with it in every respect. The Supplier's personnel working on site shall comply with occupational health, environmental and safety regulations contained in the internal regulations of the relevant site.

4.5. Specific Environmental Provisions: Where the supply of the goods and/or services is assumed to have an impact on the environment, a list shall be drawn up of specific environmental impacts that may result from the Supplier's activities in normal or accidental circumstances; to each of these impacts will be given a preventive measure. The Supplier shall train its personnel in such environmental risks and may be required to provide evidence of such training. Finally, the Supplier undertakes to comply with ELANCO's regulations in particular those relating to the management of any type of waste that it may generate, as well as noise-abatement requirements. Transport vehicles, maintenance material and heavy equipment used within the site which may constitute an annoyance to the neighbourhood, shall comply with the regulations.

4.6. Compliance with social regulations and the fight against illicit work: the Supplier shall comply with the labour law provisions in general and in particular with the regulations in force repressing concealed work. It shall provide ELANCO at the latter's request, with any records that may demonstrate that it has complied with its obligations with respect to the Labour Code. Similarly, the Supplier declares that it complies with the current temporary employment legislation, with the prohibition relating to illicit supply of workers and ensures that it adapts its practices to regulatory changes. The Parties expressly agree that the Supplier's personnel and/or sub-contractors shall be under the Supplier's sole authority without any subordination in respect of ELANCO.

4.7. REACH: In accordance with European Directive REACH N. 1907/2006, chemical co-formulations and substances used in phytosanitary products shall be pre-registered and subjected to a registration process by the manufacturer or importer into the territory of the European Union. The Supplier undertakes to comply with this regulation.

Social and Ethical Standards: The Supplier is expected to organize its business with ELANCO in line with Elanco's applicable policies found at <https://www.elanco.com/suppliers>. ELANCO shall have the right to audit the sustainability performance of the supplier, either by assessment (online, paper questionnaire, etc.) or by an onsite audit, executed directly by ELANCO or by a third party. The sustainability performance will be evaluated by comparing it with the ELANCO's applicable principles.

**ARTICLE 5 - ELANCO'S OBLIGATIONS**

Provided that the object of the order complies with the contractual specifications and that the goods and/or services are compliant pursuant to article 4.1 above, ELANCO shall proceed to the reception of the goods and/or services and pay the price in accordance with Article 3. Except as otherwise provided for by ELANCO in the back of the order, for supplied goods, ELANCO will proceed to the reception within eight (8) working days after their arrival at the receiving facility and, for services, upon their satisfactory and full performance by the Supplier. However, where the goods and/or services require the setting up of testing after their completion and/or delivery at ELANCO, the reception shall be performed within eight (8) days from the performance of such tests aimed to prove the compliance of such goods and/or services.

Where the reception of the goods and/or services is issued with reservations, ELANCO shall inform the Supplier as soon as possible. The Supplier and ELANCO shall then agree on an action plan to remedy, at the Supplier's expense, any disorder detected, associated with a deadline for corrective actions that may not, in any case, exceed one (1) month. If after expiry of the deadline, the reservations have not been lifted, or if the Supplier, after being duly summoned, were not present during the reception operations, the disorders being, in that case, deemed to be jointly detected, ELANCO may, without prejudice to any claims for damages, execute, by right, or have executed by a third party, the necessary purchases and services, at the Supplier's expense, upon presentation of the relevant evidence.

#### **ARTICLE 6 - SHIPMENT OF GOODS**

In case where the shipment method is not imposed by ELANCO, the shipment shall be performed in its best interests. The use by the Supplier of refrigerated vehicles or vehicles at a set temperature is not allowed unless otherwise provided for on the back of the order. For railway transport, the Supplier shall obtain the lowest rate. In the event of non-compliance with this clause, it will support any overpayment resulting from the rate difference charged by the railway company. Where the shipment is by truck, by post or by postal package, the Supplier shall insure, send by certified letter and/or send the goods with a declared value where such value is higher than the maximum compensation granted by the carrier or the postal company in case of loss or damage. Package labels shall display ELANCO's order references.

For each delivery, the Supplier shall send without delay to the receiving facility a WAY BILL recalling ELANCO's order references, the date and method of shipment, the number and description of packages, their brands, the detailed contents of each package, the gross and net weight and, where applicable, the number of carriages. For chemicals, the Supplier shall attach the analysis certificates of the products. Furthermore, the Supplier shall ensure that the goods are accompanied by the corresponding Material Safety Data Sheet (MSDS), prepared in both French and English. The Supplier shall be under this obligation for the first delivery of the goods, and subsequently for each review of the MSDS.

Any disbursements made by ELANCO at the time of the arrival of the goods shall be withheld from the Supplier who redirected them, ELANCO payments being made upon the receipt of an invoice from the Supplier which shall be first accepted.

#### **ARTICLE 7 - LIABILITY-WARRANTY**

The Supplier is liable to ELANCO and where applicable, to third parties, for any material, personal or moral damages, to the goods and persons, that is caused by the Supplier itself or by any third party acting on its behalf, that may have occurred during the execution of the order or that may result from any non-performance or incorrect execution of the order, in particular related to defects in the design, compliance, manufacture, operation or performance of the goods and/or services and of any apparent or hidden defects. Damages may occur both, during the performance the order or after performing the order as a direct and/or indirect consequence of those obligations.

Any assistance that ELANCO may provide to the Supplier in the manufacture of the goods and/or performance of the services, and any monitoring that ELANCO may carry out at its discretion, may not be deemed as an acceptance of the quality of the Supplier's goods and/or services. The Supplier shall remain solely liable for such goods and/or services, in the understanding that the reception by ELANCO does not exempt the Supplier from its contractual liability.

Where non-compliant goods have been used by ELANCO in the manufacture of finished products, the Supplier undertakes to communicate as soon as possible to ELANCO all relevant information necessary for ELANCO to identify and trace the noncompliant goods, and this in order to allow ELANCO to implement any actions that it deems necessary.

The Supplier grants ELANCO a warranty that covers, free of any cost and of any additional expenses whatsoever, the repair of the goods or correction of the services, in order to ensure their proper operation and to achieve the performance as defined in the Request for Quotation. This warranty will be due for a minimum of one (1) year and it will enter into force on the date of reception without reservations, unless otherwise provided for in the order. Unless otherwise specified in the order, the replacement of a defective component within the warranty period launches a new warranty period that shall be equivalent to the duration of the interruption in the use caused by the defect. However, when the replacement for defect does not relate to a component of a good but to the entire system, requiring its entire replacement, a new warranty period of a minimum of one year shall be granted upon reception, without reservations, of the new supply.

#### **ARTICLE 8 - INSURANCE**

Each Party shall obtain all the insurance policies necessary to protect the other Party, their clients or third parties, from any damage under their responsibilities such as defined in the GCP. Accordingly, each Party shall provide evidence of such insurance cover and communicate to the other Party upon request, a valid certificate of insurance coverage, indicating the nature, the duration of the coverage, the limits and deductibles. These insurance requirements do not exonerate the Parties of their responsibilities pursuant to the present GCP so that they remain liable for damages not entirely or partially supported under their insurance coverage.

#### **ARTICLE 9 - FORCE MAJEURE**

Upon occurrence of an external, unforeseeable and irresistible event, the defaulting Party shall inform the other Party as soon as possible by any means, and subsequently by registered letter with acknowledgement of receipt within seventy two (72) hours from the time at which it became aware of the event or events

constituting an event of force majeure. To the best of its ability, each Party shall take any needed provisional measures to reduce the consequences of the event of force majeure. Should the force majeure event continues for at least thirty (30) calendar days from the notification of its occurrence, the order may be terminated, by registered letter with acknowledgement of receipt, by any of the Parties, even where provisional measures have been taken.

#### **ARTICLE 10 - TRANSFER OF OWNERSHIP, CUSTODY AND RISK**

Unless otherwise provided for in the Order, the transfer of risk and of ownership takes place, by default, when the goods are made available at the location agreed upon between the Parties in the order, cost and risks associated with the delivery being charged to the Supplier in accordance with the Incoterm defined in the Order. In case the supply of the goods is accompanied with an installation performed by the Supplier on ELANCO's site, the risks associated with the supplied goods shall be transferred to ELANCO only upon signature of the certificate of reception in accordance with the provisions of Article 5 hereinabove.

#### **ARTICLE 11 - INDUSTRIAL AND INTELLECTUAL PROPERTY**

ELANCO and the ELANCO Group retain the ownership and exclusive use of all industrial and/or intellectual property rights that belong to them, and of which the Supplier may have gained knowledge, or used during the execution of the order.

The results of studies, services and/or equipment developed specifically for ELANCO by the Supplier shall become, automatically and as they accrue from time to time in the course of the execution of the order, the exclusive property of ELANCO, which may use them without any restriction as they are or after adaptation. The Supplier transfers to ELANCO exclusively, irrevocably and worldwide (save provisions to the contrary) all property rights over the creations that may be protected by industrial and intellectual property rights, in particular plans, drawings, diagrams, graphs, as well as any software developed on its behalf in the frame of the execution of an order, and in particular, the right to reproduce, represent, market, incorporate and adapt, for the legal life of these rights, and without any limitations of scope or purpose. Therefore, the Supplier may not conserve any right to the use of said creations.

It is up to the Supplier to obtain from third parties (i) the transfer to ELANCO of all the rights according to the modalities provided hereinabove; (ii) the licensing; and (iii) any potential authorisations needed. The Supplier undertakes to bear any relevant duties, royalties or compensations or to modify the supplies, at its expense, in order to ensure their free operation by ELANCO. Where the Supplier has been unable to ensure the transfer of all the rights, the Supplier undertakes to state in writing, the scope and limitations of the rights obtained by it, and shall obtain from ELANCO, prior express agreement over a limitation of transfer. The Supplier indemnifies ELANCO against any actions that may be brought against it by any third parties, based on industrial and/or intellectual property rights, or any other legal cases, regarding the supplies, materials, means and/or products used by the Supplier in its supply to ELANCO, particularly on the basis of patents, drawings, models, brands and any other industrial and intellectual property. Where a third party brings an action, whether justified or not, the Supplier shall also reimburse ELANCO in full for any expenses incurred, including in its defence.

#### **ARTICLE 12 - USE OF DOCUMENTS – CONFIDENTIALITY**

The Parties undertake to keep strictly confidential and not to disclose or allow the disclosure by any means whatsoever, of any information transmitted by the other Party and particularly the documents, data, knowhow, prototypes, information, tools, software and/or of which it may have gained knowledge in the course of its relationship with the other Party and/or that it may have developed on behalf of the other Party in the execution of the Order (hereinafter collectively "the Information"). Furthermore, both Parties undertake not to use such Information for any other purpose than those expressly authorised by the Order. The Parties undertake to disclose the Information only to members of their staff and/or sub-contractors who will need it for the successful execution of the Order, and to take any action possible to enforce their compliance with the above mentioned confidentiality obligations.

The confidentiality obligations under these GCP shall not cover any Information which the Party receiving the information may demonstrate (i) that the Information was in its possession and freely available to it before its transmission by the disclosing Party, and that it can provide evidence of this through its written records; (ii) that the Information was in the public domain at the time that it was disclosed by the disclosing Party; (iii) that the Information entered the public domain without any fault, action or omission on its part; or (iv) that the Information was made available to it without any confidentiality obligation towards a third party that was legally entitled to transmit it.

The above confidentiality obligation shall survive for ten (10) years from the time of disclosure.

The Supplier is hereby informed that the nominative records potentially transmitted by ELANCO in order to achieve the services, are regulated by the Data Protection Act of the 6st January 1978 as amended by law N 2018-493 of June 20<sup>th</sup>, 2018, relating to the Data Protection Regulation and by the General Data Protection Regulation (GDPR) UE 2016/679 of the 27st April 2016. As such, the Supplier and ELANCO shall define the terms and conditions of the achievement of the data processing services as well as their respective obligations, as a "subcontractor" and as a "Data controller", in compliance with the provisions of article 28 of the GDPR.

#### **ARTICLE 13 - TERMINATION**

Without prejudice to any claim for damages, in the case one of the Parties has committed an unjustified material breach in its obligations under this GCP, and has

failed to cure such breach within thirty (30) working days after the date of reception of a written notice requiring him to remedy such failure, the other Party may terminate the order of right. The Party at fault shall be liable for any consequences that may result from the termination of the order for the reasons invoked in this paragraph and, in particular, from the use of a third party for the achievement of the services.

In case the Supplier fails to comply with one of the undertakings included in the Supplier Code of Conduct, ELANCO shall be entitled to terminate the order without prior notice, by registered letter with acknowledgement of receipt. ELANCO shall benefit from the same rights as those specified in the paragraph above.

#### **ARTICLE 14 - SUB-CONTRACTORS**

The Supplier undertakes not to sub-contract, in whole or in part, its obligations under the order, without obtaining ELANCO's prior authorisation in writing. Where the Supplier is authorised to sub-contract, the supplier may use, under its own responsibility, a sub-contractor under the conditions provided and defined by Law No 75-1334 of 31 December 1975, as amended. The Supplier undertakes to obtain, for the benefit of its sub-contractors, the guarantees required by Section 14 of the above mentioned Law. It shall transmit a copy to ELANCO.

#### **ARTICLE 15 - APPLICABLE LAW AND JURISDICTION**

The relations between ELANCO and its Supplier are governed and construed in accordance with the laws of France (no application of the conflict-of-law rules). Any dispute between the Parties relating to the validity, interpretation or execution of these GCP, is of the exclusive competence of the Nanterre Commerce Court.

#### **ARTICLE 16 - GENERAL INFORMATION**

16.1. Independence: ELANCO and the Supplier shall each assume the normal risks of their operations and declare that they are both contracting freely and are not bound by any commitment which may jointly and severally oblige them with respect to third parties without their express consent in writing.

16.2. Amendments: The Parties may not benefit from any contractual amendment unless its terms have been expressly accepted by the way of a new Order or an amendment to the Order. Exceptionally, only in emergency situations or for safety reasons, the Supplier shall be authorized, spontaneously, to make changes and/or additions to the materials or structures, which, in the course of the execution of the order, may be necessary for safety reasons such as defined by legal standards or by the standards in the Request for Quotation; provided however, that the Supplier shall immediately inform ELANCO of such by any means that allows an acknowledgement of receipt.

16.3. Dependency: The Supplier declares that it is not economically dependent with respect to the orders issued by ELANCO. This situation is assumed to continue throughout the duration of the orders and the Supplier undertakes to declare to ELANCO any change in its situation that may cause it to become economically dependent with respect to ELANCO under applicable regulations. The Supplier declares that it is not in the situation of suspension of payment and undertakes to inform ELANCO in a timely manner, of any financial difficulties that may compromise the successful and complete execution of the orders. In case of judicial settlement or liquidation of the Supplier, ELANCO shall be entitled of right, to terminate the contractual commitments in progress, subject to the application of compulsory legal provisions in such matters.

16.4. Assignment: It is recalled that the order is concluded *intuitu personae* with the Supplier, whether the business is operated by an individual or as a company. Therefore, the order may not be transferred without prior agreement in writing from ELANCO. Without prejudice to any claim for damages, where this obligation has been breached, ELANCO reserves the right to terminate the Order of right and without prior notice. ELANCO shall have the right to assign all or part of its rights and obligations under an order to an affiliate or successor of ELANCO or towards an acquirer of all or parts of the business.

### **ADDITIONAL PROVISIONS APPLICABLE TO ELANCO HEALTHCARE SAS ORDERS**

#### **"SUNSHINE ACT" TRANSPARENCY OF RELATIONSHIPS**

The Supplier is hereby informed that ELANCO FRANCE SAS may be led to make public the business relationships under these GCP in compliance with the provisions of Section L.1453-1 of the Public Health Code and Decree N. 2016-1939 of December, 28th 2016 relating to the Public Declaration of Interests and N. 2017-89 of January 26<sup>th</sup>, 2017 provided for in article L.1451-1 of the Public Health Code and to the transparency of benefits granted by enterprises that produce or market human health and cosmetic products.

The Supplier is hereby informed that such information of a personal nature will therefore be subject to computer processing for publication as stated in the paragraph above, and implemented by ELANCO as processing controller. Personal data provided for in articles R1453-3 and following of the Public Health Code shall be published on the public website [www.transparence.sante.gouv.fr](http://www.transparence.sante.gouv.fr) for the necessity of the disclosure of links. The recipients of these data are all the persons who can have access to this website. Pursuant to the Data Protection Act of 6 January 1978 as amended by law N 2018-493 of June 20<sup>th</sup>, 2018, relating to the Data Protection Regulation and by the General Data Protection Regulation (GDPR) UE 2016/679 of the 27<sup>st</sup> April 2016, the Supplier is hereby informed that it will benefit of the right of access to, and rectification of the information relating to

it which it may exercise before ELANCO FRANCE SAS Data Privacy Officer (DPO), Crisco Uno, Bâtiment C, 3-5 avenue de la Cristallerie, CS 80022 - 92317 Sèvres CEDEXat or by e-mail at [privacy@ELANCO.com](mailto:privacy@ELANCO.com).

The Supplier is furthermore informed that it neither may object to the implementation of such processing arising from a legal obligation (article 6.1 c) of the GDPR, nor to the publication of the data, that concerns it. The information will remain online for 5 years.

The Supplier will not be processing Personal Information on behalf of Elanco. In case the Supplier processes or handles Personal Information on behalf of Elanco, the Supplier undertakes to comply with all applicable privacy laws and there must also be an agreement on the content of the Elanco's 'Supplier Privacy Standard (SPS)' which also must be signed by the Supplier (including completion of Exhibit A from the SPS) as well as the Elanco 'Information Security Standard' (ISS). Elanco's ISS and SPS can be found on Elanco's global supplier portal under the following link: <https://www.elanco.com/suppliers>.

#### **REPORTING OF ADVERSE EVENTS, ADVERSE EFFECTS, CLAIMS REGARDING PRODUCTS**

The Supplier undertakes to comply with all the laws and regulations relating to pharmacovigilance in accordance with the Public Health Code, and to carry out all required processes and formalities within the timelines provided by applicable laws.

#### **ANIMAL HEALTH PRODUCTS:**

The Supplier undertakes to communicate immediately to any ELANCO employee any pharmacovigilance report regarding humans or animals (adverse effect, overdose, misuse, lack of effectiveness, abuse, suspected transmission of an infectious agent) as well as any claim regarding a Product, of which it may become aware within the context of the resale of products.

In these GCP:

- an "adverse event" is any harmful manifestation in a patient treated with the Product(s) and which is not necessarily associated with the Product(s);
- an "adverse effect" is any harmful and incidental response to a product that manifests itself whatever the dose, where the causal relationship between the Product and the adverse effect constitutes at least a reasonable possibility;
- a "claim regarding the product" is the reporting of a potential or recognised quality defect of the Product(s). A claim may also be a suspected counterfeiting;
- a "usage problem" is the reporting of an error in usage or of a Provider satisfaction issue highlighted by the user of the Product(s).