

Appendix 8 — Example Technical Agreement

QUALITY TECHNICAL AGREEMENT FOR THE PROCUREMENT, DISPENSING AND DELIVERY OF ORAL CHEMOTHERAPY MEDICINES

Between

(CONTRACT GIVER - CG)

And

NAME AND ADDRESS OF SUPPLIER (CONTRACT ACCEPTOR — CA)

This contract is supplemental to agreement number (purchasing agreement) and any subsequent agreements, between the two parties and will last for the duration of the agreement. The Technical Agreement shall be reviewed every 24 months or earlier if requested by either party.

All parties have entered into an agreement concerning the supply of oral chemotherapy medicines via homecare and this Quality Technical Agreement shall be effective as of the date of the final signature and shall remain in effect until review or termination.

This Technical Agreement is executed in duplicate, both of which shall be deemed to be originals, and both of which shall constitute one and the same agreement binding upon both parties.

Scope

This agreement defines the roles and responsibilities between CG and CA relating to the procurement, dispensing and delivery of oral chemotherapy medicines.

All parties agree as follows:

Subject Matter

CA is a provider of licensed oral chemotherapy medicines which are procured, dispensed and delivered to CG patients as a homecare service.

CA shall procure, dispense and deliver the products as specified in this Technical Agreement and in addition to the service level agreement.

CA is subject to registration and inspection by the competent national authorities and holds the necessary dispensing authorisation according to the respective legislation.

Obligations and Responsibilities

CG is responsible for checking the authority of CA to carry out successfully the work required by periodic checks on registration status. CA will make available any internal or external audit or inspection reports as requested by CG. CA hereby acknowledges that CG is relying on the skill and experience of CA in the proper procurement, dispensing and delivery of the PRODUCTS under this Agreement and CA accordingly warrants to CG that:

The PRODUCT shall be of satisfactory quality and fit for purpose from sources approved by CG (Specification C7.1 in the contract).

The PRODUCT shall comply in all respects with the agreed specifications (Specification C7.1 in the contract).

Both parties will strictly observe the detailed responsibilities which are specified in Annex 1 ('Responsibilities').

CG and CA must appoint Contact Persons as named in Annex 3 ('Contact Persons') (Specification A9.2 in the contract).

Information related to any planned change to the product or service, overall process or specification for the PRODUCT(S) by CA is to be notified to CG in writing at the earliest opportunity, and approved by CG prior to the change being in effect.

Information related to any errors or adverse event with regards to product supplied or overall service by CA is to be notified to CG in writing at the earliest opportunity i.e. prior to the product being supplied.

CA shall ensure that product shall be supplied in accordance with agreed procedures, and records of supply and delivery shall be retained in order to affect a satisfactory audit trail in the event of recall.

Any complaints from CG or patients under the care of CG, concerning quality of supplied product or service shall be acknowledged by CA within 24 hours and investigated and documented for CG within 2 weeks. This document should include details of all corrective and preventative actions.

In the event of merger, acquisition or facility closure CA shall advise CG at the earliest opportunity, before the change is implemented.

CA shall not delegate or sub-contract any of the work entrusted to it under the Contract Agreement without prior evaluation and approval of CG. Any such arrangements made between CA and any approved third party shall ensure that the information relating to this contract is made available and remains confidential in the same way as between CG and CA. CA shall be responsible for inherent responsibilities of their sub-contractors (Specification A11.1 in the contract).

CA is responsible for notifying CG of any recall or near miss and for co-coordinating and documenting the recall process. CA is responsible for coordination and disposal of all products returned by CG or its patients. CA will co-operate with the collection, logging, storage and segregation of any recalled and returned product as required (Specifications C4.1 and C4.2 in the contract).

CA must ensure a robust contingency plan has been arranged to ensure continuity of service in the event that they cannot provide the pre-defined quantities of product as defined by CG. The use of any sub-contractors must be agreed by CG prior to implementation see above.

CA shall only dispense prescriptions for individual patients that are signed by a legally authorised prescriber of participating health boards/trusts and screened and validated by an appropriate clinical pharmacist of participating health boards/trusts.

The product must be dispensed and labelled by CA in accordance with current legislation.

CA shall arrange for the safe disposal of patients' clinical waste at agreed intervals in accordance with relevant legislation. This will include medicine delivered but unused by the patient.

Final Provision

Amendments of this Quality Technical Agreement and its Appendices may only be carried out by mutual consent and shall be made in writing.

Appendices

Annex 1 — Responsibilities

Annex 2 — Technical Agreement Approval

Annex 3 — Key Contact Persons

ANNEX 1: Responsibilities

| | CG | CA | Remarks |
|---|----|----|---------|
| <i>1. Regulatory Processes</i> | | | |
| Hold registration with the General Pharmaceutical Council (GPhC). Comply with any and all EU and other local current applicable laws, regulations and guidelines relating to GDP. CG to be informed of any changes to registration and any pending regulatory action. | | ✓ | |
| Ensure pharmacovigilance systems are in place to collect, evaluate and collate information concerning all suspected adverse events/reactions reported to CG and CA. | ✓ | ✓ | |
| Report pharmacovigilance events to CA. | ✓ | | |
| Relay any reported pharmacovigilance events to CG. | | ✓ | |
| Ensure competent authorities are notified of all complaints concerning suspected adverse events/reactions/lack of effect according to existing regulations and requirements. | ✓ | ✓ | |

| | CG | CA | Remarks |
|--|----|----|---|
| <i>2. Changes</i> | | | |
| Maintain a suitable change control system and communicate all information about planned changes before implementation. | | ✓ | CA to notify CG of all proposed changes. |
| Maintain a suitable change control system and communicate all information about planned changes before implementation. | ✓ | | CG to approve all changes proposed by CA. |
| Maintain a suitable unplanned deviation system and communicate all information about unplanned changes (adverse events) which could impact on products provided by CA. | | ✓ | This should be prior to dispensing or delivery. |
| No work should be sub-contracted without the prior agreement of CG. | | ✓ | |

| | CG | CA | Remarks |
|--|----|----|---------|
| <i>3. Patient Care</i> | | | |
| Assess whether patients are suitable to receive medicines via homecare and would actually benefit from this service. | ✓ | | |
| Completion of patient consent and registration documentation. | ✓ | | |
| Prescriptions to be signed by a legally authorised prescriber. | ✓ | | |
| Prescriptions to be screened and validated by an appropriate clinical pharmacist to ensure suitability for specific patient. | ✓ | | |
| Any suspected patient compliance issues should be fed back to the CG. | | ✓ | |
| Responsibility for patient counselling. | ✓ | | |

| | CG | CA | Remarks |
|---|----|----|---|
| <i>4. Medicines</i> | | | |
| Only purchase medicines from suppliers approved by CG at prices either listed on All Wales Drug Contracting Committee (AWDCC) contracts or at prices approved by CG if not on contract. | | ✓ | |
| If approved source of a medicine is not available, source an alternative and submit to CG for approval/assessment. | | ✓ | CG to approve all changes proposed by CA. |

| | CG | CA | Remarks |
|--|----|----|---------|
| <i>5. Dispensing</i> | | | |
| Ensure that all products for individual patients, as requested by a prescriber, are dispensed and labelled in accordance with current legislation. | | ✓ | |
| Hazardous medicines (e.g. cytotoxic medicines) will be handled with appropriate safety measures. | | ✓ | |
| Dispensing accuracy check by a registered pharmacist or accredited checking pharmacy technician under the supervision of a pharmacist. | | ✓ | |
| Report dispensing errors and near misses to CG. | | ✓ | |

| | CG | CA | Remarks |
|--|----|----|---------|
| <i>6. Storage/Distribution</i> | | | |
| Qualification/validation of storage and warehouse at all sites. | | ✓ | |
| Qualification/validation of transport of products from place of dispensing to patients of CG. | | ✓ | |
| Store and distribute all products under appropriate conditions in compliance with GDP requirements and any licence requirements. | | ✓ | |
| Maintain the integrity of the cold/ambient chain. | | ✓ | |
| Distribute to patients in a timely way as described in the contract specification and service level agreement. | | ✓ | |
| Maintain an audit trail to the patient. This should include both product and delivery details e.g. batch numbers and delivery times. | | ✓ | |

| | CG | CA | Remarks |
|---|----|----|---------|
| <i>7. Documentation</i> | | | |
| Ensure that prescriptions as well as records of procurement, dispensing and distribution are clear, readily available and retained for the period required by current legislation. Records shall ensure the traceability of the origin and destination of products. | | ✓ | |
| Ensure written procedures are available to describe all operations that may affect the quality of the products, e.g. dispensing and distribution. | | ✓ | |
| Archiving of dispensing and distribution documentation. | | ✓ | |
| Maintain a record of batch numbers of products procured, supplied or returned in the event of a recall (see section 10). Batch numbers for supply and return should be recorded to patient level. | | ✓ | |

| | CG | CA | Remarks |
|---|----|----|---------|
| <i>8. Other Quality Control and Quality Assurance</i> | | | |
| Make available evidence of closure of, and assigned risk rating for, regulatory body inspection reports as requested by CG. | | ✓ | |

| | CG | CA | Remarks |
|---|----|----|---------|
| <i>9. Complaints</i> | | | |
| Acknowledge any complaints from CG or patients of CG concerning quality of supplied product or service within 48 hours. | | ✓ | |
| Investigate and document any complaint within 2 weeks. This document should include details of all corrective and preventative actions. | | ✓ | |
| Report back to patients on the result of any complaint that they may have made, depending on nature of complaint. | ✓ | ✓ | |

| | CG | CA | Remarks |
|--|----|----|---|
| <i>10. Recalls</i> | | | |
| In the event of product being recalled, arrange for the collection, stocking and segregation of such goods. Credit CG for any goods already delivered but unused by the patient including part-used product and or medicine. | | ✓ | |
| Maintain a product recall procedure for use when it is necessary to recall a defective product from market, and test the procedure at least annually. | | ✓ | |
| Performance of recall for product supplied to patients of CG. | | ✓ | Must comply with timelines as specified in regulations. |
| Supply information to CG about recalls concerning products supplied to patients of CA. | | ✓ | Must comply with timelines as specified in regulations. |
| Supply information to prescribers about recalls concerning products supplied to patients of CA. | ✓ | | |

| | CG | CA | Remarks |
|---|----|----|---------|
| <i>11. Waste</i> | | | |
| Arrange for the safe disposal of patients' clinical waste at agreed intervals in accordance with relevant legislation. This will include medicine delivered but unused by the patient. (Also refer to section 10 above on recalls.) | | ✓ | |

| | CG | CA | Remarks |
|--|----|----|---|
| <i>12. Training</i> | | | |
| Staff involved in all aspects of the service will be adequately trained as appropriate to their role. | ✓ | ✓ | Information on training plans to be provided to CG. |
| Staff will comply with relevant legislation and NHS requirements concerning both patient and commercial confidentiality e.g. Data Protection Act, and NHS Conditions of Contract for the Purchase of Goods and the Supply of Services. | ✓ | ✓ | |

Annex 2: Technical Agreement Approval

Agreed on behalf of CG

Name:

Title:

(Procurement)

Signature: _____

Date: _____

Agreed on behalf of CA

Name:

Title:

Signature: _____

Date: _____

Annex 3: Key Contact Persons

CG

| Name | Designation | Contact number | E-mail |
|------|-------------|----------------|--------|
| | Procurement | | |

CA

| Name | Designation | Contact Number | E-mail |
|------|-------------------|----------------|--------|
| | Customer Services | | |