Document No. 04

Invitation to offer for NHS Generic Pharmaceuticals Wave 10b
Offer reference number: CM/PHG/15/5465
Period of framework agreement: Dates detailed below with options to extend up to a maximum period of 48 months
Potential periods of call-offs under the framework agreement:

100% products:	**All regions:**	**01/11/2016 to 28/02/2019 (28 months)**
33% products:	**DCE & DSW:**	**01/11/2016 to 30/06/2018 (20 months)**
Housekeeping:	**DLS & DNE:**	**01/11/2016 to 30/06/2017 (8 months)**
	DLN & DNW:	**01/11/2016 to 30/06/2017 (8 months)**

NHS Supplementary conditions of contract for the purchase of pharmaceuticals

October 2012

These conditions of contract are supplementary to the *NHS conditions of contract for the purchase of goods (supplementary)*. In the event of a conflict between these supplementary conditions and the *NHS conditions of contract for the purchase of goods (supplementary)*, these supplementary conditions shall prevail (unless otherwise stated in these supplementary conditions).

The Supplier has agreed under a framework agreement with the Secretary of State for Health acting through the Commercial Medicines Unit ("the framework agreement") to supply the goods to Participating Authorities (as defined in the framework agreement) on the basis of the terms set out therein and the *NHS conditions of contract for the purchase of goods (supplementary)* as supplemented by these conditions. In the event of conflict between the framework agreement and the *NHS conditions of contract for the purchase of goods (supplementary)* as supplemented by these conditions, then the framework agreement shall prevail.

1. **Interpretation**

Unless the context otherwise requires, definitions of terms used in these supplementary conditions shall have the same meanings as set out in the *NHS conditions of contract for the purchase of goods (supplementary)* except for the following additional words and expressions which shall have the meanings set out opposite them below:-

"authorised officer"	means the person notified to the Supplier by the authority from time to time as the health and safety officer;
"authority"	means, for the avoidance of doubt, "authority" as defined in *NHS conditions of contract for the purchase of goods (supplementary)*;
"award notice"	means the notice issued by the Commercial Medicines Unit, part of the Department of Health (CMU) to the Supplier confirming the selection of the Supplier as a supplier of the goods;
"B.P.C."	means British Pharmaceuticals Codex;
"B.P."	means British Pharmacopoeia;
"CEDR"	means Centre for Dispute Resolution;
“conditions”	means these supplementary conditions of contract;

"contract"	means the contract concluded pursuant to these conditions and attached schedules made between the authority and the Supplier for the supply of the goods;
"controlled drugs"	has the meaning contained in section 2 of the Misuse of Drugs Act 1971 as amended, modified or re-enacted from time to time;
"E.M.E.A."	means European Medical Evaluation Agency;
"medical device"	has the meaning contained in the Medical Device Directive 93/42/EEC as amended modified or re-enacted from time to time;
"MHRA"	means Medicines and Healthcare Products Regulatory Agency;
"month"	means a calendar month;
"Commercial Medicines Unit "	means the Commercial Medicines Unit whose principal office is at Premier House, 60 Caversham Road, Reading, RG1 7EB, acting as agent for the authority;
"offer document"	means all the documents forming the Supplier's offer to supply the goods;
"order"	means an order raised by the authority for the supply of goods by the Supplier pursuant to the framework agreement;
"quality control technical sheet"	means the document labelled "quality control technical sheet" issued by the Commercial Medicines Unit, completed by the Supplier and forming part of the offer document;
"regional quality control pharmacist"	means the person notified to the Supplier by the Commercial Medicines Unit from time to time as the regional quality control pharmacist;

2. **Termination**

The Termination Condition of the *NHS conditions of contract for the purchase of goods (supplementary)* shall apply to these conditions.

3. **Delivery**

3.1 The Supplier shall supply with every delivery of the goods an advice note giving full and accurate details of the goods delivered (including, without limitation, their description, weight, measure and number). No goods shall be delivered without an Order. The Supplier shall deliver the goods during normal working hours unless otherwise agreed by the parties to such location at the authority's premises, as the Supplier may agree with the authority prior to delivery. All third party carriers engaged to deliver the goods shall be deemed to be an agent of the Supplier and not of the authority.

3.2 If the Supplier has notified the authority in the offer document (or otherwise in writing) that it has appointed, or it intends to appoint, a third party (including, without limitation, a full line national or regional pharmaceutical wholesalers as appointed by the Department of Health) to act as its distribution agent:-

3.2.1 such appointment shall not relieve the Supplier of its obligations under the contract; and

3.2.2 the Supplier shall be liable for the acts or omissions of its distribution agent. Without prejudice to the generality of the foregoing, the Supplier agrees that any delivery time agreed between the authority and the distribution agent in writing shall be binding on the Supplier.

4. **Orders**

4.1 The Price and Payment Condition of the *NHS conditions of contract for the purchase of goods (supplementary)* shall apply to these conditions.

The right is reserved by the authority to place orders with alternative suppliers whenever desired in order to comply with any reasonable directions of the medical staff concerned.

5. **Invoices**

The Forms Condition of the *NHS conditions of contract for the purchase of goods (supplementary)* shall apply to these conditions.

6. **Failure to Supply**

6.1 The Supplier shall deliver the exact quantity of goods within 14 days of receipt of the order, or within such other time period as may have been agreed in writing between the parties, ("the delivery time") to the address specified by the authority in the order.

6.2 In the event the Supplier is unable to supply the goods in accordance with condition 6.1 due to circumstances beyond its reasonable control, the Supplier shall be entitled to provide essentially similar goods to the authority provided that:

6.2.1 the Supplier notifies the authority without delay and within the delivery time when it becomes aware that it will not be able to supply the goods in accordance with condition 6.1 ("failure to deliver");

6.2.2 the notice referred to in condition 6.2.1 above stipulates the reason for the Supplier's failure to deliver;

6.2.3 the Supplier supplies to the regional quality control pharmacist or the authority that placed the order all information set out in the quality control technical sheet in respect of the alternative goods;

6.2.4 the alternative goods shall be approved in writing by the regional quality control pharmacist or the authority that placed the order; and

6.2.5 the Supplier must provide such quantities of alternative goods as are necessary to make up any shortfall in the goods, to the authority prior to expiry of the delivery time.

6.3 In the event the Supplier fails to deliver the exact quantity of goods or the essentially similar goods within the delivery time in accordance with condition 6.2 above, then the authority shall be entitled to terminate this contract with immediate effect on giving written notice to the Supplier to that effect and the authority shall be entitled to purchase other goods to make good such default and recover from the Supplier the amount by which the cost of purchasing other goods from a third party exceeds the amount that would have been payable to the Supplier in respect of the goods replaced by such purchase provided that the authority uses all reasonable endeavours to mitigate its losses. In the event the Supplier has been paid in advance for the goods, then the Supplier shall reimburse the authority for the monies paid in respect of those goods it has failed to deliver.

6.4 In the event that the authority wishes to claim any sum from the Supplier under condition 6.3, the authority shall give a written notice to the Supplier to that effect. The Supplier shall pay any such sum within 1 calendar month of the authority giving the written notice in respect thereof.

7. Notices

The Notices Condition of the *NHS conditions of contract for the purchase of goods (supplementary)* shall apply to these conditions.

8. Shelf Life

8.1 Where any goods are supplied under these conditions the period of time between the date of supply of these goods to the authority and the expiry date shown on the goods ("the shelf life") shall be not less than 12 months provided that it is

acknowledged that, in respect of goods containing certain ingredients, the shelf life of those goods shall be less than 12 months. In such circumstances the minimum shelf life shall be indicated by the Supplier on the offer document or in an accompanying letter.

8.2 In the event that the Supplier supplies goods with a shelf life of less than 12 months (or such other period as the Commercial Medicines Unit may have agreed) ("the minimum amount"), the Supplier shall, upon request by the authority and at no cost to the authority, immediately replace those goods with a shelf life of less than the minimum amount with goods which have a shelf life greater than the minimum amount. Alternatively, the authority shall be entitled to terminate the contract with immediate effect on giving written notice to the Supplier.

9. Health and Safety

The Supplier shall comply with the requirements of the Health and Safety at Work etc Act 1974 in all respects.

10. Accidents and Untoward Incidents

10.1 When delivering the goods at the authority's premises, the Supplier shall procure that its employees are aware of the nature of the Hospitals/Units and NHS Trusts and other such bodies and the special care they should have for patients generally, and in particular for geriatric and mentally ill patients who may be aggressive and careless of danger and may at times solicit gifts or valuables or steal and misuse property.

10.2 The Supplier is responsible for instituting a safe system of working in these circumstances and should take particular care that vehicles or equipment are not left open or unattended. In the event of an accident or an untoward incident the Supplier and/or his employee(s) will be required to submit a report of the occurrence to the authorised officer.

11. Authority Care

The Supplier shall notify the authority in writing of all relevant details of its authority services representative. If requested by the authority by notice in writing the Supplier shall as soon as reasonably practicable procure that its authorised services representative shall visit the authority to advise on the selection of goods and to resolve any difficulties that may arise.

12. Training

If requested by the authority, the Supplier shall as soon as reasonably practicable and at the Supplier’s expense provide reasonable assistance to the authority in the training of such persons as the authority may reasonably specify in the use of the goods.

13. Delivery Arrangements

13.1 The Supplier will need to agree a reasonable timetable for delivery with the authority placing the Order. The Supplier shall ensure that the goods are delivered safely and securely to the appropriate delivery point. Furthermore when delivering and handling controlled drugs the Supplier shall comply at all times with the Misuse of Drugs Act 1971 (as amended, modified or re-enacted from time to time).

13.2 The Supplier shall be responsible for ensuring security of delivery to the appropriate delivery point.

14. Packaging Requirements for Delivered Goods

14.1 The Supplier shall comply strictly with the pack sizes and units of issue specified in the award notice unless otherwise agreed in writing by the parties.

14.2 The Supplier's name and address must be shown on the outside of every package.

14.3 The weight of every package should be clearly specified on the external packaging of the goods.

14.4 All goods should be packed in such a way as to give them adequate protection from damage during transit. The authority reserves the right to return/reject goods which, upon inspection, after delivery, are found to be in a damaged condition.

15. Physical Delivery Arrangements for Bulk Items

15.1 The Supplier shall procure that its delivery vehicles are at all times equipped appropriately for the delivery of bulk items to all delivery sites indicating such a requirement (e.g. appropriate tail lift for the delivery of palletised items).

15.2 The Supplier shall procure that any agent or sub-contractor engaged by it in the performance of this contract shall comply with the Supplier's obligations under this condition 15.

16. Product Recall

In the event of the goods being recalled, initiated by the manufacturer of the goods, the Secretary of State for Health or MHRA (or any such similar regulatory body), the Supplier shall, without delay and at its own expense, arrange for the collection of such goods and credit the authority for any goods delivered but unused by the authority including part used packs.

17. Compliance with the Appropriate Policies

The Supplier shall procure that its employees and agents shall in the performance of this contract comply with all relevant health and safety policies and working practices in force within the authority from time to time (including without limitation smoking and alcohol consumption policies).

18. **Quality Control**

The Supplier shall operate and maintain a quality control monitoring system which meets the requirements of the MHRA and is approved by the Commercial Medicines Unit and make available to the Commercial Medicines Unit on demand the results of such quality control monitoring.

19. **The Supplier's Premises**

19.1 The Supplier shall keep its production facilities used in the manufacture of the goods in a state and condition necessary to enable it at all times to manufacture the goods in accordance with the specification.

19.2 The Supplier shall permit the Commercial Medicines Unit or its nominee during normal business hours having given reasonable advance notice access to its premises to enable the Commercial Medicines Unit to review the Supplier's production process in relation to the goods.

20. **Quality**

20.1 The Supplier warrants represents and undertakes that the goods supplied by it will:-

20.1.1 pass any tests and trials the Commercial Medicines Unit requires to satisfy itself that the goods are not injurious to health including without limitation any tests and trials conducted by NIBSC where applicable;

20.1.2 be free from defects as defined by Section 3 of Part I of the Consumer Protection Act 1987 (as amended, modified or re-enacted from time to time);

20.1.3 conform to the general safety requirement and all orders regulations and notices imposed by or issued in respect of the goods pursuant to Part II of the Consumer Protection Act 1987 (as amended, modified or re-enacted from time to time);

20.1.4 meet the Specification therefor and any samples of the goods given by the Supplier and accepted by the authority. In the event of any dispute as to whether the goods have been supplied in accordance with the relevant Specification and samples referred to above, the authority shall refer the matter to the regional quality control pharmacist who shall keep a sample of the goods which the regional quality control pharmacist has previously approved as being in accordance with the specification and this sample shall be used as the standard against which all goods shall be measured in order to determine whether they have been supplied in accordance with the relevant specification; and

20.1.5 comply with duties imposed on it by the Health and Safety Work etc Act 1974 and any amendment thereto or re-enactment thereof and will conform to and comply with all other statutory provisions bye-laws or regulations relating to the manufacture and supply of the goods applicable to the contractor.

20.2 The goods shall be of first class quality, fit for purpose and shall be supplied strictly in accordance with the quantities, specifications, standards and stipulations contained in the specification and, unless otherwise agreed in writing pass such inspection as may be required by the Commercial Medicines Unit or any UK Government department.

20.3 Without prejudice to any other provisions of this contract the Supplier shall supply the goods in accordance with sections 13 to 15 of the Sale of Goods Act 1979, the Medicines Act 1968 & 1971, and the Human Medicines Regulations 2012 (as amended, modified or re-enacted from time to time). For the avoidance of doubt the Human Medicines Regulations 2012 take precedence in all matters covered therein. Although the goods may undergo quality assurance assessment by the authority, such assessment shall not affect the Supplier's obligations under this condition 20 and shall not of itself constitute acceptance or approval by the authority of the goods (or any part of them).

20.4 In the event that any of the goods are defective, damaged or otherwise manufactured not in accordance with the terms of this contract or the Specification, the authority shall be entitled to reject such goods and also terminate this contract in accordance with condition 2 hereof.

20.5 The Supplier shall not make any change to the specification without the prior written consent of the Commercial Medicines Unit.

20.6 Nothing contained in this contract shall in any way detract from the Supplier's obligations under common law or statute.

21. Quality Issues

21.1 The Supplier shall reply promptly in writing to all enquires and complaints by the Commercial Medicines Unit relating to the quality, performance and availability of the goods notwithstanding that the grounds for such enquiry or complaint may be inherent in the specification.

21.2 The Supplier shall as soon as reasonably practicable notify the Commercial Medicines Unit in writing of all matters affecting or which may affect in any way the performance of the goods or any part thereof including without limitation any claim brought against the Supplier and/or any customers of the Supplier for the goods by another person arising out of or relating to the performance of the goods.

22. Intellectual Property

The Supplier warrants, represents and undertakes to the authority that it is either the sole proprietor and legal and beneficial owner of all intellectual property rights in the goods including without limitation all letters patent and the right to make application therefor and all copyrights and design rights, know how and confidential formulae or that it is legally entitled by way of a valid licence or otherwise to deal with the goods in the manner set out in the contract.