

# Radboud Translational Medicine – General Terms and Conditions, December 2023

## 1. DEFINITIONS

- 1.1. **General Terms and Conditions:** these general terms and conditions.
- 1.2. **Side Effect:** an harmful, undesirable response to a medicine (radiopharmaceutical).
- 1.3. **Services:** the services stipulated in an Agreement that RTM provides to a Client, which are deemed to include the manufacture and distribution of Products and the Development of specific Products at a Client's behest.
- 1.4. **Documentation:** any manuals, instructions and all other user or safety directives which RTM supplies in relation to Products and Services;
- 1.5. **Defect/Deficiency:** substantial non-compliance of a Product and/or Service with the agreed Specifications;
- 1.6. **Client:** a legal entity or natural person with whom RTM enters into an Agreement;
- 1.7. **Quotation:** a Written offer which RTM presents to a Client for the supply of Products and/or Services.
- 1.8. **Development:** the development by RTM of a new Product based on a Client's specific requirements, specifications and/or instructions.
- 1.9. **Agreement:** a Quotation consented to by a Client or any agreement which the relevant parties conclude with each other for the Development or supply of Products and/or Services by RTM for or to the Client.
- 1.10. **Product:** any medicine (radiopharmaceutical) which RTM manufactures in its outfitted cyclotron.
- 1.11. **Product Specification:** a document in which the specifications of a Product (to be developed) are recorded in the form of a registration dossier, SmPC or some other Written document.
- 1.12. **RTM:** the private company with limited liability, Radboud Translational Medicine B.V., having its registered office and place of business in Nijmegen, the Netherlands, and registered in the commercial register maintained by the Chamber of Commerce under Number 092118811.
- 1.13. **In Writing/Written:** by letter, email, fax or any other electronic means of communication, such as WhatsApp.
- 1.14. **SmPC:** a summary of a radiopharmaceutical's product characteristics.
- 1.15. **Specifications:** the specifications which any Products and/or Services to be supplied need to conform to as set out in the relevant Product Specification. Where no Specifications are stipulated in the relevant Product Specification, those in the Quotation concerned shall apply.

## 2. SCOPE OF APPLICATION

- 2.1. These General Terms and Conditions shall govern all

Quotations and Agreements pertaining to RTM's supply of Products and/or Services to a Client.

- 2.2. Any derogation from or addendum to these General Terms and Conditions, a Quotation and/or an Agreement – which is deemed to include any oral agreement – shall only be valid provided that RTIM confirms it In Writing.
- 2.3. The application of a Client's procurement or other terms and conditions is explicitly rejected.
- 2.4. In the event that and in so far as the provisions of a Quotation conflict with the substance of a Product Specification, the latter shall prevail.
- 2.5. Should any provision of these General Terms and Conditions or an Agreement be void or nullified, or is otherwise invalid or inapplicable, their or its other provisions shall continue to apply in full. In that case the Parties shall enter into consultation with each other to agree on a new provision to replace the invalid one, ensuring that the purpose and meaning of the invalid provision are approximated as far as possible.
- 2.6. RTM shall be entitled to amend or add an addendum to these General Terms and Conditions. In the event that RTM avails itself of this right, the amended General Terms and Conditions shall apply after RTM sends them to a Client.

## 3. CONCLUSION OF AN AGREEMENT

- 3.1. All Quotations, as well as any prices, increases or deadlines stipulated by RTM shall always be free of obligation and RTM may revoke them, unless explicitly specified otherwise.
- 3.2. An Agreement shall come into effect at such time as a Client consents to an unamended Quotation In Writing. Should a Client require an amendment, RTM shall issue a new Quotation.

## 4. EXECUTION OF AN AGREEMENT

- 4.1. All Products and Services supplied by RTM shall be supplied or provided as part of a duty of care, unless explicitly stipulated otherwise in the relevant Agreement In Writing.
- 4.2. Having regard to the special nature of the Products, their highly limited shelf life following their manufacture and RTM's dependence on other parties (such as transporters, raw material suppliers and other parties with whom it collaborates) and the availability of raw materials, RTM cannot warrant that it can continue to supply Products constantly and without disruption during the term of an Agreement in spite of the fact that it has adopted precautionary measures to prevent a disruption of its manufacturing process from occurring. Amongst other things, this means that RTM quotes (delivery) deadlines as estimates and that a failure to meet such a deadline cannot automatically lead to it being in default.

## 5. PRODUCT DEVELOPMENT

- 5.1. Before or when an Agreement is concluded, the relevant Client shall supply RTM with the specifications and/or instructions based on which RTM may develop a specific Product. The Client shall warrant that they are accurate and complete. Should such specifications and/or instructions not be supplied, the parties shall specify the Products which are to be developed In Writing and in consultation with each other, and the manner in which such Development will occur.
- 5.2. RTM shall exercise due care in the course of the Development of a Product based on the information supplied by the relevant Client or the Specifications agreed to with the latter.

## 6. QUALITY

- 6.1. The Products shall comply with all relevant applicable legislation and regulations, the Product Specification and the (security) directives which apply at the time when supply to the Client concerned occurs.
- 6.2. In the event that a Client is of the opinion that a Product exhibits a Defect, the Client shall be required to notify RTM of this immediately, partly given RTM's (legally stipulated) duty to ensure the safety and quality of its Products and to notify the competent authorities of any Defect within fifteen (15) days as the case may be. In the event of a Defect RTM shall do all in its power to replace the relevant Product free of charge within a reasonable period of time without having a duty to provide the relevant Client with any other form of compensation. This duty to provide a replacement shall cease to apply in the event that RTM determines at its sole discretion that such Defect is entirely or partly due to the Client having provided incorrect specifications, used or stored the Product concerned carelessly or improperly, or used it other than as stipulated in the Product Specification, an external cause such as fire or water damage, or the Client has made modifications without RTM's consent or has arranged for this to be done.
- 6.3. In the event of a Defect a Client shall heed any instructions issued by RTM and shall refrain from destroying a Product on their own initiative. Should RTM instruct a Client to proceed with the destruction of a Product, such destruction must always occur in accordance with the applicable legislation and regulations (including the Nuclear Energy Act [*Kernenergiewet*]).
- 6.4. RTM shall charge for any work or replacement costs not covered by this warranty in accordance with its normal rates.
- 6.5. RTM shall carry out all replacement work to the best of its ability, irrespective of whether this occurs free of charge or in return for payment. Nevertheless, RTM cannot guarantee that any Defect will be remedied or

that it is possible to remedy it in all cases.

## 7. DELIVERY OF PRODUCTS

- 7.1. RTM or a third party whom it engages shall transport and ship any Products. RTM shall bear any risks associated with transporting and shipping a Product to a Client. RTM shall be entitled to charge a Client for any (additional) expenses incurred pursuant to expedited delivery at a Client's request.
- 7.2. Any risk of damage to or the theft, destruction and the like of any Product shall pass to the relevant Client when the latter takes receipt of the Product. A Client shall sign to indicate receipt of a Product when requested to do so.
- 7.3. RTM shall sell and deliver to a Client any Product which is mentioned in the relevant Agreement. Any lead shielding and transport containers supplied along with the delivery of a Product shall remain the property of RTM and the relevant Client shall return same to RTM or its transporter.

## 8. CLIENT'S OBLIGATIONS

- 8.1. A Client shall only use a Product in the manner and for the purposes which RTM has stipulated and/or as described in the relevant Product Specification and in accordance with any additional instructions issued by RTM. RTM reserves the right to modify and upgrade its Products and Services, and also to amend and improve its Product Specifications and other Documentation as it deems useful or necessary and/or pursuant to any amendment of the relevant legislation and regulations or any directives issued by other competent authorities. A Client shall consent to such amendments and improvements, and shall heed any instructions issued by RTM.
- 8.2. A Client shall be required to report any (potential) Side Effects following the use of a Product to RTM and the Netherlands Pharmacovigilance Centre Lareb [Nederlands Bijwerken Centrum Lareb] ([www.lareb.nl](http://www.lareb.nl)), partly in view of RTM's (legally stipulated) obligations in relation to pharmacovigilance.
- 8.3. A Client shall provide RTM with every assistance for the purposes of the latter executing the relevant Agreement, which is also deemed to include granting access to the Client's premises for the competent authorities to conduct audits and inspections and, when first requested to do so, to provide RTM with any information that is required for it to execute the Agreement concerned and to comply with any legally stipulated duties which it has.
- 8.4. Acting at a Client's request, RTM or any other party whom it has engaged shall provide advice concerning any Product or Service, for example but not confined to, its composition, effects, manufacture or use. RTM shall endeavor to provide a Client with all of the advice

that they request, although it may be unable to provide advice in all cases. Any advice provided shall always be based on the information supplied by the relevant Client. As such, a Client shall warrant that any information which is supplied to RTM by them or on their behalf and which serves as the basis for advice is accurate and complete.

- 8.5. A Client shall also impose the obligations arising for them pursuant to this article on any staff whom they have engaged or whom they have in any way involved in the use of the relevant Product.

## **9. FEES AND PAYMENT**

- 9.1. The fees which a Client owes RTM for any Products and/or Services supplied shall be stipulated in the relevant Agreement. Unless otherwise agreed, any prices shall be expressed in euros (€) exclusive of VAT and any other government levy.
- 9.2. RTM reserves the right to index its rates and fees on 1 January every year in accordance with the price index figures issued by the Dutch Healthcare Authority, with the most recent price index figures for the cost of materials and labor each being applied to the extent of one half (½). Furthermore, RTM shall at all times be entitled to pass on any proven supplier price increase to a Client. In such a case RTM shall naturally notify the relevant Client of this promptly.
- 9.3. RTM may include a schedule of payments in an Agreement in accordance with which it will issue invoices for the agreed fees.
- 9.4. A Client shall pay an invoice within thirty (30) days after receiving it. Where a Client disputes an invoice, they shall notify RTM of this In Writing within fourteen (14) working days, citing reasons for doing so.
- 9.5. In the event that an invoice is not paid on time, the relevant Client shall be liable – without any further notice of default – for any legally stipulated commercial interest (pursuant to Article 6:119a of the Dutch Civil Code) as of the due date of the invoice until the date on which it is paid in full. This shall not in anyway affect any other rights held by RTM, which is deemed to include its entitlement to suspend all or part of its obligations immediately. A Client shall be liable for any costs, such as judicial and extrajudicial expenses, which RTM incurs in order to secure the Client's compliance with their (financial) obligations. Such extrajudicial expenses are hereby set at 15% of the invoiced amount subject to minimum of €150.00.

## **10. LIABILITY**

- 10.1 RTM has insured itself against all liability pursuant to an Agreement in an appropriate and customary form in accordance with generally accepted standards and shall continue to do so. RTM's liability shall be confined to the sum of a one-off assignment or (in case of a continuing performance agreement) to the value

of the annual fee under the Agreement. In no event shall RTM be liable for an amount exceeding €100,000.00 (one hundred thousand euros).

- 10.2 Any liability on the part of RTM on the grounds of its culpable default shall only arise provided that the relevant Client properly notifies RTM In Writing that it is in default, affords it a reasonable period of time within which to remedy its non-compliance and RTM also remains culpably in default after that period. Such notice of default must include as comprehensive and detailed a description of the relevant non-compliance as possible, so as to ensure that RTM can respond appropriately.
- 10.3 Any entitlement to compensation shall only arise on condition that the relevant Client reports such loss to RTM as soon as possible after it occurs but at any rate by no later than within fourteen (14) days.

## **11. FORCE MAJEURE**

- 11.1. In so far as is not already applicable pursuant to the law, RTM shall not be liable for any loss, nor shall it have a duty to comply with any obligation where such loss or non-compliance is due to circumstances beyond its control, such as but not confined to a power failure, computer virus, hacking, culpable default on the part of any third party or supplier engaged by RTM, a boycott, the outbreak of hostilities, rioting or war, a terrorist attack, fire, an explosion, flooding, the breakdown of the cyclotron or any other machine, measures adopted by any domestic, foreign or international public authority or body, measures adopted by a regulatory authority, as well as anything else.
- 11.2. In the event that a period of force majeure persists for longer than two (2) months or it is certain that it will last for at least as long as that, either party shall be entitled to cancel the relevant Agreement without having any duty to provide compensation for a loss suffered by the other party. Should a situation of force majeure occur, the relevant parties shall notify each other of this immediately and shall present the requisite proof.

## **12. INTELLECTUAL PROPERTY**

- 12.1. All intellectual property rights to the Products, Services and Documentation shall be solely vested in RTM or its suppliers. A Client shall acknowledge these rights, and shall warrant that they will refrain from any infringement thereof.
- 12.2. Unless otherwise agreed, a Client shall only acquire a non-exclusive, non-transferable license in relation to the intellectual property rights to any Product supplied by RTM. Any other use, such as the independent trade in or commercial exploitation of any Product or Service, or the further development thereof, shall not be permitted.

- 12.3. In the event that it is agreed that a Client may modify a Product or develop it further for its own use, when first requested to do so by RTM, the relevant parties shall make additional arrangements concerning the party in whom the intellectual property rights to such modification or further development will be vested and how its commercial expectation will occur.
- 12.4. Where the parties stipulate in an Agreement that the relevant Client may independently modify a Product or develop it further, the Client shall do this at its own risk and expense. RTM shall not be liable for any loss suffered pursuant to such modification or further development. A Client shall indemnify RTM against any claim or action instituted by another party on the grounds that a modification or further development infringes any of that party's rights or otherwise causes harm to any other party.
- 12.5. RTM warrants that the Products which it has developed do not infringe any intellectual property or propriety rights of any other party. Nevertheless, should it be irrevocably established in law that any Product supplied by RTM infringes any third-party intellectual or industrial property right or where RTM deems there to be a good chance that such infringement will occur, RTM shall ensure as soon as possible that the relevant Client can continue to use what has been supplied or any functionally similar Product without disruption, for example, by modifying any infringing part or by acquiring a license for the Client. Any other form or extension of liability or duty to provide indemnification on the part of RTM on the grounds of an infringement of intellectual property rights held by some other party shall be precluded.

### **13. NON-DISCLOSURE**

- 13.1. A Client shall have a duty not to disclose any information that they know or reasonably ought to know is of a confidential nature. 'Confidential information' shall at any rate be deemed to refer to any information concerning RTM or any other party engaged or appointed by it, including financial data, which comes to a Client's knowledge pursuant to the execution of the relevant Agreement and any information which RTM has supplied to a client for the purposes of using the relevant Product and/or Service (such as its composition).
- 13.2. A Client shall agree to an identical duty of non-disclosure with their staff and/or any other party working for them who may acquire actual access to the information referred to in the foregoing clause and shall warrant RTM that such staff and/or other party will comply with it.
- 13.3. A Client shall adopt appropriate technical and organizational security measures to secure any (confidential) information concerning RTM and any other party which they acquire pursuant to the

execution of the relevant Agreement against any loss or any form of unlawful processing. Such measures shall be no less onerous or strict than those which the relevant Client employs in relation to its own confidential information.

### **14. TERM, TERMINATION AND CONSEQUENCES OF TERMINATION**

- 14.1. Where no term is stipulated in an Agreement and it does not automatically terminate upon its completion by virtue of its nature, it shall have an initial term of one (1) year as of its effective date.
- 14.2. Unless an Agreement stipulates otherwise, its initial term shall be automatically renewed by one (1) year at a time, unless it is cancelled in accordance with this article.
- 14.3. Cancellation shall be effected In Writing but only towards the end of the (renewed) term of the Agreement subject to a term of notice of no less than three (3) months. An Agreement may not be terminated prematurely or in the interim.
- 14.4. RTM shall be entitled to cancel all or part of an agreement In Writing with immediate effect in the absence of any refund of monies already received or any duty to provide compensation in the event that:
- an application is filed on behalf of the relevant Client for a moratorium on payments (provisional or otherwise) or one is granted;
  - an application is filed for the relevant Client's bankruptcy or the Client is declared bankrupt;
  - the relevant Client's business is liquidated or closed down other than for the purposes of restructuring it or merging it with any other business;
  - amended legislation or regulations render(s) it impossible for RTM to manufacture its Products any longer.
- 14.5. Where a Client terminates an Agreement by rescinding it and has already received performance from RTM for the purposes of executing it, such performance and the associated financial obligation shall not be covered by such rescission, unless the Client can show that RTM is in default in respect of such performance. Any amount for which RTM has issued an invoice prior to such cancellation or rescission in connection with what it has already properly done or supplied for the purposes of executing the relevant Agreement, shall remain payable in full and shall fall due immediately at the time of rescission subject to the provisions of the foregoing sentence.
- 14.6. Upon the termination of an Agreement in any way whatsoever (rescission, cancellation and so forth), those provisions of these General Terms and Conditions and the Agreement which are designed to continue to apply following its termination as well by virtue of their nature shall continue to apply in full.

**15. OTHER PROVISIONS**

- 15.1. A Client may not assign their rights and obligations pursuant to an Agreement to any other party except with RTM's prior Written consent. RTM may grant such consent subject to conditions.
- 15.2. An Agreement and any contract concluded pursuant or in relation to it shall be solely governed by and construed in accordance with the law of the Netherlands. The Vienna Sales Convention (CISG) 1980 shall explicitly not apply.
- 15.3. Any dispute which arises pursuant or in relation to an Agreement shall only be brought before the District Court of Arnhem to adjudicate.