MRP MEDI-RADIOPHARMA Ltd.
Your Global Nuclear Medicine Supplier

GENERAL TERMS AND CONDITIONS OF

MEDI-RADIOPHARMA LTD.
(Registered seat: H-2030 Érd, Szamos u. 10-12; Hungarian tax No.: 12090503-4-13; EU tax No.: HU12090503; company reg. No.: 13-09-119709)

AND

RADIOPHARMACY LABORATÓRIUM LTD.
(Registered seat: H-2040 Budaörs, Gyár u. 2. 10324/66.; Hungarian tax No.: 13589439-4-13; EU tax No.: HU13589439; company reg. No.: 13-09-119341)

(jointly hereinafter: the "**Supplier**")

In effect from: April 1, 2026
Version No.: V3

Capitalized terms in these General Terms and Conditions shall have the following meaning:

"**Affiliate**"	means any corporation or business entity that directly or indirectly, controls, is controlled by, or is under common control. The term "control," "controlled by" or "under common control with" shall mean the possession of the power to direct or cause the direction of management and policies of such corporation or business entity, whether through direct or indirect ownership of more than fifty percent (50%) of voting securities or otherwise. Affiliates shall include, in connection with the Supplier, **Medi Radiopharma US LLC** (registered seat: 10559 Greencrest Drive, Tampa, FL, 33626; postal address: 12191 W Linebaugh Ave. Suite 756, Tampa, Fl, 33626, incorporated in the State of Florida, United States of America).
"**Business Day(s)**"	refers to any day on which banks and other services are open for regular operations, excluding weekends and public holidays. In Hungary, this typically means weekdays (Monday through Friday), unless a specific public holiday falls on a weekday.
"**Customer**"	means the person/legal entity placing an Order for the supply of Products manufactured by the Supplier.
"**Confidential Information**"	means (to the fullest extent permitted by law), without this list being exhaustive, (i) any and all information, data, samples, operational methods, specifications, analytical methods, study, analysis or material of any nature whatsoever of the Supplier, any of its Affiliates or any of its or their respective past, present or prospective customers, suppliers or other third party business relations (whether disclosed orally or disclosed, accessed or otherwise observed in written, electronic or other form or media; whether or not identified as "confidential"); (ii) those portions of any and all notes, analyses and other materials prepared by or on behalf of the Customer or any of its representatives to the extent containing, based on, or otherwise reflecting, to any degree, any of the foregoing; and (iii) any information about any discussion and possible evaluation, negotiation, and execution of one or more potential consensual, negotiated business transactions, and any other facts relating to that due diligence, discussions and/or negotiations are taking place or have taken place. For the avoidance of doubt, the material terms of the contractual relationship between the Parties governed by this GTC will be also considered Confidential Information.
"**Force Majeure Event**"	means all events, circumstances, and occurrences beyond the reasonable control of a Party hereto, which materially affects the performance of any of its obligations under this GTC and could not reasonably have been foreseen or provided against, including, but not limited to fire, flood, earthquake or like acts of God, wars, revolution, civil commotion, explosion, acts of public enemy, embargo, labor difficulties, including without limitation, strikes, slowdowns, or boycotts.
"**GTC**"	means these General Terms and Conditions.
"**Incoterms 2020, EXW (Érd, Hungary)**"	means EXW parity under the international rules for the interpretation of trade terms of the International Chamber of Commerce as amended from time to time.
"**Import Authorization**"	means an official authorization granted by the competent authority, allowing the importation of medicinal products before MA granted into a country under defined conditions and requirements.

"**IP Rights**"	means the Supplier's intellectual property rights pertaining to the Products as specified in Section 7.
"**Logger**"	means that a temperature data logger packaged into the shipping box of the Products which is a portable measurement instrument capable of autonomously recording temperature over a defined period of time and to monitor and gather the temperature conditions that the Products have been exposed to during shipping.
"**Offer**"	means the Supplier's individual offer that sets out the Parties' agreed price, the Products, the quantity of Products to be purchased, and any special terms and conditions agreed by the Parties that may deviate from this GTC.
"**Order**"	means the individual order for sale and delivery of Products placed by the Customer to the Supplier which is in turn confirmed by the Supplier and specifying the exact quantity and Supply Price of Products requested for delivery.
"**Partner Manager**"	means the Supplier's sales colleagues who are responsible to receive the Customer's request for an Offer, and who are the Supplier's key contact persons regarding any sales activities.
"**Party**", "**Parties**"	means either the Customer or Supplier or both if used in the plural form.
"**Product(s)**"	means any and all pharmaceutical products manufactured and supplied by the Supplier at any time during the term of these General Terms and Conditions.
"**Supply Price**"	means the sale price of the Products requested by the Customer as quoted by the Supplier.

1. SUBJECT OF THESE GENERAL TERMS AND CONDITIONS AND PREVAILANCE

1.1 The terms of the GTC regulates the processes relating to the order and supply of Products based on a one-time Order (i.e., without a framework agreement) placed by the Customer directly to the Supplier, along with the pertaining rights and obligations of the Parties. It excludes any other terms that the Customer seeks to impose or incorporate, or which are implied by trade, custom or course of dealing.

1.2 The Parties acknowledge that the Customer does not qualify as a consumer under Hungarian consumer protection and civil laws, due to the nature of the manufacturing, distribution, marketing, storage and use of the Products, which requires special knowledge and expertise in the pharma-industry.

1.3 The Parties may only deviate from the provisions herein with an express written agreement (Order or any other formalized agreement). In case Supplier and Customer have signed a framework agreement or other form of commercial agreement concerning the supply of Products, and there is a discrepancy between the provisions of such agreement and this GTC, the terms and conditions of the agreement shall apply and prevail.

1.4 **By accepting the Supplier's individual Offer, the Customer acknowledges and accepts the terms of this GTC, including but not limited to the Pharmacovigilance clause and the Quality Annex with Responsibility Matrix, which is the integrated part of this GTC under Annex 1, also Annex 2 on the Pharmacovigilance.** The person acting on behalf of the Customer furthermore understands and accepts that all statements and undertakings made in the name of the Customer shall be considered by the Supplier as binding on the Customer and considered as a statement and undertaking thereof. The Supplier shall not be under obligation to verify the authority of the person acting on behalf of the Customer and will consider such person to have full power and authority to represent the Customer.

1.5 The Supplier reserves the right to unilaterally amend the terms of the GTC, of which the Customer will be notified when placing the subsequent Order, and no such amendment shall apply retroactively to Orders already placed and confirmed.

2. SUPPLIER'S OFFER AND ITS ACCEPTANCE; ORDER

2.1 The Customer can request an Offer from the Supplier via the "Fast Track Order" feature on the Supplier's official website (https://mediradiopharma.com/) or via email address order@mediradiopharma.hu or the Partner Managers' individual email address.

2.2 All request for Offer shall contain at least the following information:

- Product(s) to be purchased;
- Quantity of the Product(s);
- Destination address which must be suitable for the appropriate storage of the Product(s);
- special requests of the Customer (if any).

2.3 Based on the information provided by the Customer, the Supplier shall send its Offer to the Customer within five (5) business days from the date of receipt of the Customer's request, except between December 15 and January 5, which constitutes the Supplier's annual shutdown period. If the Customer's request is incomplete or unclear, the Supplier shall first send clarifying questions to the Customer. In such cases, the five (5) business day deadline shall commence only after the Customer has provided all information reasonably required for the preparation of the Offer. The Parties may also engage in discussions and consultations regarding potential commercial or contractual terms, such as pricing, quantities or any special contractual conditions (e.g. minimum annual quantity), prior to the issuance of the final Offer.

2.4 **The Customer shall accept the Supplier's Offer by returning to the Supplier a duly signed copy of the Offer. The signed Offer shall be deemed to constitute an Order placed by the Customer.**

2.5 The Customer, by acceptance of the Offer, shall also provide the Supplier with all information necessary to ensure that the distributed product complies with the requirements set forth in the import authorization and with the applicable local law and regulations. At a minimum, but not limited to, the following information shall be provided:

- The reference authorities whose Marketing Authorization forms the basis for placing the product on the market in the target country;
- Instruction regarding the packaging material (e.g. language, compliance to the reference Marketing Authorization)
- Validity of the import authorization or other certificate (e.g. date or batch)
- Local requirement regarding the certificate of analysis accompanying the packed product released to the target market (additionally refer to 3.4).

2.6 Upon receipt of the signed Offer, the Supplier shall inform the Customer of the estimated delivery date of the ordered Products. While the Supplier will endeavor to meet the estimated delivery date, it will not have any obligation to do so, and the Customer shall have no right to enforce any penalties or claim damages in relation to the delivery date not being met.

2.7 The Customer shall be entitled to amend or cancel the Order only by written notice delivered to the Supplier at least 30 (thirty) days before the advised delivery date. Any amendments or cancellations made after this date oblige the Customer to pay the full Supply Price indicated in the Order, without any further actions or requests of the Supplier.

3. PACKAGING AND DELIVERY OF PRODUCTS

3.1 Unless otherwise agreed in writing by the Parties, all Products will be delivered EXW Incoterms 2020 (Érd) according to which the Supplier shall only be liable for the packaging of the Products (including the placement of the Logger) and the risk of loss shall transfer to the Customer simultaneously with the uploading of the Products at Supplier's premises. The costs of shipment shall be borne entirely by the Customer, including the insurance of the delivery.

3.2 The Supplier shall use reasonable efforts and care in packing the Products for shipment (such as sealing, cooling packs etc.) considering the foreseeable conditions of the freight, including the weather at the place of origin and at the place of destination. However, the Customer acknowledges that the Supplier cannot foresee all circumstances and conditions beyond reasonable prudency and, therefore, cannot be held liable for circumstances beyond its reasonable control, including any damage to Products caused by the weather conditions (temperature, humidity etc.) which could not have been reasonably foreseen on the date of the dispatch by a pharmaceutical professional acting with due care. In addition, the Supplier shall in all cases offer the Customer a choice between different types of transport boxes with varying protective performance levels. Although the Supplier recommends the use of the transport box designed to provide enhanced temperature stability – particularly as this may be important during airport handling or other extended transits – the Customer may elect to use a less protective, standard transport box if it considers the cost of the enhanced option or the associated higher freight charges to be excessive. In such a case, the Customer acknowledges and accepts all risks arising from its choice of a lower-protection packaging solution.

3.3 With respect to the above, the Customer is advised to insure the shipment at its own cost. The Supplier shall not be held liable for the safe, intact, and timely delivery of the Products. The Customer shall furthermore be responsible and liable to take all measures and issue all statements and payments required for any customs clearance and entry into any state or crossing of any state borders.

3.4 All packaging elements (carton, labels, Summary of Product Characteristics, Package leaflet as applicable) are used in the language as required by the local authority of the target country based on information received from the Customer.

3.5 Quality certificates of the Products shall be enclosed in the shipping box.

4. SUPPLY PRICE AND PAYMENT

4.1 The Customer shall pay the full Supply Price of the Products ordered in advance and without any deductions, commissions, or transactional fees, based on the duly issued invoice of the Supplier. The Supplier shall have no obligation to dispatch or deliver the Products until the full payment has been received on its bank account. If the Customer fails to make the payment by the due date indicated on the invoice, any resulting delay in the delivery of the Products compared to the estimated delivery date shall not be attributable to the Supplier, and the Supplier shall not be liable for any consequences arising from such delay. The estimated delivery date shall be extended accordingly by the duration of the Customer's delay.

4.2 In the event that the Supplier does not receive the full invoiced amount for reasons beyond its control and/or as a result of any transactional fees or deduction during the course of the bank transfer procedure, the Customer shall be under obligation to clarify with the bank initiating such transfer and/or the intermediary bank(s) (bank(s) that sit(s) between the sending bank and the receiving bank when an international wire transfer cannot go directly from one bank to the other) the cause of such deduction and shall take all measures necessary to rectify any such deduction. If the Customer fails to rectify such errors and therefore the Supplier does not receive the full amount of the Supply Price, the Supplier shall have the right to charge the missing amount to the subsequent invoice issued to the Customer without any further explanation for as long as Supplier does not receive the entirety of the amounts due to it pursuant to the delivered Products and the issued invoices. Payment shall be considered made, when the full amount of the Supply Price is credited on Supplier's bank account.

4.3 Any value added tax or other duties shall be paid by the Customer, as well as the cost of packaging, cooling, and handling, which will vary according to the weight and size of the package(s).

4.4 All payments shall be in EUR, unless otherwise agreed by the Parties. Any foreign exchange risks and commissions shall be borne by the Customer.

4.5 In case of late payment, the Supplier shall be entitled to charge a late payment penalty, the value of which shall equal to 1.5% of the invoice/each month of late payment.

4.6 Ownership of the Products shall pass to the Customer only upon the Supplier's receipt of full payment of the duly issued invoice for the Supply Price.

4.7 The Customer acknowledges that any additional request for documentation required by local authorities shall be subject to additional fees as determined by the Supplier depending on the type of document and formalities required (e.g. translation, notarization, apostille etc.). The Customer further understands that the Supplier may request the signing of a separate non-disclosure agreement in case the documentation required by the Customer contains confidential information or trade secrets or any other data which the Supplier deems – at its own discretion – sensitive. In such cases, the Supplier shall not be obliged to disclose any documents or data until such non-disclosure agreement is duly signed by the Customer. This Section does not apply to documentation related to quality assurance (e.g. QA certificates); such documents shall be governed by the provisions of the Quality Annex.

5. PHARMACOVIGILANCE

5.1 The Parties shall comply with all applicable pharmacovigilance obligations as set out herein and in the Pharmacovigilance Provisions under the General Terms and Conditions (see Annex 2).

5.2 The Supplier maintains a pharmacovigilance system and retains overall responsibility for pharmacovigilance activities relating to the Products.

5.3 The Customer acknowledges that the Supplier, as the global safety database holder of the Products, is responsible for ensuring pharmacovigilance compliance as outlined in the SDEA. Accordingly, if the Customer fails to provide required information under the SDEA or fails to comply with any of the provisions in a timely manner, the Supplier may suffer certain detriments. The Customer shall therefore indemnify and hold harmless the Supplier against any losses, costs, fines, penalties or other charges imposed by authorities in connection with such failure or omission. Furthermore, the Supplier shall be entitled to claim

damages for any reputational harm, or loss of goodwill in the market resulting from non-compliance with pharmacovigilance-related rules, guidelines, or regulations.

5.4 No costs, expenses, or fees related to the pharmacovigilance matters shall be invoiced to the Supplier by the Customer unless explicitly approved in advance by the Supplier.

5.5 Where a separate SDEA is in effect between the Parties, its provisions shall take precedence over the Pharmacovigilance Provisions forming part of this GTC with regard to pharmacovigilance activities, in the event of any inconsistency.

6. USE AND MARKETING OF THE PRODUCTS BY THE CUSTOMER

6.1 The Customer shall not, without Supplier's prior written consent, sell or offer for sale any Products for delivery to a purchaser outside the destination country indicated on the signed Offer or to a purchaser within the place of destination which the Customer knows or ought to know intends to sell Products outside the said place of destination.

6.2 The Customer shall ensure that its end-users receive adequate and timely after-sales services.

6.3 The Customer shall not make or give any representations or warranties with respect to any Products other than those specifically authorized in writing by Supplier.

6.4 The Customer shall acknowledge that the Supplier is the MA holder and the manufacturer and wholesaler of the Products and the Customer is provided solely the right to sell, provided that applicable (local) law does not prescribe otherwise in which case the Parties shall agree separately about the regulatory affairs relating the Products.

6.5 The Customer shall ensure that the Supplier's good name and reputation is maintained at all times.

6.6 The Customer shall only use marketing materials provided and/or approved by the Supplier.

6.7 The Customer shall not manufacture, produce, commission to produce, submit regulatory documents or apply for registration or seek any legal protection for any of Supplier's Products or Products with the same active pharmaceutical ingredient (API) or indication without the Supplier's written consent, and shall procure that none of its employees, agents, subcontractors or other third parties appointed by it directly or indirectly do so. For avoidance of doubt, the Customer (and any of its affiliates) shall not be entitled to manufacture any products with the same active pharmaceutical ingredients (before and after labelling) and any same indication as the Products for a period of 5 (five) years after delivery of the last Order of the Customer. In the event that the Customer breaches the provisions of this foregoing Section, the Customer shall be under obligation to pay a penalty for such breach equaling to EUR 100,000 and shall immediately cease the manufacturing activity causing the breach hereof upon such request by the Supplier. In the event that the Customer does not desist from the manufacturing activities under the foregoing Section upon the request of the Supplier, the Customer shall be under obligation to pay EUR 20,000 for each month subsequent to the month when the restricted manufacturing activity first occurred for as long as the Customer fails to cease such restricted activity. The Parties further agree that the Supplier shall be entitled to enforce any additional damages (including any consequential damages, loss of profits or other such damages) which arise in connection with the restricted activity of the Customer and is incurred and substantiated by the Supplier.

6.8 The Customer shall maintain product quality during storage and transport of the Products to the end-user by maintaining qualified warehouses, equipment and vehicles.

6.9 The Customer shall maintain written procedures to handle quality complaints, recalls and shall partake immediately in the so-called mock recall initiated by the Supplier for assessing of the recall procedure.

6.10 The Customer shall maintain a quality system that complies with local pharmaceutical rules (such as GDP) and obtain the relevant permissions, wholesale licenses or equivalent authorization **(including individual import authorization or similar)** in accordance with local regulation for selling medicinal products and shall provide it to the Supplier's Quality Assurance unit for qualification and audit purposes.

7. PATENTS AND INTELLECTUAL PROPERTY

7.1 The Customer acknowledges that all IP Rights, including names, trademarks, service & brand marks (logo), copyright, patents and other intellectual property rights registered or non-registered (including any know-how), as amended from time to time and including all variations and improvement of such rights in relation to the Products are the exclusive property of the Supplier and the Customer shall not acquire any rights in Supplier's IP Rights under this GTC.

7.2 The Customer shall promptly notify the Supplier if the Customer becomes aware of any infringement or threatened infringement of the Supplier's IP Rights or of any counterfeit products and shall, in consultation

with Supplier, take all steps reasonably required by Supplier to protect the Supplier's IP Rights and to prevent the infringement.

8. LIABILITY

8.1 The Customer shall keep the Supplier indemnified against all claims, liability, costs and proceedings arising out of (a) any breach of the GTC by the Customer, and (b) any misrepresentation or negligent or wrongful act or omission of the Customer or of anyone under its control and/or any claims arising from the Customer's promotion or sale or other disposition of the Products after the risk of loss has passed on to the Customer or any of its subcontractors.

8.2 The Supplier shall not be liable – with the exception of intentional acts or omissions or personal injury, death or gross negligence – for any indirect or consequential damages, or loss of profit or revenue.

8.3 The Supplier shall not be under obligation to investigate or to certify the authorization of the Customer to distribute or market the Products at the place of destination and shall accept no responsibility for the misuse or unauthorized use of the Products by the Customer.

8.4 The Supplier shall be entitled to refuse delivery of the Products to the Customer if the government or other authorities in the place of destination impose any restrictions, whether on the transfer of funds or import of products or otherwise which adversely affect the ability of the Parties to perform the Order, in which case the Parties shall settle any outstanding invoices and claims.

9. CONFIDENTIALITY

9.1 Unless otherwise approved by the Supplier in a prior written form, the Customer (including its Affiliates, defined as below) shall:

9.1.1 (i) protect and safeguard the confidentiality and security of all of the Supplier's Confidential Information with at least the same degree of care as it would use to protect its own Confidential Information, but in no event with less than a commercially reasonable degree of care, and (ii) notify the Supplier as promptly as reasonably practicable after discovery of any loss or unauthorized disclosure or use of the Supplier's Confidential Information and use commercially reasonable efforts to retrieve that Confidential Information;

9.1.2 not copy, reproduce, summarize, distribute, disclose or disseminate the Supplier's Confidential Information in any manner to any person other than to the Customer and those representatives of the Customer who (i) have a reasonable need to know the Supplier's Confidential Information in connection with (A) the subject of the Order, (B) the exercise of the Customer's rights or any other written agreement or (C) any dispute between the Parties and/or their respective Affiliates, (ii) are advised as to the confidential nature of the Confidential Information and (iii) are bound by obligations or fiduciary duties of confidentiality and restrictions on use of the Supplier's Confidential Information;

9.1.3 not modify, reverse engineer, decompile or disassemble any embodiments of the Supplier's Confidential Information;

9.1.4 undertakes to institute and maintain security procedures for the Confidential Information and to strictly limit access of such Confidential Information;

9.1.5 not use the Confidential Information in any way for the development of similar products based on the Confidential Information received or to attempt to manufacture and produce any products employing the same methodology as provided and disclosed by the Supplier;

9.1.6 not use the Supplier's Confidential Information (or permit it to be accessed or used) for any purpose other than in connection with (i) the subject of the Order, (ii) the exercise of the Customer's rights under this GTC or any other written agreement that relates hereto or (iii) any dispute between the Parties and/or their Affiliates;

9.1.7 within thirty (30) days of the Customer receiving a written request from the Supplier, either (i) return to the Supplier or (ii) destroy (and confirm in writing (email is sufficient) that destruction) all tangible embodiments of the Supplier's Confidential Information; provided, however, that the Customer may retain written or electronic copies of Confidential Information (in a secure location) as required for compliance with applicable laws or bona fide document retention policies or for back-up/archival purposes, in which cases, the obligations with respect to the retained Confidential Information will survive any expiration or termination for so long as it is retained; and

9.1.8 be responsible for any disclosure or use by of the Supplier's Confidential Information that is not expressly authorized under this GTC.

9.2 If the Customer or any of its representatives is required by law or by a court, governmental or regulatory agency, arbitrator or other legal proceeding or process to disclose any of the Supplier's Confidential

Information, then the Customer will (i) provide (to the extent practicable and not prohibited by law) the Supplier with prompt written notice of that requirement, so that the Supplier may (at its own cost and expense) seek a protective order and/or other remedy and/or waive the Customer's compliance with the terms of this GTC with respect to that Confidential Information and (ii) reasonably cooperate with the Supplier (at the Supplier's reasonable cost and expense) in protecting the confidential and/or proprietary nature of, and limiting the disclosure and use of, the Confidential Information that must be disclosed. The Parties further agree that if, in the absence of a protective order or the receipt of a waiver, the Customer or any of its representatives is, upon advice of its legal counsel, required to disclose any Confidential Information, then the Customer or that representative may disclose that Confidential Information (but only to the extent necessary to comply with that disclosure requirement).

9.3 The obligations as set forth herein shall not apply however to such part of the Confidential Information for which the Customer can evidence:

9.3.1 was known by the Customer prior to its disclosure by the Supplier; or

9.3.2 was part of the public domain or knowledge, or generally available to the public prior to its disclosure by the Supplier; or

9.3.3 became part of the public domain or knowledge or generally available to the public after the date of disclosure by the Supplier, through no breach of this GTC by the Customer; or

9.3.4 was lawfully obtained by the Customer from a third party, provided that such information had not been acquired directly or indirectly by such third party from the Supplier under a confidentiality obligation; or

9.3.5 was independently developed by the Customer without access to or use of the Information of Supplier.

9.4 This GTC does not grant the Customer or any of its representatives any title, interest or rights (by license or otherwise), express or implied, to the Supplier's Confidential Information other than for use in strict accordance with the terms of this GTC.

9.5 Upon the breach of any confidentiality obligation by the Customer, the Supplier shall be entitled to a penalty in the amount of 5% of the total Supply Price of the Order which shall be due and payable promptly upon notice sent to the Customer.

9.6 The obligations of confidentiality and of non-use of the Confidential Information set forth herein shall remain in full force and full effect for a period of seven (7) years after the last Order of the Customer, with respect to any trade secret within the Confidential Information identified as such in writing, the rights and obligations of the Parties hereunder shall continue for so long as such information remains a trade secret.

10. GENERAL

10.1 No Agency. The Customer may not hold itself to be the Supplier's agent and may not make or enter into any commitments for or on behalf of the Supplier in any way.

10.2 No Assignment. The Customer shall not assign or transfer any of its rights and obligations arising from the business relationship with the Supplier and pursuant to the Order and the provisions herein without Supplier's prior written consent.

10.3 No Subcontractors. The Customer shall not, without Supplier's prior written consent, appoint any sub-distributor or agent for the sale of Products. The Customer shall, in any event, be wholly responsible for any act or omission of any such person.

10.4 Notices. All notices and communications relating to the Products and Orders shall be sent to order@mediradiopharma.hu and any pharmacovigilance relation communication shall be forwarded to safety@mediradiopharma.hu. All notices sent under this GTC or in relation thereto shall be in writing (including e-mails), including any communication or emergency calls made over the telephone which shall be followed-up in a written form as soon as practicable.

10.5 Force Majeure. If the performance of any obligation under this GTC is prevented or delayed by a Force Majeure Event, the affected Party shall give a written notice to the other Party thereof, specifying the Force Majeure Event, the manner in which such Force Majeure Event prevents the Party from complying with the terms and conditions herein, the expected duration, and the measures taken by the affected Party to mitigate the ramification thereof. During a Force Majeure Event, the affected Party shall be released from the performance of its obligations hereunder but shall nonetheless use its best efforts to ensure continued performance. If such Force Majeure Event continues for longer than 90 calendar days, then either Party may rescind the Order or be exempted to perform delivery without further legal consequences. In such cases the Customer shall pay the Supplier all Products delivered prior to termination. For avoidance of doubt, the Parties do not regard any global pandemic as a Force Majeure Event.

10.6 Data Protection. The data provided by the Customer is required for the purposes of performing a business arrangement and agreement of the Parties and only those information will be retained by the Supplier which are strictly necessary for said purpose and only to the extent that the applicable law allows. The detailed rules of data protection are available at http://mediradiopharma.com/privacy-policy.

10.7 Entire Agreement. This GTC and the Order contain the entire agreement of the Parties and supersedes any previous agreements whether verbal or written.

10.8 Governing Law and Dispute Resolution. The Parties shall endeavor to resolve any dispute amicably and in good faith. If the dispute cannot be resolved by negotiation or mediation, any disputes or claims arising out of or in connection with this GTC and the Order, including disputes regarding their validity, breach, termination, or nullity, shall be governed by the laws of Hungary, and the Hungarian courts shall have exclusive jurisdiction and competence to finally settle such disputes.

10.9 Supplier's Whistleblowing Policy is available **here.**

Annex 1 – Quality Annex

Concerning the Distribution of Medicinal Products between

(1) MEDI-RADIOHARMA LTD. a company incorporated under the laws of Hungary, whose registered office is located at 2030 Érd, Szamos u.10-12, Hungary (Site 1). The company operates in close cooperation with its Affiliate company **RADIOPHARMACY LABORATORIUM LTD.**, located at 2040 Budaörs, Gyár utca 2. 10324/66, Hungary; with manufacturing facilities located at both sites. Both affiliate companies shall collectively be referred to as **"MRP" or Contract Acceptor** hereinafter.

(2) CUSTOMER is a company or a healthcare provider (hospital or radiopharmacy centre) incorporated under the laws of **CUSTOMER's Country** whose registered office and registered warehouse/registered address of service is found in the **CUSTOMER's** authorisations, licenses and certificates shall be referred to as **Customer or Contract Provider hereinafter.**

Purpose

The purpose of this Quality Annex is to define the respective roles and responsibilities of the Parties in the manufacture and distribution of radiopharmaceutical kits (herein referred to as "**Products**") as detailed in Appendix 3 of this Quality Annex.

The responsibility for selling and distribution the Product to its customers/to use the Product during healthcare service will be borne by **Customer**.

MRP is an authorized manufacturer of medicinal products and, as such, has suitable premises, equipment and licenses, as well as sufficient suitably trained personnel.

Customer is an authorized wholesaler of medicinal products/healthcare provider (hospital/radiopharmacy centre) in the Territories where Products are to be sold/used.

Appendix 1 of this Quality Annex contains a detailed definition of the pharmaceutical responsibilities borne by the Parties for all Products ordered.

Definitions

"cGDP" means the current EU Guideline on Good Distribution Practice (2013/C 343/01) of November 5, 2013, as replaced or amended from time to time.
"cGMP" means the current principles and guidelines of good manufacturing practice in respect of medicinal products for human use referred to in the Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use and EudraLex Volume 4, as amended or replaced from time to time.
"Operating license" is an official approval, permit or authorization or registration issued by a governmental authority or regulatory body that which are necessary for the lawful and effective operation by the healthcare provider in a specific location and activity. It ensures the compliance with local laws, safety, personnel and facility standards, and environmental regulations.
"Marketing Authorization" means the authorization referred to in Article 5 of the Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use, as amended or replaced from time to time, or equivalent legislation in non-EU/EEA Territories, related to the authorisation and sale of medicinal products.
"Pharmacovigilance Agreement" means the agreement relating to pharmacovigilance, entered into between the **Customer** and the Responsible Person for Pharmacovigilance of MRP.
"Products" means the products detailed in Appendix 3 of this Quality Annex.
"Quality Annex" means this Quality Annex entered into between the Parties.
"Qualified Person" or **"QP"** means the person that is referred to in EU GMP Annex 16 responsible for ensuring that each individual batch has been manufactured and checked in compliance with laws in force in the Member

State where certification takes place, in accordance with the requirements of the marketing authorisation (MA) and with Good Manufacturing Practice (GMP).

"Specifications" means a list of tests, references to analytical procedures, and appropriate acceptance criteria which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a drug substance or drug product should conform to be considered acceptable for its intended use.

"Territory" means the markets in which the Products are sold or distributed.

Basis of the Quality Annex

MRP is a manufacturer of medicinal products and holds a manufacturing authorisation and appropriate regulatory licenses for the manufacture of Products pursuant to applicable European law.

Customer is a wholesale customer of medicinal products/healthcare provider (hospital/radiopharmacy centre) and holds all relevant necessary and valid authorisations, certificates and licences required by the competent local authority of the Territory in order to import and wholesale the Product/use the Product for healthcare service included but not limited to

i. Wholesale Distribution Authorisation and/or Marketing and Import Authorisation or equivalent
ii. Certificate of GDP and/or GMP Compliance or equivalent
iii. unique/individual import license
iv. operating license (in case of healthcare providers)
v. other relevant authorisations, licenses and certificates

When manufacturing the Products, MRP shall comply with all applicable pharmaceutical guidelines and regulations, the requirements of EU GMP.

MRP shall permit the relevant local authorities to perform all the necessary inspections in connection with the manufacture of the Products, as required under applicable law.

MRP has full responsibility for the handling and storage of the Products, until handover to the transport company according to MRP's GTC.

Products are delivered with Incoterms according to the MRP's GTC, which means the cost and responsibility of shipping lies on the **Customer**.

The Parties shall cooperate and assist each other to obtain the shortest transportation time possible.

Customer is responsible to hold adequate, trained personnel on site at the time of receival of the Product.

Customer shall provide a copy of any relevant licenses and their official translations in English upon request and a change regarding the authorisations/lincenses/certificates. In case of loss or expiry of authorisations/lincenses/certificates, Customer shall immediately inform MRP.

Customer is responsible for claiming for the import license in case the Product to be imported does not have Marketing Authorisation in the Territory. **Customer** shall provide a copy of the import license and their official translations in English upon request and change of the license. In case of loss or expiry of authorisations/lincenses/certificates, Customer shall immediately inform MRP.

Customer shall only distribute the Product(s)/use the Product(s) for healthcare service.

Customer shall inform MRP without delay of any change, reneval or extension of, or restriction imposed on its authorisations, licenses, certificates that may be related to the wholesale of the Product(s) or use the Product(s) during healthcare.

Both Parties are responsible for providing each other with accurate contact details of for mutual information giving. All of these contact details shall be kept on file by the Quality Assurance Department of MRP.

In case of wholeasale distribution, the Parties shall cooperate and assist each other in answering relevant questions raised by competent authorities with respect to the manufacture and distribution of Products.

The Parties explicitly acknowledge and agree that MRP is responsible for the quality of Products until holding it on MRP's site, and MRP shall ensure that the Quality Systems, processes, and procedures used by MRP are adequate in all respects in accordance with GMP.

Wholeasale Distributor is responsible and shall ensure that the Quality Systems, processes, and procedures used by **Customer** are adequate in all respects in accordance with and GDP. **Healthcare service providers** are responsible and shall ensure that the Quality Systems, processes, and procedures used by **Customer** are adequate in all respects.

MRP periodically performs risk assessment on **Customer** based on the fulfilment of the requirements set forth in this Quality Annex.

This Quality Annex shall be accessible to competent government authorities upon request.

In the event **Customer** wishes to perform activities not specified in this Quality Annex, **Customer** will be responsible for obtaining any necessary authorisations/ certificates/licenses to permit **Customer** to perform the operation in a compliant manner, and Customer will provide such authorisation/certificate/license to MRP. MRP may permit Customer to perform such activity.

Where such activity constitutes a GxP activity, Quality Annex will be modified accordingly.

Quality, QUALITY Control and Release

MRP, acting under its own responsibility, shall produce, process, package, label, control and certify the Products in accordance with the Specifications. MRP`s QP is responsible for the batch release and certification.

MRP shall ensure that there is a Qualified Person (as defined in Eudralex Volume 4 Annex 16) to certify the Products according to the Products Specifications. The Qualified Person shall have adequate knowledge of the manufacturing procedures and Marketing Authorisation of Products.

MRP is responsible for quality testing on the Product in accordance with the Specifications. In case of deviations, MRP's Qualified Person decides whether the Product may be released to the market.

MRP shall send a change notification in case of all changes related to the Marketing Authorisation. **Customer** shall respond to the change within 30 days. If **Customer** does not respond, the change is considered accepted.

If Customer is a Wholesale Distributor and MRP shall maintain a deviation management system.

If Customer is a Wholesale Distributor and MRP shall maintain a change management system.

If Customer is a Wholesale Distributor is responsible for release the batches of the Product (transferring to saleable stock) for distribution in the Territories according to written procedures.

Storage and Transport

The Products shall be stored by MRP in accordance with the Specifications and with EU GMP.

MRP should ensure that packing shall be made in the manner not to damage products and MRP send to **Customer** specified warehouse/distribution centres or in case of hospitals/radiopharmacy centres, registered address of services.

Products are delivered with EXW Incoterms, which means all responsibilities regarding to the transportation including the decision on the temperature control strategy, selection of packing for transport, mode of transport (road/air) and transport company is of the **Customer**.

MRP shall include in each shipping package a single-use temperature logger in order to verify shipping conditions to **Customer** warehouse/distribution centres or in case of hospitals/radiopharmacy centres, registered address of services. **Distributor** shall read out the registered temperature data.

MRP shall provide the **Customer** with a declaration in the event of temperature excursions occurred during shipping and storage at the Customer's warehouse in order to support its decision on release the Product to the Territory (transferring to saleable stock). Both Parties shall provide all reasonable assistance and support in the investigation, assessment of the excursion and sentencing of the affected Products.

If **Customer** is a Wholesale Distributor, it is responsible for and shall ensure that the end-users in the Territories are in the possession of all required governmental and other relevant authorizations for receiving, handling and using Products, with frequent check-ups according to written procedures.

If **Customer** is a Wholesale Distributor, it is responsible and shall ensure that the local carriers in the Territories are in the possession of all required governmental authorizations for transportation and/or storage of Products in accordance with GMP and GDP.

Rejection, Complaints AND Recalls

The Parties shall have written procedures in place to handle product complaints, recalls and mock recalls, and batch rejection. Both Parties shall keep each other currently informed about complaints concerning Products.

MRP shall communicate any problem likely to cause potential recall of the Product to **Customer's** contact persons as soon as possible, by e-mail. The recall of Product must be initiated by the Marketing Authorization Holder to the relevant local authorities in case the Product has Marketing Authorisation in the Territory. In case the Product is distributed with a unique/individual import license in the Territory, **Customer** is responsible for consulting with the relevant local authority.

Customer is responsible for the identification of the end-users and to collect, report and put into quarantine all Products from the affected batch(es) if instructed to do so by MRP in the event of a recall.

Both Parties shall conduct periodic assessment of their recall processes (also called mock recall). **Customer** shall, if requested, take part in such process and respond within 24 hours. Customer is responsible for designating a person responsible for the coordination of recalls and mock recalls and its substitute.

Customer shall collaborate with MRP on further actions regarding Product quality assurance and the Quality Assurance of the Parties shall cooperate on any mutually agreed-upon corrective and preventative actions and required timelines.

MRP shall provide to **Customer** customer service and quality representatives a complaint report in order to permit **Customer** to respond to its customer.

Customer is responsible for communication with the end-users, according to **Customer**'s complaint handling procedure.

In all cases the investigation of complaints and quality defects, the report shall be closed by MRP within 45 calendar days. The extension may be granted by **Customer** under the following circumstances:
- from when all necessary information is available for carrying out the investigation
- in the event of late receipt of complaint samples
- when an external laboratory is used for analytical controls of complaint samples, e.g. particulate characterization

In case **Customer** rejects the Product, it shall attest the rejection by sending the report of rejection and the report of destruction within 1 business day to MRP.

The responsibilities of the Parties for Adverse Events and lack of efficacy is defined in the Pharmacovigilance Agreement (SDEA).

Duration and Termination

The duration and termination clauses for this Quality Annex are the same as those set forth in GTC.

This Quality Annex shall be reviewed and updated in case of any change to the GTC, if necessary or at longest every 3 years. Such review shall be initiated by MRP. The Parties shall co-operate to conduct this review in an efficient manner.

Confidentiality

The Parties shall treat as confidential all data supplied by the other in connection with the manufacture and distribution of the Products, and identified as confidential, and not themselves use or disclose said data to a third party, other than the competent Marketing Authorization or relevant local authority.

List of annexes

Schedule 1: MRP-QAA-000 A01-1 Responsibility Matrix

Schedule 1
Responsibility Matrix

	Resp. of Customer	Resp. of MRP	Remarks
Quality Management			
Compliance with cGMP, guidelines and regulations		X	
Compliance with cGDP, guidelines and regulations.	X	X	if Customer is a Wholesale Customer
Compliance with local laws, safety, personnel and facility standards, and environmental regulations	X		if Customer is a healthcare service provider
Customer Qualification	X	X	if Customer is a Wholesale Customer
Qualification of supplier of outsourced activities (including transport companies and storage)	X	X	if Customer is a Wholesale Customer
Training of Personnel	X	X	
Self-Inspection	X	X	
Inform MRP about outsourced activities related to storage and transport	X		if Customer is a Wholesale Customer
Periodic risk assessment on Customer based on the fulfilment of the requirements set forth in Quality Annex		X	
In the event Customer wishes to perform activities not specified in this Quality Annex, Customer will be responsible for obtaining any necessary authorisations/ certificates/licenses to permit Customer to perform the operation in a compliant manner, and Customer will provide such authorisation/certificate/license to MRP. MRP may permit Customer to perform such activity.	X	X	
Where such activity constitutes a GxP activity, Quality Annex will be modified accordingly.	X		
Regulatory Requirements			
Hold a valid Manufacturing Authorisation, GMP Certificate and other relevant certificates, licenses in the country of origin.		X	
Obtain required and maintain Regulatory documents in accordance with specifications.		X	
Customer holds all relevant necessary and valid authorisations, certificates and licences required by the competent local authority of the target Territory in order to import and wholesale the Product (included but not limited to Wholesale Distribution Authorisation and/or Marketing and Import Authorisation or equivalent, Certificate of GDP and/or GMP Compliance or equivalent, import license, other relevant authorisations, licenses and certificates).	X		if Customer is a Wholesale Customer

	Resp. of Customer	Resp. of MRP	Remarks
Customer holds all relevant necessary and valid authorisations, certificates and licences required by the competent local authority of the target Territory in order to import use the Product for healthcare service included but not limited to operating license (in case of healthcare providers, unique/individual import license, other relevant authorisations, licenses and certificates).	X		if Customer is a healthcare service provider
Provide a copy of the relevant authorization / licenses/certificates.	X		
Answering relevant questions raised by relevant local authorities with respect to the manufacture and distribution	X	X	If the Product has a Marketing Authorization in the Territory, it is the responsibility of the Marketing Authorization Holder. If the Product is imported solely based on a unique/individual import license, it is the responsibility if the Customer.
Incoming Material Control			
Procurement, testing and release for manufacturing of APIs, excipients, primary and secondary packaging material		X	
Approval of printed packaging material mock-ups		X	
Perform incoming goods control and visually inspect the incoming Product(s) upon receipt to detect - any apparent and visible defects - visible discrepancy of quality, quantity - discrepancy of certificates.	X		
Manufacturing			
Unique batch number assignment		X	
Expiry date assignment in accordance with the shelf life defined in the valid regulatory documentation		X	
Production according to EU GMP & specifications		X	
In-Process Controls		X	
Packaging according to EU GMP & specifications		X	
Quality Control			
Specification verfification against the regulatory documentation of the reference country		X	
Performing Quality Control tests against established specifications		X	
Reference / Retention Samples		X	
Release and Certification			
Batch release by Qualified Person (QP) of MRP		X	

	Resp. of Customer	Resp. of MRP	Remarks
Batch certification by QP (CoA, CoC)		X	
Transfer the Product to saleable stock and release for distribution in the Territory on basis of the delivered certificates of MRP and the corresponding processes by the warehouse.	X		if Customer is a Wholesale Customer
Storage and Transport			
Shipping the Product with EXW Incoterms 2020 to Customer's warehouse, which means all responsibilities regarding to the transportation including the decision on the temperature control strategy, selection of packing for transport, mode of transport (road/air) and transport company is of the Customer.	X		
Provide the shipping packaging with single-use temperature logger in order to verify shipping conditions		X	
Read out the registered temperature data	X		
Provide the Customer with a declaration in the event of temperature excursions occurred during shipping and storage at the Customer's warehouse in order to support its decision on release the Product to the Territory (transferring to saleable stock)		X	
Local transportation to Customers	X		if Customer is a Wholesale Distributor
Providing documentation for the delivery: - Delivery Note - Certificate of Analysis and Certificate of Compliance of the medicinal product - EU Official Control Authority Batch Release Certificate only for HSA API of plasma-derivate based medicinal products on request		X	
Maintain a system for the determination of the status of finished Product/medicinal product in the warehouse	X	X	
Store finished Product/medicinal product in accordance with their respective specifications and storage conditions (including temperature monitoring)	X		
Pest Control	X		
Measures against theft and falsified medicinal products for example security measures and procedures)	X	X	
Stability			
Annual stability testing		X	
Change Control			
Maintain a change management system.	X	X	if Customer is a Wholesale Distributor

	Resp. of Customer	Resp. of MRP	Remarks
Informing the Customer about changes affecting Regulatory documentation, product storage and shipment		X	
Informing the Regulatory Authority of changes affecting Regulatory documentation of a Product imported to the Territory under individual import authorisation	X		
Complaints			
Written procedures to handle complaints	X	X	
Provide information about complaints, evidences and samples.	X		
Obtain information and evidences about complaints (including from the end users)	X		
Investigation of complaints	X (co-operate)	X	
Communication with end-users regarding complaints	X		if Customer is a Wholesale Distributor
Recalls, Mock Recalls and Batch rejection			
Written procedures to handle recalls and mock recalls	X	X	
Designate a person responsible for the coordination of recalls and mock recalls and its substitute	X	X	
Notify the other contract party immediately (latest within 24 hours) about justification of a (potential) recall by e-mail.	X	X	if Customer is a Wholesale Distributor
Initiation of the recall of the Products with Marketing Authorisation on the Territory		X	
Initiation of the recall of the Products distributed with import authorisation to the relevant local authority on the Territory.	X		
Coordinate a recall with respect to the Product	X	X	
Identification of end-users and execution of recall	X		
Inform competent authorities in the Territory	X	X	
Provide a complaint report in order to Customer to respond to its end-users		X	
Communication with the end-users	X		
Initiate and assess a Mock Recall periodically	X	X	if Customer is a Wholesale Distributor
Cooperate and collect information and respond within 24 hours during the Recall and the Mock Recall process.	X		
Collaborate on further actions regarding Product quality assurance cooperate on any mutually agreed-upon corrective and preventative actions and required timelines.	X	X	
Distribution			
Local transportation to Customer and healthcare service providers (hospitals/radiopharmacy centres)	X		

	Resp. of Customer	Resp. of MRP	Remarks
Notification of medicinal products that do not have Marketing Authorization in the target Territory to the relevant local Authorities according to local regulations.	**X**		
Deviations			
Maintain a deviation management system.	**X**	**X**	if Customer is a Wholesate Distributor
Investigation of deviations	**X (co-operate)**	**X (co-operate)**	Depends on origin

Annex 2 – Pharmacovigilance Annex

Pharmacovigilance Provisions under the General Terms and Conditions

The SUPPLIER and the CUSTOMER may be hereinafter referred to as the "Parties" or either one of them as a "Party"

WHEREAS

a) The SUPPLIER is the Manufacturer / Global Safety Database Holder of the pharmaceutical products.
b) The CUSTOMER placing an order for the supply of Product(s) manufactured by the SUPPLIER for diagnostic use in the Territory.

By ordering the medicinal Product(s) of the SUPPLIER, CUSTOMER acknowledges and accepts the following pharmacovigilance obligations and agrees that all related communication shall be conducted in English.

1. **The CUSTOMER** declares that it has an adequate Quality Management system in place and has ensured business continuity to perform the below detailed procedures.

2. **The CUSTOMER** shall notify the COMPANY QPPV via e-mail of all valid and invalid Adverse Events (AEs), adverse reactions (ARs), medical information queries, and product technical/quality complaints reported to or observed by the CUSTOMER in connection with the ordered Products, independently whether the case is assessed as serious or non-serious. Notification must be made immediately upon receipt and, in any case no later than three (3) business days from Day 0, by using CIOMS form or equivalent report form, (see Schedule 1 for definitions, Schedule 2 for CIOMS form and Schedule 3 for Contacts). **The CUSTOMER** shall make all reasonable efforts to collect the minimum necessary information to ensure the case is valid. However, non-valid cases shall also be forwarded to the SUPPLIER without delay.

3. **The CUSTOMER** shall notify the SUPPLIER QPPV via e-mail of following cases, regardless of whether an AE is present, within three (3) business days as required by Module VI of the EU GVP guideline:
    a) Overdose
    b) Off-label use
    c) Misuse/Abuse
    d) Accidental and Occupational Exposure Reports
    e) Pregnancy or Breastfeeding Exposure Reports
    f) Falsified Medicine Reports
    g) Suspected adverse reactions related to quality defect
    h) Drug-to-drug interactions
    i) Lack of Efficacy Reports
    j) transmission of an infectious agent
    k) medication errors

4. **The CUSTOMER** shall cooperate with the SUPPLIER in follow-up activities, if the case follow-up is necessary for valid case generation.

5. **The CUSTOMER** commits itself to informing the SUPPLIER in a timely manner if, for any reason – whether within or beyond its control - it is unable to fulfil its obligation. In this event, the CUSTOMER shall propose alternative solution to meet the relevant requirements.

6. **The CUSTOMER** commits to informing promptly the SUPPLIER in case of lack or inadequacy of the documentation, data or instructions provided by the CUSTOMER, if these deficiencies may result in a failure to perform the assigned task.

7. **The CUSTOMER** shall provide its employees with training on basic pharmacovigilance definitions and tasks required to fulfil the duties outlined in this Clause.

8. **The SUPPLIER** shall be responsible for assessing the incoming information and forward all reportable cases to the relevant European Competent Authorities in accordance with applicable regulations.

9. Reporting the reportable cases to the National Competent Authorities, where required, shall be the responsibility of **the CUSTOMER**. **The CUSTOMER** shall notify **the SUPPLIER** within three (3) working days following the completion of such national reporting.

10. **The SUPPLIER** shall maintain the Products' related Global Safety Database, manage Product Informations (including packaging material elements), handle the aggregate reporting, conduct signal detection activities, and RMP-related duties.

11. **The Parties** shall inform each other by e-mail about any emerging safety issue/urgent safety issue, or change of Product Informations which may affect the Product's safety profile upon receipt, and in any case, as soon as possible, but no later than one (1) business day or three (3) calendar days, whichever is earlier.

12. **The SUPPLIER** reserves the right to conduct pharmacovigilance audits at CONSUMER. **The Customer** acknowledges that **the Supplier** may be required to conduct regular audits to monitor compliance with this SDEA. **The Customer** shall provide the access and cooperation necessary for the performance of such audits.

Annexes

Schedule 1	Definitions
Schedule 2	CIOMS form
Schedule 3	Contact of SUPPLIER

Schedule 1

Definitions and abbreviations

Abuse of a Medicinal Product
Persistent or sporadic, intentional excessive use of medicinal products, which is accompanied by harmful physical or psychological effects.

Adverse Event (AE)
Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product, and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Adverse Drug Reaction (ADR)
A response to a medicinal product which is noxious and unintended [DIR 2001/83/EC Art 1(11)]1.Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility (see GVP Annex IV, ICH-E2A Guideline).An adverse reaction, in contrast to an adverse event, is characterised by the fact that a causal relationship between a medicinal product and an occurrence is suspected. For regulatory reporting purposes, if an event is spontaneously reported, even if the relationship is unknown or unstated by the by healthcare professional or consumer as primary source, it meets the definition of an adverse reaction (see GVP Annex IV, ICH-E2D). Therefore, all spontaneous reports notified by healthcare professionals or consumers are considered suspected adverse reactions, since they convey the suspicions of the primary sources, unless the primary source specifically state that they believe the event to be unrelated or that a causal relationship can be excluded. Adverse reactions may arise from use of the product within or outside the terms of the marketing authorisation or from occupational exposure [DIR 2001/83/EC Art 101(1)]. Use outside the marketing authorisation include off-label use, overdose, misuse, abuse and medication errors.

Serious Adverse Event/Adverse Reaction
A Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR) is any untoward medical occurrence or effect that at any dose:

- results in death
- is life-threatening (i.e. the patient was at risk of death at the time of the event/reaction; it does not refer to an event/reaction which hypothetically might have caused death if it were more severe)
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity (where disability is defined as a permanent or substantial disruption of ability to carry out normal life functions, either reported or defined as per clinical judgement)
- is a congenital anomaly/birth defect
- medically significant event

Any suspected transmission via a medicinal product of an infectious agent is also considered a serious AE/ADR.

A **non-serious AE/ADR** is any adverse event that does not meet the criteria listed above for a serious AE/ADR.

Audit
A systematic, disciplined, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Consumer
For the purpose of reporting cases of suspected adverse reactions, a person who is not a healthcare professional such as a patient, lawyer, friend or relative/parent/child of a patient.

Day 0

Day 0 is the date the first **Parties** or contractor's employee becomes aware of the minimum information for considering a case valid (i.e. (i) an identifiable patient, (ii) a suspect product, (iii) an identifiable reporting source, and (iv) an event).

Emerging Safety Issues (ESI) / Urgent Safety Information (USI):
Safety issue, which could have a significant impact on the benefit-risk balance for the product and/or have implications for public health and require immediate action, including but not limited to the following:

- Major safety concerns identified in a non-interventional post-authorisation study or clinical trial;
- Possible teratogenic effects of the Product or other significant hazard to public health;
- Safety issues published in the scientific and medical literature;
- Safety issues arising from signal detection impacting the Product's benefit/risk balance and/or have implications for public health;
- Safety issues related to the use outside the terms of the marketing authorization;
- Safety issues due to misinformation in the product information of the Product;
- Withdrawal, non-renewal, revocation or suspension of a marketing authorization in any country for safety reason;
- Urgent safety restrictions imposed by any governmental authority;
- Safety issues related to manufacturing / product quality
- Unexpected event in a clinical trial that is likely to seriously affect the benefit-risk balance of the product

Event of Special Interest
Event of special interest to Regulatory Authorities, and therefore required to be recorded by marketing authorisation holder (MAH), regardless whether an adverse reaction is associated:

- Drug interaction
- Parental exposure (pregnancy and breastfeeding)
- Lack or loss of expected pharmacological action/efficacy
- Use in paediatric population
- Use in elderly population
- Overdose
- Abuse
- Off-label use
- Misuse
- Medication errors
- Occupational exposure
- Falsified medicinal products
- Suspected transmission of infectious agents.

Global Safety Database Holder

Good pharmacovigilance practices (GVP) for the European Union
A set of guidelines for the conduct of pharmacovigilance in the EU, drawn up based on Article 108a of Directive 2001/83/EC, by the European Medicines Agency in cooperation with competent authorities in Member States and interested parties, and applying to marketing authorisation holders in the EU, the Agency and competent authorities in Member States.

Healthcare professional
For the purposes of reporting suspected adverse reactions, healthcare professionals are defined as medically qualified persons, such as physicians, dentists, pharmacists, nurses and coroners (see Annex IV, ICH-E2D Guideline).

Individual Case Safety Report (ICSR)
Format and content for the reporting of one or several suspected adverse reactions to a medicinal product that occur in a single patient at a specific point of time. For the purpose of reporting cases of suspected adverse

reactions, the minimum data elements for a case are: an identifiable reporter, an identifiable patient, an adverse reaction and a suspect medicinal product

Medication Error
An unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient (see EMA-PRAC Good Practice Guide on Recording, Coding, Reporting and Assessment of Medication Errors, 23 October 2015).

Minimum criteria for reporting
For the purpose of reporting cases of suspected adverse reactions, the minimum data elements for a case are: an identifiable reporter, an identifiable patient, an adverse reaction and a suspect medicinal product.

Misuse of a medicinal product
Situations where the medicinal product is intentionally and inappropriately used not in accordance with the authorised product information.

Misuse of a medicinal product for illegal purposes
Misuse for illegal purposes is misuse with the additional connotation of an intention of misusing the medicinal product to cause an effect in another person. This includes, amongst others: the sale, to other people, of medicines for recreational purposes and use of a medicinal product to facilitate assault.

Occupational exposure to a medicinal product
For the purpose of reporting cases of suspected adverse reactions, an exposure to a medicinal product as a result of one's professional or non-professional occupation.

Off-label use
Situations where a medicinal product is intentionally used for a medical purpose not in accordance with the authorised product information.
Examples include the intentional use of a product in situations other than the ones described in the authorised product information, such as a different indication in terms of medical condition, a different group of patients (e.g. a different age group), a different route or method of administration or a different posology. The reference terms for off-label use are the terms of marketing authorisation in the country where the product is used

Overdose
Administration of a quantity of a medicinal product given per administration or cumulatively which is above the maximum recommended dose according to the authorised product information. Clinical judgement should always be applied.

Package leaflet
A leaflet containing information for the user which accompanies the medicinal product [Dir 2011/83/EC Art 1(26)].

Periodic safety update report (PSUR)
Format and content for providing an evaluation of the risk-benefit balance of a medicinal product for submission by the marketing authorisation holder at defined time points during the post-authorisation phase.
In the EU, periodic safety update reports should follow the format described in Module VII.

Personal Data
Personal data refers to any piece of information that could specifically identify an individual (e.g. name, initials, postal and/or email address, ID card, clinical records ID). Date of birth (DOB) is considered demographic data and not personal data.

Pharmacovigilance
Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem (see WHO).
In line with this general definition, underlying objectives of pharmacovigilance in accordance with the applicable EU legislation for are:
• preventing harm from adverse reactions in humans arising from the use of authorised medicinal products within or outside the terms of marketing authorisation or from occupational exposure; and

• promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public.
Pharmacovigilance is therefore an activity contributing to the protection of patients' and public health.

Pharmacovigilance system
A system used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities listed in Title IX of Directive 2001/83/EC and designed to monitor the safety of authorised medicinal products and detect any change to their risk-benefit balance [DIR 2001/83/EC Art 1(28d)].
In general, a pharmacovigilance system is a system used by an organization to fulfil its legal tasks and responsibilities in relation to pharmacovigilance and designed to monitor the safety of authorised medicinal products and detect any change to their risk-benefit balance.

Pharmacovigilance System Master File (PSMF)
A detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised medicinal products.

Risk-benefit balance
An evaluation of the positive therapeutic effects of the medicinal product in relation to the risks [DIR 2001/83/EC Art 1(28a)], i.e. any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health [DIR 2001/83/EC Art 1(28)].

Serious adverse reaction
An adverse reaction which results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect [DIR 2001/83/EC Art 1(12)].
Life-threatening in this context refers to a reaction in which the patient was at risk of death at the time of the reaction; it does not refer to a reaction that hypothetically might have caused death if more severe (see Annex IV, ICH-E2D Guideline).
Medical and scientific judgement should be exercised in deciding whether other situations should be considered serious reactions, such as important medical events that might not be immediately life threatening or result in death or hospitalisation but might jeopardise the patient or might require intervention to prevent one of the other outcomes listed above. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalisation or development of dependency or abuse (see Annex IV, ICH-E2D Guideline).
Any suspected transmission via a medicinal product of an infectious agent is also considered a serious adverse reaction.

Signal
Information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action [IR 520/2012 Art 19(1)]. New aspects of a known association may include changes in the frequency, distribution (e.g. gender, age and country), duration, severity or outcome of the adverse reaction.
For the purpose of monitoring data in the EudraVigilance database, only signals related to an adverse reaction shall be considered [IR 520/2012, Art 19(1)].
For the purpose of Section 16.2 of the periodic benefit-risk evaluation report, signals relate to adverse effects (see Annex IV, ICH-E2C(R2) Guideline).

Spontaneous report, synonym: Spontaneous notification
An unsolicited communication by a healthcare professional or consumer to a company, regulatory authority or other organisation (e.g. the World Health Organization, a regional centre, a poison control centre) that describes one or more adverse reactions in a patient who was given one or more medicinal products and that does not derive from a study or any organised data collection scheme (see Annex IV, ICH-E2D).
In this context, an adverse reaction refers to a suspected adverse reaction.
Stimulated reporting can occur in certain situations, such as after a direct healthcare professional communication (DHPC), a publication in the press or questioning of healthcare professionals by company representatives, and adverse reaction reports arising from these situations are considered spontaneous reports (see Annex IV, ICH-E2D), provided the report meets the definition above. Reporting can also be stimulated by

invitation from patients' or consumers' organisations to their members. Reporting made in the context of early post-marketing phase vigilance (EPPV), e.g. in Japan, is also considered stimulated reporting.

Summary of product characteristics (SmPC)
Part of the marketing authorisation of a medicinal product setting out the agreed position of the product as distilled during the course of the assessment process which includes the information described in Article 11 of Directive 2001/83/EC. It is the basis of information for healthcare professionals on how to use the product safely and effectively. The package leaflet is drawn in accordance with the summary of product characteristics (based on A Guideline on Summary of Product Characteristics, Volume 2C of the Rules Governing Medicinal Products in the EU).

Business Day(s)
Business Days means any day from Monday to Friday, excluding Saturdays, Sundays, and national public holidays in the respective Territories.

Schedule 2
CIOMS FORM

SUSPECT ADVERSE REACTION REPORT	

I. REACTION INFORMATION

1. PATIENT INITIALS	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL
(first, last)		Day	Month	Year	Years		Day	Month	Year	APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)										□□PATIENT DIED □□INVOLVED OR PROLONGED INPATIENT HOSPITALISATION □□INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY □□LIFE THREATENING □□CONGENITAL ANOMALY □□OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? □□YES □□NO □□NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRO-
17. INDICATION(S) FOR USE		DUCTION? □□YES □□NO □□NA
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnoses, allergies, pregnancy with last menstrual period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		26-26a. NAME AND ADRESS OF REPORTER (INCLUDE ZIP CODE)
ORIGINAL REPORT NO.	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE □□STUDY □□LITERATURE □□HEALTH PROFESSIONAL □□REGULATORY AUTHORITY □□OTHER	
DATE OF THIS REPORT	25a. REPORT TYPE □□INITIAL □□FOLLOW-UP	

Schedule 3
Contact of SUPPLIER

Central Safety Units:

Medi-Radiopharma Ltd. / Radiopharmacy Laboratórium Ltd.
Common Drug Safety Unit contact details for day-to-day exchange (SDEA-related issues, AE reports, medinfo and safety queries) Tel*:* *+36-30 096 9147* **Email**: safety@mediradiopharma.hu (SDEA-related issues, AE reports) **Email**: medinfo@mediradiopharma.hu (medinfo and safety queries)
Laszlo Kunos MD Qualified Person Responsible for Pharmacovigilance Medi-Radiopharma Ltd. Radiopharmacy Laboratórium Ltd. Hungary, 2030 Erd, Szamos utca 10-12 **Tel:** *+36-30 096 9147* **Email:** laszlo.kunos@qualipharmacon.hu