

Template for Local Adaptation

[Company Name]

Service Level Agreement

For the Supply of

Compounded Systemic Anti-Cancer Therapy

Products

To

[Hospital Name]

Ref: xxxxxxx

This template document has been developed and approved by the NCCP, considering the input of the parenteral SACT Resilience Group, HBS Procurement, the Health Products Regulatory Authority and third party SACT suppliers. The template is developed with consideration for the needs of hospitals and outsourcing suppliers.

Please note that this is a template document and should be adopted and adapted to meet the arrangements agreed between the hospital and third party supplier. This template can be used in conjunction with the NCCP “Guidance on the management of sourcing and supply of SACT products from third party suppliers”.

All comments and feedback are welcome at oncologydrugs@cancercontrol.ie

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| Version | Date | Amendment | Approved By |
| 1.0 | 16/04/2021 |  |  |

**THIS AGREEMENT** is

**BETWEEN**

1. [Company Name] a limited company registered in **[XXXX]** (Company number XXXXXX) and whose registered office is at **XXXXXX** (the **“Service Provider”**), and
2. **[xxxx Hospital], of [address],** having its principal headquarters at [state address] is included within the scope of this contract and is hereafter referred to as (**the “Hospital”),** each a “**Party**” and together the “**Parties**”
3. This Service Level Agreement complements the existing commercial agreement between the hospital and company

## BACKGROUND

1. The HSE National Cancer Control Programme **(“NCCP”)** is a public health programme designed to reduce the number of cancer cases and deaths and improve the quality of life of cancer patients. The NCCP helps reduce the cancer burden and improve services for cancer patients and their families.
2. This template Service Level Agreement (SLA) was developed by the NCCP to support hospitals who outsource systemic anticancer therapy (SACT) from a third party provider.

## AGREEMENT

**1 Definitions**

* 1. In this Agreement, unless the context otherwise requires:
		1. “**Agreement**” means this Agreement, comprised of the clauses and Schedules hereto, together with all amendments thereto made in accordance with these terms, and any other document expressly included by reference herein;
		2. “**Change** ” means any change whatsoever to this Agreement or its terms, including (but not limited to) any change in the Services, the System and/or quality procedures;
		3. “**Change Control Procedure**” means the procedure, as set out in Schedule 6, for agreeing Change Control;
		4. “**Change Order**” has the meaning ascribed in Clause 16.4;
		5. “**Charges**” means the monies payable to the Service Provider in accordance with Clause 8 and as are more particularly set out in the Schedule 2 (excluding VAT);
		6. “**Commencement Date**” means xx/xx/20XX;
		7. “**Confidential Information**” means all information (in any form) designated as such by the parties, in writing, together with (i) all information which relates to the business, affairs, developments, trade secrets, software, know-how, personnel, customers and suppliers of the parties and (ii) any other information which may reasonably be regarded as the confidential information of the disclosing party;
		8. “**Default**” means any breach of the obligations of any party, or any default (including non-payment of valid invoices), act, omission, negligence, or statement, of any party, their employees, agents or sub-contractors in connection with, or in relation to, the subject matter of this Agreement, which causes a material direct loss or material damage to another party;
		9. “**Euro**” or “**€**” means the common currency adopted by one or more members of the European Union, including Ireland;
		10. “**Healthcare Professional**” means a member in good standing of a healthcare profession, regulated under applicable laws and includes a medical doctor, a registered pharmacist and/or a registered nurse employed who is engaged by or on behalf of the Hospital;
		11. **“Intellectual Property”** means patents (including patent applications), registered designs, trademarks and service marks (whether registered or otherwise), copyright, database rights, design rights and other intellectual property rights, including in other jurisdictions that grant similar rights as the foregoing, including those subsisting in inventions, drawings, performances, software, semiconductor topographies, improvements, discussions, business names, goodwill and the style of presentation of goods or services, and in the applications for the protection thereof throughout the world (and “Intellectual Property Rights” means rights, title and interest in such Intellectual Property);
		12. “**Patient**” means any person who is prescribed Compounded SACT under the terms of this Agreement and “**Patients**” shall be construed accordingly;
		13. “**Periodic Review**” means the periodic review that the Review Group will carry out in respect of assessing the performance of the parties in connection with their respective obligations pursuant to this Agreement;
		14. **“Products”** means Compounded SACT approved for treatment of patients in Ireland.
		15. “**Proprietary Materials**” has the meaning ascribed in Clause 9.1;
		16. “**Service Personnel**” has the meaning given in Clause 22.1;
		17. “**SACT**” means systemic anticancer therapy and for the purpose of this document relates to parenteral anti-cancer therapies, including but not limited to chemotherapy, targeted therapies and immunotherapies
		18. “**Territory**” means the Republic of Ireland;
		19. “**Treatment Sites**” means any healthcare treatment sites involved in the treatment of Patients as notified by the Hospital to the Service Provider from time to time; and
		20. “**Working Days**” means Monday to Friday inclusive, excluding bank and public holidays in Ireland.
	2. Clause, schedule and paragraph headings shall not affect the interpretation of this Agreement. References to clauses and schedules are to the clauses and schedules of this Agreement, references to paragraphs are to paragraphs of the relevant schedule.
	3. The schedules and annexes form part of this Agreement and shall have effect as if set out in full in the body of this Agreement and any reference to this Agreement includes the schedules and annexes.
	4. A “person” includes a natural person, corporate or unincorporated body (whether or not having separate legal personality).
	5. A reference to a “company” shall include any company, corporation or other body corporate, wherever and however incorporated or established.
	6. Words in the singular shall include the plural and vice versa. A reference to one gender shall include a reference to the other genders.
	7. A reference to a statute, statutory provision or any subordinate legislation made under a statute is to such statute, provision of subordinate legislation as amended or re-enacted from time to time whether before or after the date of this Agreement and, in the case of a statute, includes any subordinate legislation made under that statute whether before or after the date of this Agreement.
	8. Where the words “include(s)”, “including” or “in particular” are used in this Agreement, they are deemed to have the words “without limitation” following them.
	9. Any obligation in this Agreement on a person not to do something includes an obligation not to agree or allow that thing to be done.
	10. Any term or condition of this Agreement which requires one party:
		1. to make a request of the other party;
		2. to report to the other party; or
		3. to give or obtain notice, notification, confirmation, approval, agreement, consent or permission to or from the other party,

shall (unless expressly stated otherwise) be deemed to include an obligation requiring that party to make that request or report in writing, and to give or obtain such notice, notification, confirmation, approval, agreement, consent or permission in writing.

1. **SCOPE**
	1. This agreement define the roles and responsibilities between the hospital and Service Provider pertaining to the manufacture and delivery of ready-to-administer SACT for patients under the care of the hospital.
	2. In consideration of the payment of the Charges, and subject to the Hospital materially complying with its duties and responsibilities under this Agreement, the Service Provider shall, in accordance with the terms and conditions of this Agreement and subject as may be agreed from time to time:
		1. provide the Products in accordance with Schedule 1 and Schedule 2;
		2. comply with the undertakings set out in Schedule 4; and
	3. For the avoidance of doubt, the parties confirm that the HSE Standard Terms for Supplies & Services, and the terms therein are incorporated into this Agreement unless otherwise varied by the specific terms of this Agreement. The HSE Standard Terms for Supplies & Services is available for download at [www.hse.ie](http://www.hse.ie).
	4. The Parties hereby acknowledge and agree that the HSE may continue to develop new standards/guidelines and/or service levels in connection with the provision of the Products in co-operation and conjunction with the Service Provider. Once agreed by the Parties in accordance with the Change Control Procedure (Schedule 5), the Parties will be expected to adhere to any such new standards/guidelines and/or service levels save that where any guidelines and/or standards are introduced pursuant to applicable law, the Parties shall be responsible at all times to ensure the Products hereunder are provided in accordance with applicable law at all times.
	5. The Hospital hereby acknowledges and accepts that the overall governance of the clinical care of the Patients will be based on the continued association between the Patient and the Healthcare Professionals in the Hospital providing clinical support to the Patient.
	6. The Service Providerwill provide the Products whereby SACT product is compounded by [Company Name] and delivered to the hospital on foot of receipt of an order using the up to date, version controlled [Company Name] order form.
2. **OBJECTIVE**

To establish a service level agreement with agreed indicative volumes, agreed order, delivery processes and timelines as appropriate to the hospital

1. **MANAGEMENT**
	1. The implementation and operation of this Agreement will be overseen by nominees of the Hospital and of the Service Provider.
	2. The Hospital shall nominate the following person for the purpose specified in Paragraph 4.1 above
		1. [XXXXXXX] or substitute or replacement as notified in writing to the Service Provider.
	3. The Service Provider shall nominate the following persons for the purpose specified in Paragraph 4.1 above
		1. [XXXXXXX] or substitute or replacement as notified in writing to the Hospital.
	4. The nominees from both Parties shall meet if required to monitor all aspects relating to the provision of the Products.
	5. The Hospital may, upon reasonable prior written notice to the Service Provider, cause an audit and/or inspection and/or review to be made of the Service Provider’s equipment, records, books of account and other documentation that relate directly to the provision of the Products in order to verify the Service Provider’s compliance with the terms of this Agreement and to verify statements issued by the relevant Service Provider at any time during the term of this Agreement. Any such inspection shall be made by Hospital (or subject to the relevant Service Provider’s consent, a third party designated by the Hospital subject to such third party entering into confidentiality agreement on terms equivalent to those set out in this Agreement). Any audit and/or inspection shall be conducted during regular business hours at the Service Provider’s premises.
2. **DURATION**

The Agreement shall be effective from the Commencement Date and shall remain in force for XX months, unless terminated earlier in accordance with Clause 14 hereof. The terms of this Agreement shall be applicable for the full treatment duration of all Patients who initiate their treatment up to and including xx / xx / 20xx.

1. **INSURANCE**

The Service Provider shall procure that the insurance cover as detailed in Schedule 2 shall be maintained at all times during the Term.

1. **PAYMENT TERMS/CHARGES**
	1. All [Company Name] compounded products are supplied subject to agreed pricing. Prices will be valid for the duration of agreement regardless of when quoted, and will be reviewed annually. Contract prices may be agreed for a specified contract period (greater than 12 months).
	2. The prices quoted are for standard patient specific and/or stock code orders and are inclusive of standard overnight delivery. Additional charges may apply for any delivery outside of standard overnight delivery and these charges may vary depending upon location, level of urgency and courier availability. This will be negotiated and documented in Schedule 1.
	3. Note: All prices quoted are exclusive of VAT.
	4. The hospital should ensure they are in line with HSE requirements when obtaining supply from an outsource provider. This should consider any restrictions on procurement of the base molecule e.g. items being reimbursed via ODMS claims must be procured through an Irish supplier and the claims should reflect the correct vial size and product used in the manufacture of that product.
	5. Additional charges may apply for certain ‘TBC’s’ or ‘on-hold’ orders or urgent orders as highlighted in paragraph 1.5.1. and 1.5.2 of Schedule 1. These should be discussed and agreed before orders are processed.
	6. The prices for the Products to be supplied under this Agreement shall be as follows:

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| --- | --- | --- | --- |
| **Drug name****(INN / Generic name)** | **Brand name - if MAB or Biosimilar** | **Price** | **Unit of Measure** |
| e.g. Rituximab  | e.g. Mabthera |  |  |
| e.g. Cyclophosphamide |  |  |  |
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* 1. In consideration of the provision of the Products, and in accordance with the terms of this Agreement, the Hospital shall pay the Charges, in accordance with Schedule 1.
	2. The Service Provider shall also ensure that the requisite datasets are provided to the Hospital on or after the Commencement Date so as to facilitate electronic payment of the Charges in accordance with this Agreement.
	3. The Service Providershall meet the requirements of the Hospital including the supply of invoices and supporting documentation.
	4. The Charges are exclusive of Value Added Tax (“VAT”). Upon receipt of a valid invoice for VAT purposes, the Hospital shall pay to the Service Provider in addition to the Charges, a sum equal to the VAT chargeable on the Charges. VAT payable by the Hospital on the Products supplied shall be at the rate(s) prescribed by law. The Charges shall be invoiced by the Service Provider to the Hospital.
	5. Payment of Charges shall be made in accordance with the Prompt Payments Act 1997 (as amended) upon receipt of the Service Provider’s invoices to the bank account nominated in writing by the Service Provider. All Charges shall be paid in Euro or Sterling as agreed between parties.
	6. In the event that the Hospital fails to pay any Charges that are due in accordance with this Clause 7, then the Hospital shall pay interest on the overdue amount in accordance with the Prompt Payments Act 1997 (as amended).
	7. Subject to this Clause 7.7 and Clause 7.11, all Charges payable to the Service Provider under this Agreement shall be made free and clear of and without deduction or set off whether for or on account of taxes or otherwise, save to the extent of monies due and payable from the Service Provider to the Hospital during the Term that may be agreed in writing between the parties in connection with the provision of the Products.
	8. In the event of termination of this Agreement in accordance with its terms, payments by the Hospital to the Service Provider shall be due and owing only up to the date of termination and cessation of the provision of the Products.
	9. The Service Provider shall provide satisfactory evidence of tax compliance by providing the Hospital with evidence of its Tax Clearance status on request.
	10. The parties acknowledge and confirm that the payment by Hospital to the Service Provider of all Charges under this Agreement shall fully satisfy the Hospital’s payment obligations in respect of the provision of the Products under this Agreement.
	11. Payment queries will be addressed by the Service Provider directly with [XXXXXXX].
1. **OBLIGATIONS**
	1. The Service Provider shall
		1. be responsible for the manufacture and delivery of the Products to the Hospital in accordance with this Agreement;
		2. provide the Products in accordance with all applicable laws, regulations, licences and consents;
		3. immediately or as soon as reasonably practicable notify the Hospital of any matter which may affect the provision of the Products, and agree and implement the appropriate corrective action necessary;
		4. record the matter and corrective action as specified in 8.1.3 and make same available to the Hospital on request;
		5. respect the individuality of the Patient and the principle of the promotion of the well-being of each Patient;
		6. In the event the Hospital amends or cancels an order for the Products after the Products have been provided to the Hospital, the Hospital accepts that it shall be liable to the Service Provider for the costs reasonably incurred by the Service Provider in connection with the provision of the Products up until the date of receipt of the amendment and/or cancellation, such costs not to exceed the total Charges that would ordinarily be incurred in respect any such order for the Products. The Parties agree to discuss in good faith at Review Group meetings the extent to which costs are being incurred in respect of any such amendments and/or cancellations with a view to ensuring mechanisms are agreed to seek to minimise any such costs being incurred. [Specify time and cancellation fee arrangement]
2. **INTELLECTUAL PROPERTY RIGHTS**
	1. All Intellectual Property Rights, including patent rights, in any pre-existing works of authorship, inventions, trademarks, service marks, databases, designs, software (including without limitation the software), methodologies, know-how, Processes, records, documentation, information or other material (“**Proprietary Materials**”), provided or made available by any party to this Agreement, the title to which is vested and shall remain vested in the relevant party (or its licensors) who provided or made available such Proprietary Materials.
	2. For the avoidance of doubt, title to all Patient data shall vest and remain vested in the Hospital.
	3. This Agreement does not assign (and shall not be deemed to assign) any Intellectual Property Rights of any party hereto existing prior to the Commencement Date or developed independently of this Agreement.
3. **DATA PROTECTION AND DATA SECURITY**
	1. The parties herby acknowledge and agree that the Service Provider will provide the Products in accordance with the HSE Service Provider Data Processing Agreement set out in Schedule 6 and in line with EU General Data Protection Regulations.
4. **WARRANTIES**
	1. Each party warrants and represents to each other that:
		1. it has full capacity and authority and all necessary consents to enter into and to perform this Agreement, and this Agreement is executed by a duly authorised representative;
		2. save as expressly set out in this Agreement it has no right, title or interest in or to any and all Proprietary Materials of the other parties collected, processed, created and managed by it, all of which will belong exclusively to the other relevant party and it shall not disclose, divulge, offer, supply, licence, rent, exchange, resell or re-use any of the other relevant party’s Proprietary Materials, save as expressly permitted, whether now or at any time in the future;
		3. at all times in matters arising from or in connection with the performance of this Agreement it will be and remain in full compliance with all applicable legislation in Ireland;
	2. The Service Provider warrants to the Hospital that:
		1. where the Service Provider is required to hold a valid Marketing Authorisation for the Products, he shall hold such licence (as applicable) during the Term, and will operate in compliance with the provisions therein in the context of the Products being provided. The Service Provider shall produce evidence of such licences to the Hospital if requested to so do;
		2. he will ensure that the disposal of healthcare waste arising from the provision of the Products will be fully compliant with the provisions of any applicable permits and all local and European legislation. He further warrants that copies of all relevant permits and licences are kept on file for auditing and review purposes.
		3. he will operate a comprehensive Quality Management System in line with best practice covering all elements of his business processes including; Clinical Governance, Customer Service/ Administration & Operational Staff Training, Manufacturing, Quality Assurance, Pharmacy, Purchasing, Warehousing, Distribution, Sales & Marketing, Documentation, Recalls & Traceability, Near Misses, Internal SOP's, Complaints Handling and Customer Services.
		4. to the best of his knowledge, the provision of the Products shall not infringe any Intellectual Property Rights of any third party;
		5. the Products shall be supplied by appropriately experienced, qualified and trained personnel with all due skill, care and diligence that would be reasonably expected from a skilled and experienced person engaged in the same or similar type of undertaking;
		6. he shall allocate appropriate and sufficient capacity to meet his obligations in the provisions of the Products;
		7. he shall comply with relevant applicable standards in relation to the inventory and traceability of all Products supplied; (including batch numbers, dates of manufacture, delivery and retrieval of Products, and return of outdated Products).
		8. he shall provide the Products in all material respects in accordance with this Agreement and its Schedules;
		9. where applicable, he is the owner of or is authorised to use any hardware, software, machines and/or equipment which are in his custody or control and which are necessary for the provision of the Products; and
		10. he shall obtain warranties and representations from any sub-contractors employed in the provision of the Products equivalent to those contained in this Clause 11.2.
	3. The Hospital warrants to the Service Provider:
		1. that it shall comply with its undertakings as set out in Schedule 3 at all times during the Term;
		2. that it shall co-operate as reasonably necessary with the Service Provider and his approved sub-contractor(s) during the term of the Agreement and that its representatives on the Review Group shall have full authority to make final decisions in relation to the Agreement, for and on behalf of the Hospital and shall conduct itself and make all decisions in a timely and efficient manner; and
		3. it will provide lawful access to such of its premises, software and systems as is reasonably necessary (which such access will be subject to Hospital’s applicable standard and procedures) in order for the Service Provider and his sub-contractor(s) to provide the Products.
	4. Except as expressly set forth in this Agreement and as provided for in section 12 and section 13 of the Sale of Goods Act, 1893 (as amended), all warranties, terms and conditions whether oral or written, express or implied by law custom or otherwise are hereby excluded to the extent permitted by law.
5. **LIMITATION OF LIABILITY**

12.1 The following provisions in this Clause 12 set out the Service Provider’s entire aggregate liability to the Hospital (including any liability for the acts and omissions of the Service Provider’s employees, agents or sub-contractors) in respect of:

* + 1. a direct or indirect breach or negligent performance or failure in performance by the Service Provider (including by or as a consequence of the actions of their sub-contractors, agents, employees or other persons in the Service Provider’s control) of the terms of this Agreement; or
		2. a tortious act or omission for which the Service Provider is liable and arising in connection with the provision of the Services, or the performance or contemplated performance of this Agreement.
	1. In no event shall any party be liable for:
		1. loss of profits, loss of revenue or loss of anticipated savings;
		2. loss of business or opportunity, loss of goodwill or injury to reputation;
		3. any special, indirect or consequential loss or damages, arising out of or in connection with this Agreement. This shall not affect the liability of any party to perform their obligations under this Agreement.
	2. Notwithstanding anything to the contrary contained in this Agreement, a party’s liability to the other for:
		1. death or personal injury resulting from their negligence or that of its employees, agents or sub-contractors; or;
		2. fraud, or fraudulent misrepresentation, misstatement, act or omission;
		3. a material breach of Clause 13;
		4. deliberate personal repudiatory breaches of this Agreement which deprive the non-breaching Party of the whole or substantially the whole of the benefit of this Agreement;
		5. any matter in respect of which it would be unlawful to exclude or restrict liability pursuant to applicable laws, shall not be limited.
	3. The parties hereby acknowledge and agree that in the event that any party is subject to a third party claim in connection with any aspect connection to the provision of the Products (a “**Third Party Claim”**) and such Third Party Claim arises as a result of the other party (or parties) (i) negligence, or (ii) reckless act or omission, or (iii) breach of this Agreement (the “**Breaching Party** or **Breaching Parties**”), the liability of the Breaching Party (or Breaching Parties) shall be the direct costs, expenses and/or damages awarded to the relevant third party the subject of the Third Party Claim or such proportion of the award to the third party as a court may direct the Breaching Party and/or Breaching Parties is responsible for.
	4. The Parties expressly agree that should any limitation or provision contained in this Clause 12 be held to be invalid under any applicable statute or rule of law it shall, to that extent, be deemed omitted, but if any party thereby becomes liable for loss or damage which would otherwise have been excluded or limited such liability shall be subject to the other limitations and provisions set out herein.
	5. Nothing in this Agreement shall prevent or restrict either party from obtaining such injunctive or equitable relief, or remedy, as may be granted to it by an appropriate court.
	6. Except as expressly provided by this Agreement, nothing in this Agreement creates, is intended to create, or shall be deemed to create, any benefits, rights, claims, obligations, or causes of action, in, to, or on behalf of, any party, or entity, other than those parties to this Agreement.
1. **CONFIDENTIAL INFORMATION**
	1. The Parties undertake to hold confidential any information provided by either Party in the operation of this Agreement subject to their obligation under Law.  The Parties, however, may share information received with relevant Government Departments, who are subject to Freedom of Information Act[[1]](#footnote-2).

13.2 In respect of any confidential information, including patient details which it may receive from the other party, and subject always to the remainder of this Section 13, each party undertakes to keep such Confidential Information secret and strictly confidential and shall not disclose it to any third party without the prior written consent of the disclosing party, provided that:

13.2.1 The receiving party shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the commencement of the Agreement;

13.2.2 The provisions of this Clause 13 shall not apply to any Confidential Information which:

 (a) is in or enters the public domain other than by breach of the Contract or any other act or omission of the receiving party, or

 (b) is obtained by a third party who is lawfully authorised to disclose such information, or

 (c) is authorised for release by the prior written consent of the disclosing party.

13.3 Nothing in this Clause 13 shall prevent the receiving party from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim, or otherwise by applicable law or, where [Company Name] is the receiving party, to its immediate or ultimate holding company.

13.4 For the avoidance of doubt, Confidential Information shall be deemed to include, but not be limited to, all Product prices and service fees and all information pertaining to [Company Name]’s method of operation.

1. **TERMINATION**
	1. Unless terminated earlier in accordance with the provision of this Agreement, this Agreement shall continue in effect for the Duration.
	2. The Hospital may terminate this Agreement immediately upon notice:
		1. Where the Service Provider is in Default of any obligation set out in this Agreement and:
			1. the Default is, by its nature, capable of remedy and the Service Provider shall have failed to remedy the Default within thirty (30) days of written notice by the Hospital or such longer period as the Hospital, in its sole discretion, may determine to be appropriate, specifying the Default and requiring its remedy; or
			2. the Default is a breach of a fundamental term of this Agreement and, by its nature, not capable of remedy;
	3. The Service Provider may terminate this Agreement immediately upon notice where the Hospital is in Default of any obligation set out in this Agreement, and;
		1. where the Default is, by its nature, capable of remedy and the Hospital shall have failed to remedy the Default within thirty (30) days of written notice by the Service Provider or such longer period as the Service Provider, in its sole discretion, may determine to be appropriate, specifying the Default and requiring its remedy;
		2. where the Hospital is in Default which is a breach of a fundamental term of this Agreement and, by its nature, not capable of remedy;
	4. The Hospital may terminate this Agreement immediately upon notice where the Service Provider, being a company, passes a resolution, or the court makes an order that it be wound up otherwise than for the purpose of a bona fide reconstruction or amalgamation, or a receiver, receiver and manager, administrator, or examiner is appointed in respect of the business or any part thereof of or circumstances arise which entitle the court or a creditor to appoint a receiver, administrator or examiner or which entitle the court otherwise than for the purpose of a bona fide reconstruction or amalgamation to make a winding up order, or any similar event occurs under the law of any other jurisdiction.
	5. In the event of any termination or expiry of this Agreement:
		1. the Service Provider and the Hospital shall, using good faith endeavours, agree an exit plan to ensure the smooth conclusion of their commercial arrangements and exit from the Services in a manner consistent with patient safety;
		2. subject always to the Intellectual Property Rights of the Service Provider, the Service Provider shall provide the Hospital or a replacement contractor nominated by Hospital with any and all Hospital Proprietary Materials in their possession relating to the provision of the Products, either in its then current format or in a format nominated by Hospital (in which event, the Hospital will reimburse the Service Provider the reasonable data conversion expenses). Alternatively, on Hospital’s written instruction the Service Provider shall cease to use Hospital’s Proprietary Materials and, at the request of Hospital, shall destroy all copies of Hospital Proprietary Materials then in their possession. In either event, the Service Provider hereby agrees to Hospital audit of their performance of its obligations set out in clause 3.5 which shall include, but not be limited to, the relevant senior management of the Service Provider executing a certificate of compliance in a reasonable format produced by Hospital and permitting a Hospital site visit to the Service Provider’s business locations upon not greater than 3 Working Days’ notice. The Service Provider hereby grants the Hospital a licence to enter their business locations, for the purpose of conducting such audit, subject always to compliance by the Hospital with its obligations under this Agreement.
	6. Termination in accordance with this Clause 14 shall not prejudice or affect any right of action, liability or remedy, which shall have accrued or shall thereafter accrue to any party.
	7. All provisions of this Agreement which are, by their nature, intended to survive expiry or earlier termination shall survive expiry or earlier termination of this Agreement.
	8. In the event of termination of this Agreement in accordance with its terms for any reason, payments of the Charges shall accrue only up to the date of termination and cessation of the provision of the Products.
2. **ASSIGNMENT AND SUB-CONTRACTING**
	1. The Service Provider shall not without the written consent of the Hospital assign the benefit or burden of this Agreement or any part thereof.
	2. The Service Provider must obtain the prior written consent of the Hospital if it wishes to engage an agent, subcontractor or third party in the provision of the Products or part thereof.
	3. No sub-contracting by the Services Provider shall in any way relieve the Service Provider of his responsibilities under this Agreement.
3. **AMENDMENTS AND CHANGE CONTROL**
	1. This Agreement shall not be varied or amended, unless such variation or amendment has been agreed in writing by the Service Provider and by a duly authorised representative of the Hospital.
	2. If any party identifies a requirement for a Change, or wishes to make any Change, such Change shall be governed by the provisions of the Change Control Procedure, specified in Schedule 5
	3. In the event that the parties cannot agree to a Change pursuant to Change Control Procedure, the matter shall be escalated in accordance with Clause 17.
	4. A Change can only become effective when it is documented in writing and is signed by all parties in accordance with the Change Control Procedure (“Change Order”).
4. **DISPUTES**
	1. To the extent any dispute arises as between any of the parties hereto (other than in respect of the non-payment of Charges), any party may at any time initiate the dispute resolution procedure set out in Part Six of the HSE’s Standard Terms for Supplies and Services[[2]](#footnote-3).
5. **NOTICES**
	1. Any notice given under this Agreement shall be in writing and signed by or on behalf of the party giving it and shall be served by sending it by email for the attention of the relevant party set out in Clause 18.2 (or as otherwise notified by that party pursuant to this clause). Any such notice shall be deemed to have been received provided that if deemed receipt occurs before 9am on a business day the notice shall be deemed to have been received at 9am on that day, and if deemed receipt occurs after 5pm on a business day, or on a day which is not a business day, the notice shall be deemed to have been received at 9am on the next business day.
	2. The contact details of the parties for the purposes of Clause 18.1 are:

[Company Name] Limited

For the attention of: [XXXX XXXXX]

Email: [XXXXXXX]

[XXXXXXX Hospital]

For the attention of: [XXXX XXXXX]

Email: [XXXXXXX]

* 1. In proving such service it shall be sufficient to prove that the email containing such notice was sent to the email address of the relevant party set out in Clause 18.2 (or as otherwise notified by that party hereunder) and confirmation that the email has been received.
1. **GOOD FAITH**

Each party will act with utmost good faith toward the other parties in the performance of this Agreement.

1. **FURTHER ASSURANCE**

Each party shall promptly execute and deliver all such documents, and do all such things, or procure the execution of documents and doing of such things as are required to give full effect to this Agreement and the transactions contemplated by it.

1. **FORCE MAJEURE**
	1. A Party, provided that it has complied with the provisions of Clause 21.3, shall not be in breach of this Agreement nor liable for any failure or delay in performance of any obligations under this Agreement (and, subject to Clause 21.4, the time for performance of the obligations shall be extended accordingly) arising from or attributable to acts, events, omissions or accidents beyond its reasonable control (“Force Majeure Event”), including but not limited to any of the following:
		1. Acts of God, flood, earthquake, windstorm or other natural disaster;
		2. epidemic or pandemic (but only where such epidemic or pandemic could not have been reasonably foreseen by the Service Provider and where such epidemic or pandemic causes an unexpected surge in demand for the Services);
		3. war, threat of or preparation for war, armed conflict, imposition of sanctions, embargo, breaking off of diplomatic relations or similar actions;
		4. any law or government order, rule, regulation or direction, or any action taken by a government or public authority which materially adversely affects the direct performance of the Services in accordance with this Agreement;
		5. terrorist attack, civil war, civil commotion or riots;
		6. nuclear, chemical or biological contamination or sonic boom;
		7. extreme adverse weather conditions;
		8. strikes, industrial action or lockouts.
	2. The corresponding obligations of the other Party will be suspended to the same extent as those of the Party first affected by the Force Majeure Event.
	3. Any Party that is subject to a Force Majeure Event shall not be in breach of this Agreement provided that:
		1. it promptly notifies the other party in writing of the nature and extent of the Force Majeure Event causing its failure or delay in performance; and
		2. it could not have avoided the effect of the Force Majeure Event by taking precautions which, having regard to all the matters known to it before the Force Majeure Event, it ought reasonably to have taken, but did not; and
		3. it has used all reasonable endeavours to mitigate the effect of the Force Majeure Event, to carry out its obligations under this Agreement in any way that is reasonably practicable and to resume the performance of its obligations as soon as reasonably possible.
	4. In the event of any Force Majeure Event, the Parties shall look to take all reasonable actions as are possible having regard to the circumstances giving rise to the Force Majeure Event to ensure the continuity of Patient care.
	5. If the Force Majeure Event prevails for a continuous period of more than three (3) months, any Party may terminate this Agreement by giving 14 days’ written notice to the other Party. On the expiry of this notice period, this agreement will terminate. Such termination shall be without prejudice to the rights of the Parties in respect of any breach of this Agreement occurring prior to such termination.
	6. For the avoidance of doubt non-payment of any amount due to a Party pursuant to this Agreement shall not be excused by a Force Majeure Event.
2. **SERVICE PERSONNEL**
	1. For the avoidance of doubt, this Agreement is a contract for provision of Products between the Hospital and the Service Provider and personnel engaged by the Service Provider in the provision of the Products (the “Service Personnel”) shall in all respects be the responsibility of the Provider and not of the Hospital. The Hospital acknowledges that all Healthcare Professionals and personnel engaged by the Hospital in relation to the provision of the Products shall in all respects be the responsibility of the Hospital and not the Service Provider.
	2. The Service Provider (as the employer) must be satisfied with and is responsible for the suitability of all Service Personnel employed by it.
	3. The Hospital and the Service Provider hereby agree that for so long as this Agreement remains in force, it remains the intent of all Parties that all Service Personnel shall not be, nor deemed to be, employees of the Hospital by virtue of this Agreement during the Term and that all Hospital personnel shall not be, nor deemed to be, employees of the Service Provider by virtue of this Agreement.
	4. The Service Provider will indemnify the Hospital against all claims, expenses, liabilities and awards (including reasonable legal fees) whatsoever arising out of or in connection with claims (statutory, contractual or otherwise) made by or on behalf of any Service Personnel which relates to their employment by the Service Provider (or any of their sub-contractors) during the Duration, including any for which the Hospital is or becomes liable for any reason upon the expiry or termination of this Agreement.
3. **23 GENERAL**
	1. Each Party shall at all times comply with all applicable laws and regulations and the highest standards of business conduct.
	2. Neither this Agreement nor any rights or duties hereunder may be assigned or transferred by either Party without the prior written consent of the other party.
	3. This Agreement, together with the documents incorporated herein in accordance with Clause 2.3, constitutes the complete and exclusive understanding of the parties and supersedes all other agreements, representations, (excluding only fraudulent misrepresentations) proposals or arrangements between the Parties, regarding the subject matter hereto.
	4. Nothing in this Agreement is intended to, or shall operate to, create a partnership between the Parties, or (save where expressly stated) to authorise any Party to act as agent for the other, and no Party shall have authority to act in the name or on behalf of or otherwise to bind the other in any way (including the making of any representation or warranty, the assumption of any obligation or liability and the exercise of any right or power).
	5. A waiver of any right or remedy under this Agreement is only effective if given in writing in a timely manner (as agreed by both parties) and shall not be deemed a waiver of any subsequent breach or default. A failure or delay by a Party to exercise any right or remedy provided under this agreement or by law shall not constitute a waiver of that or any other right or remedy, nor shall it preclude or restrict any further exercise of that or any other right or remedy. No single or partial exercise of any right or remedy provided under this Agreement or by law shall preclude or restrict the further exercise of any such right or remedy.
	6. If any provision of this Agreement is void or unenforceable at law, such provision shall be severed and the remainder of the Agreement shall continue in full force and effect.
	7. The construction, performance and validity of this Agreement shall be governed by the laws of Ireland and the parties hereby submit to the exclusive jurisdiction of the Courts of Ireland.

**Schedule 1**

**THE REQUIREMENT**

**1.1 Quality Assurance and Regulatory Compliance**

The [Company Name] compound aseptically prepared medicinal products according to the Health Products Regulatory Authority (HPRA) *Manufacturing Authorisation* and is compounded to cGMP standards. All compounded products are deemed by the regulatory authorities to be unlicensed exempt medicinal products. All product is distributed in accordance with HPRA Good Distribution Practice license.

**OR**

The [Company Name] holds a current manufacturer’s licence or a manufacturer’s “specials” licence issued by the Medicines Health Regulatory Authority (MHRA) covering the manufacture of aseptically prepared medicinal products. All compounded products are deemed by the regulatory authorities to be unlicensed exempt medicinal products (EMPs). All product is distributed in accordance with GDP requirements. From 1st January 2021, all EMPs sourced from the UK will need to be sourced through an authorised operator, i.e. a holder of a manufacturer and import authorisation or a wholesaler authorisation located in the EU/EEA.

 [Company Name] compounds all hospital SACT products against an ‘order’ received from the hospital. [Company Name] does not screen for licensed maximum doses or routes of administration. The screening of clinical protocols remains the responsibility of the customer and [Company Name] does not take responsibility for any compounded product which is ordered and / or used outside the terms of the product marketing authorisation.

 Communication of this order by, or under supervision of a Pharmacist/ prescriber via fax, electronic transmission or [Company Name] future web ordering web portal constitutes placing of a bona fide unsolicited order.

 Incidences of Products Quality Complaints and Adverse Events should be reported to the company representative or customer services at the time of occurrence or as soon as practicable.

 **1.2** **SACT Labelling**

 All SACT doses will be labelled in accordance with [Company Name] procedures, HPRA requirements and NCCP recommendations for product label format at the time of manufacture, including drug name, diluent, batch number, expiry date, dosage, patient name and number(where required), storage instructions for the dose.

 **1.3** **Customer Service**

 [Company Name] Compounding Unit Customer Service Staff will be contactable to assist the hospital with any queries, between the hours Xam and Xpm, Monday to Friday (excluding Bank Holidays) Phone XX-XXXXXXX or email Compounding Orders@company.com

 **1.4** **Order Process**

 All orders must be placed using version controlled [Company Name] **Order Forms for both Patient Specific and Stock codes. These order forms may be paper based (ensure up to date versions available) or online.**

**Note:** Should a web-based ordering tool or an automated / manual data exchange from an electronic medicines management system become available, both parties will work to transition to this mode and this would be subject to agreement.

Both ‘parties’ agree that **product is to be compounded and delivered to the ‘hospital** **pharmacy’ by ‘**[Company Name]**’ for the treatment of patients attending the Hospital** over a XX month time period commencing DD/MM/YYYY

 **All** orders for Monoclonal antibodies to be manufactured using biosimilar products must be ordered by brand name.

 **1.5** **Order Turnaround Times:**

 1.5.1 **Standard patient specific (PS) orders**

 A standard order for patient specific is defined as an order placed not less than XX

 working days ahead of the treatment date (i.e. order on XXXday for treatment on XXXday).

 [Company Name] shall deliver standard PS orders the day before the treatment date. The price of standard compounded orders is inclusive of standard overnight delivery charges.

Standard orders for patient specific product shall be placed before XXpm Monday – Friday (excluding Bank Holidays see Section 1.7)

|  |  |  |
| --- | --- | --- |
| **Day X – order before time** | **Day X – Delivered****(Standard overnight)** | **Day X – Treatment day** |
| **Specify days** |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

 It may not be possible for a hospital to confirm a dose for a certain patient when placing an order. The hospital place this order as a ‘To be confirmed’ (TBC) or ‘on hold’. TBC items should be pre-agreed with [Company Name] in view of the impact on production efficiency and capacity.

[Company Name] will endeavour to work with Hospitals who may have specific requirements around specific drugs in this regard.

‘To be confirmed’ or ‘on hold’[[3]](#footnote-4) orders are agreed as follows;

|  |
| --- |
|   |

 1.5.2 **Urgent orders (to define time period for urgent items)**

 Where possible, [Company Name] will endeavour to respond to any urgent requirements that may arise on the part of the hospital within XX working days. Please note that additional courier charges may apply and are as agreed at the commencement of this agreement in (YY) or will be discussed at the time of order.

 1.5.3 **Short shelf life product**

 Product with stability of less than 24 hours may require a same day delivery. Delivery arrangements and respective delivery charges on short shelf life product will vary depending upon locations and hospital requirements. Delivery requirements and charges will need to be specified and agreed as follows:

|  |
| --- |
|  |

 1.5.4 **Stock Codes (e.g. Dose banded items e.g. infusors)**

 Orders for stock codes shall be placed before [specify time and days] (excluding Bank Holidays) and will be delivered as follows;

|  |  |
| --- | --- |
|  **Day 1 – order before XXXX am/pm** | **Delivery Day (standard overnight)** |
| Monday | XXXday |
| Tuesday | XXXday |
| Wednesday | XXXday |
| Thursday | XXXday |
| Friday | XXXday |

Should a stock be unavailable at the time of order the customer may choose to order patient specific

Product at patient specific pricing.

Product will be shipped with the best available shelf life. Minimum shelf life may vary based on products ordered. Both parties agree to the following minimum shelf life on the following products; shorter stock may be supplied in agreement with the customer;

|  |
| --- |
| Minimum guaranteed shelf life for items:Minimum guaranteed shelf life for batch pumps:Other batch items shelf life guarantee: |

**1.5.5 Unavailability to Supply:**

Should [Company Name] be unable to supply a particular dose due to unavailability of one or more raw materials, it will notify the Hospital as soon as possible, and provide an estimate of the expected availability.

**1.6 Volume:**

Both ‘Parties’ agree that approximately \_\_\_\_\_\_\_units of compounded product per annum will be the indicative volume of product ordered by the ‘Hospital’ from ‘[Company Name]’, or \_\_\_\_\_ units weekly for the duration of this agreement. This will be reviewed on a quarterly basis.

See Appendix 1 for estimated volumes template.

The guaranteed number of items to be received by [XXXXXXX Hospital] each week is: \_\_\_\_\_\_\_

The volume percentage margin is +/- (XX)%

**1.7 Notice periods**

Each party must give a minimum of XX days notice should there be a change to an order or indicative volumes agreed previous.

**1.7 Bank Holidays and Holiday periods**

The weekly guaranteed volumes ordered by [XXXXXXX Hospital] will not be impacted by increased demand around holiday periods. Holiday orders in excess of guaranteed volumes will be received up to XX working days before the beginning of the holiday period (Christmas, Easter). This date will be agreed by both parties XX weeks before the Holiday period.

**OR**

The Holiday order will be received up to XX working days prior to the beginning of the holiday period. Please specify.

Easter:

Christmas:

Bank Holidays:

Orders for holiday periods in excess of the minimum weekly volume shall be ordered separately. Delivery times may vary during these periods and should be discussed and agreed.

**1.8 Hospital Obligations**

1.8.1 The Hospital shall ensure that all orders placed under this Agreement are done so using the[Company Name] Specified Order Forms, and are placed by [insert time] each day, for delivery as per service requirement. The Hospital shall ensure that all staff raising orders are appropriately trained and qualified. The Hospital accepts that it is solely responsible for all clinical checks in respect of doses ordered from [Company Name].

1.8.2 Patient Specific orders should include the following information: hospital name, purchase order number, patient name, patient number, dosage requirements and treatment date. For short-dated items the intended time of administration to the patient is also required.

1.8.3 Dose banded stock orders should include the following information: Drug name, drug dose, final volume, drug form

1.8.4 Should it be necessary to amend an order, this should be done by contacting customer services on XXX-XXXXXXX. If the dose has already been manufactured, the order cannot be amended and the dose will be supplied to the Hospital and charged for in accordance with this agreement. Where necessary, the Hospital must raise new orders for any doses which cannot be amended.

1.8.5 Should it be necessary to cancel an order, this must be done via email or as per provider requirements. If the dose has been manufactured, the order cannot be cancelled, and the dose will be supplied to the Hospital and charged for in accordance with this agreement. Where necessary, the Hospital must raise new orders for any doses which cannot be cancelled and are required to be resupplied.

1.8.6 If reporting a product complaint or adverse event associated with doses supplied under this agreement, the Hospital must report these to [Company Name] using the following email addresses;

* Adverse Event reporting – XXXXX@company.com
* Product Complaint reporting – XXXXXX@company.com

**1.9 Training and Support**

Training and updates will be offered to the ’Hospital’ staff by [Company Name] on all [Company Name] relevant products, [Company Name] devices, and the [Company Name] compounding service/systems as required/if applicable.

**1.10 Key performance indicators**

The quality of the service should be monitored and reviewed regularly to ensure both parties are satisfied with the agreement. These performance indicators should be decided at the outset of the agreement and documented below.

Suggested List of KPIs:

* Guaranteed volume of items being delivered weekly
* Guaranteed volume of items being ordered by [XXXXXXX Hospital]
* Order Lead times being met
* Order management – processing, cancellations by [Company Name]
* Order management – processing, amendments or cancellations by [XXXXXXX Hospital]
* Quality – defect, errors, cancelled orders
* Other:
* Other:

**Schedule 2**

**INSURANCE**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Insurance** | **Minimum Cover for any one claim** | **Permitted deductible for any one claim** | **Period** |
| Product Liability | €6.5 million | €6,500 | Commencement Date until completion of the Term |
| Professional Indemnity | €6.5 million | €6,500 | Commencement Date until six years following the completion of the Term |
| Public liability | €6.5 million | €6,500 | Commencement Date until completion of the Term |
| Employer’s liability | €12.7million | €0 | Commencement Date until completion of the Term |

**Schedule 3**

**UNDERTAKINGS OF SERVICE PROVIDER**

1. There will be no Patient contact on the part of the Service Provider, other than that required in the performance by the Service Provider of his obligations under this Agreement.
2. The Service Provider will not release data on Product usage to any third party without the written consent of the Hospital.
3. The Service Provider will respect and observe the privacy of the Patients to be provided with Products under this Agreement, and treat all dealings with such Patients as confidential in accordance with the confidentiality obligations in this Agreement.
4. The Hospital must be immediately advised by the Service Provider of any health and safety/risk management adverse findings which may impact on Patient care and any action(s) taken or planned to reduce/negate any potential adverse outcomes.

**Schedule 4**

**UNDERTAKINGS OF THE HOSPITAL**

1. Clinical care of the Patients, including all clinical decisions in respect of the Patients shall remain the responsibility of the Hospital and its Healthcare Professionals at all times. The Patient’s Healthcare Professional shall write prescriptions in respect of the Products for the Patient and shall, as appropriate, and make all clinical decisions in respect of the Patient.

**Schedule 5**

**CHANGE CONTROL PROCEDURES**

1. A Change Request must set out the following details:

1.1 the date of the Change Request;

1.2 the reason for the requested Change;

1.3 the proposed timetable for implementation of the requested Change; and

1.4 whether or not the party issuing the Change Request believes the Change to be of a minor nature.

2. Subject only to Paragraph 4 of this Schedule, the Service Provider shall within XX Working Days of receipt of the Change Request or, if it is a Service Provider issuing the Change Request, together with the Change Request, provide the Hospital with:

2.1 a statement of the effect of the requested Change upon the:

2.1.1 the services and/or the system;

2.1.2 quality procedures; and

2.1.3 Charges and any tax (including VAT) liability;

2.2 any other contractual issues as applicable;

2.3 the availability of any reasonable alternatives to the requested Change; and

2.4 such other information as the Service Provider may deem appropriate (the “**Impact Statement**”).

3. All Parties shall within ten (10) Working Days of the receipt of the Impact Statement discuss the Change Request and the Impact Statement in good faith in order to settle the terms of the Change Order. Each Party shall promptly provide to the other such further and other information that any Party reasonably requests in connection with such discussions.

4. The Service Provider or the Hospital shall be entitled to reduce the time limits referred to in Paragraph 2 to five (5) Working Days where, acting reasonably and in good faith, if it considers the Change Request needs to be dealt with urgently.

5. If the Party (or in respect of the Hospital issuing a Change Request, the Service Provider) receiving the Change Request agrees that the Change requested in the Change Request is of a minor nature or needs to be implemented as a matter of urgency then the Parties shall not, if a nominee from each party on the Review Group agrees, be obliged to follow the procedure set out at Paragraph 2 above. In such circumstances, the Parties shall, acting reasonably and in good faith, agree a fast track procedure to settle such Change. In the event that the Parties (for whatever reason) cannot agree whether the Change requested in the Change Request (i) is of a minor nature, or (ii) requires implementation urgency, and/or (iii) the format of fast track procedure to effect such Change or any Party (for whatever reason) no longer considers (prior to any such Change being settled) any Change requested to be of a minor or urgent nature, then the Parties will follow the procedure set out at Paragraph 2 above.

6. The Service Provider shall provide details of all Changes implemented pursuant to this Paragraph 5 in each calendar month. The details shall be provided in the form of a report (the “**Urgent Changes Report**”) and shall include:

6.1 a summary of the Change;

6.2 the reasoning for the Change;

6.3 details of how the Change was implemented by the Service Provider, together with any feedback on the implementation of the Change; and

6.4 the impact, if any, of the Change on the provision of the Services; and

6.5 in addition, the Service Provider shall provide to the Hospital such additional Information that the Hospital may reasonably request following receipt of the Urgent Changes Report.

7. Any discussions between the Service Provider and the Hospital in connection with a Change and/or a Change Request shall be without prejudice to the rights of each Party.

8. The Service Provider shall keep a true copy and a detailed record of each Change Request, Impact Statement and Change Order.

9. Unless otherwise agreed, each Party shall be responsible for its own costs incurred in dealing with a Change Request, Impact Statement and Change Order.

10. Each Party shall act reasonably and in good faith in considering and agreeing any Change and Change Request and agreeing any Change Order.

11. Neither party shall be bound by a Change Request until it is signed by both Parties.

**Schedule 6**

**DATA PROTECTION**

**SERVICE PROVIDER DATA PROCESSING AGREEMENT**

The Company shall comply with the Data Protection Acts 1988-2018, and the General Data Protection Regulation (GDPR) (EU) [2016/679](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32016R0679), in respect of all patient information received in order to provide this service.

Please print and sign the HSE Data Processing Agreement Document available at:

<https://www.hse.ie/eng/services/publications/pp/ict/hse-service-provider-data-processing-agreement-v1.pdf>

Data Transfer outside the EU

Companies based outside the EU (e.g. the UK) who wish to supply a product / service to Ireland are also required to sign a set of Standard Contractual Clauses. This clause agreement is between the non-EU entity (data importer) and the hospital (data exporter).

The document linked below must be signed by both parties:

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010D0087&from=en>

This Contract Agreement is hereby agreed by us.

Signed by; \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

being a duly authorised signatory of [Company Name]

Name (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Job Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signed by; \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

being a duly authorised signatory of **the [Hospital Name]**

Name (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Job Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Appendix 1: Table for estimated SACT volumes**

|  |  |  |  |
| --- | --- | --- | --- |
| **Drug name****(INN / Generic name)** | **Brand name - if mAb or Biosimilar** | **Estimated Volume per week** | **Comment** |
| Bevacizumab bags |  |  | Patient Specific |
| Bleomycin bags |  |  | Patient Specific |
| Bleomycin syringes |  |  | Patient Specific |
| Cabazitaxel bags |  |  | Patient Specific |
| Cisplatin bags |  |  | Patient Specific |
| Carboplatin bags |  |  | Patient Specific |
| Cyclophosphamide bags |  |  | Patient Specific |
| Cyclophosphamide syringes |  |  | ☐Batch ☐Patient Specific |
| Dacarbazine bags |  |  | Patient Specific |
| Docetaxel bags |  |  | Patient Specific |
| Doxorubicin bags |  |  | Patient Specific |
| Doxorubicin syringes |  |  | ☐Batch ☐Patient Specific |
| Etoposide bags |  |  | Patient Specific |
| Eribulin bags |  |  | Patient Specific |
| Fluorouracil bags |  |  | Patient Specific |
| Fluorouracil syringes |  |  | ☐Batch ☐Patient Specific |
| Fluorouracil Infusors |  |  | ☐Batch ☐Patient Specific |
| Gemcitabine bags |  |  | Patient Specific |
| Ipilimumab | Yervoy |  | Patient Specific |
| Irinotecan bags  |  |  | Patient Specific |
| Liposomal Doxorubicin | Caelyx |  | Patient Specific |
| Methotrexate bags |  |  | Patient Specific |
| Methotrexate syringes |  |  | Patient Specific |
| Nab-paclitaxel (Abraxane®) bags |  |  | Patient Specific |
| Nivolumab bags |  |  | ☐Batch ☐Patient Specific |
| Oxaliplatin bags |  |  | ☐Batch ☐Patient Specific |
| Paclitaxel bags |  |  | Patient Specific |
| Pemetrexed bags |  |  | Patient Specific |
| Panitumumab bags |  |  | Patient Specific |
| Pertuzumab | Perjeta |  | Patient Specific |
| Pembrolizumab | Keytruda |  | Patient Specific |
| Rituximab bags | Truxima |  | ☐Batch ☐Patient Specific |
| Trastuzumab Emtansine | Kadcyla |  | Patient Specific |
| Trastuzumab bags | Herceptin |  | Patient Specific |
| Vincristine bags |  |  | ☐Batch ☐Patient Specific |
| Vinblastine bags |  |  | Patient Specific |
| Vinorelbine bags |  |  | Patient Specific |

1. <https://foi.gov.ie/> [↑](#footnote-ref-2)
2. <https://www.hse.ie/eng/about/who/healthbusinessservices/procurement/hsestandardtermsforservicessupplies.pdf> [↑](#footnote-ref-3)
3. Should be defined during negotiation period [↑](#footnote-ref-4)