SUPPLIER ROLE SPECIAL CONDITIONS OF CONTRACT FOR THE SUPPLY OF CHEMICALS, MEDICINES AND MEDICAL DEVICES

## Application

These Special Conditions of Contract for the Supply of Chemicals, Medicines and Medical Devices (“the Goods”) will apply to the Contract and shall supplement and be read in conjunction with the General Contract Conditions and any other Special Contract Conditions. In the event of any conflict between these Special Conditions of Contract for the Supply of Chemicals, Medicines and Medical Devices and the General Contract Conditions or other Special Contract Conditions, the former shall prevail.

# Standards

* The Goods to be supplied must be manufactured in accordance with the standards of Good Manufacturing Practice (GMP). The GMP standards shall have been accredited by:
* a Stringent Regulatory Agent (SRA);
* or the Guidelines as published by the World Health Organisation (WHO).
* All ingredients used, and finished Goods must be manufactured in accordance with an internationally recognised Monograph published in either the British Pharmacopoeia (BP), the United States Pharmacopoeia (USP) the European Pharmacopoeia (EP), or shall meet another recognised and stated standard acceptable to Crown Agents. Where there is a monograph for the Goods offered, they shall comply with the standards of the current edition of the B.P., U.S.P., E.P, and/or British Pharmaceutical Codex (B.P.C) or of the latest edition in which they are included. Where the Goods are not defined in one of the publications mentioned, and no other standard is specified, the Goods shall be manufactured in accordance with a validated ‘in-house’ formulation so as to be suitable for use as a human medicine.
* All Goods must at least have a World Health Organisation Certificate of a Pharmaceutical Product (WHO CoPP), which fulfils the basic functions of GMP and Marketing authorisation.
* All Goods must be provided with a Certificate of Analysis (CoA) for each batch of finished product supplied.
* All Goods must be provided with a statement to certify that the Goods supplied are produced entirely from materials of synthetic origin and therefore are free from human or any other animal derived materials including bovine products. In addition, the statement shall certify there are no animal derived components used in the manufacturing or handling processes of the Goods. Therefore the Goods can be declared free of Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).
* Information about relevant stability studies must be available, where required by the End-User, for sensitive Goods (such as, by way of example only, Rifampicin) and also a guarantee of the quality of raw materials in the form of the Drug Master File or a certificate of Conformity with the European Pharmacopoeia (CEP).
* It is the responsibility of the Supplier to ensure that any Medical Devices are supplied with the correct Conformité Européene (CE) marking and documentation, or equivalent.
* All premises used for the manufacture of the Goods to be supplied must hold a current License to operate as a Pharmaceutical Manufacturer as proof that the site (including warehouse) and equipment used respect the conditions stipulated in an international quality certification system. The manufacturing Licence must be issued by the relevant Ministry of Health or National Medicines Regulatory body, as the case may be, and the premises must be open to visits from Inspectors appointed by Crown Agents Health Inspection Service.
* Where required by the End-User, all Goods must be registered with their National Medicines Regulatory body. (It should be noted that compliance with the other points above will usually be sufficient to expedite registration where the National Medicines Regulatory body is willing).

**Good Distribution Practice**

In the event that the Supplier is not the manufacturer of the Goods, the Supplier must comply with the EU Guidelines on Good Distribution Practice (GDP) or equivalent GDP Guidelines of the National Competent Authority, or equivalent

For the purpose of these Special Conditions of Contract “National Competent Authority” means any relevant authorised national registration authority responsible for the registration of chemicals, medicines and medical devices or authorised for issuing of documents that proves the conformity of medical devices to technical regulations.

Crown Agents reserve the right, prior to the delivery of the Goods, to request any data or other information required by us to meet our obligations to the UK Medical and Healthcare products Regulatory Agency (MHRA).

**Controlled Drugs**

Where applicable, the Supplier is wholly responsible for ensuring that the handling of controlled drugs, as identified in the Contract, shall comply with all applicable statutory and regulatory requirements within the county of export and the country of import

Where the Goods are or maybe classified as controlled drugs, the Supplier must ensure that consideration is given to restrictions that may apply in certain countries through which the Goods may pass whilst in transit and distribution routes are adjusted accordingly. Suppliers must ensure that controlled drugs are distributed via approved means at all times.

**Expiry Dates**

The shelf life remaining, for all Goods to be supplied must match that stated in your bid. If there are any changes to the shelf life for whatever reason, this must be agreed in writing with Crown Agents **prior to despatch**.

Unless otherwise agreed in writing, the Goods supplied must be of **fresh manufacture** and thus have maximum possible molecular shelf-life. All Goods supplied should, in any case, have a minimum of at least 24 months or ¾ (75%) remaining of the total shelf life, whichever is the longer, on delivery to the named destination , except Goods that are known to have limited stability. **No Goods will be accepted which do not comply with this strict requirement unless there has been a prior written agreement issued by Crown Agents following representations by the Supplier. The expiry date must be shown on your invoice and where applicable on your application for shipping or airfreight despatch.**

**Tropical Compositions**

The composition of Plasters, Liquid Extracts and Ointments supplied shall be modified, where necessary, to render them suitable for use in the country of destination, but the specified proportion of the active ingredients must, in all cases, be maintained.

**Stability**

Goods must maintain their appearance and efficacy for the complete length of the shelf-life when stored in the final marketing pack under any storage condition as permitted on the label.

During operations such as (but not limited to) reconstitution or dilution, the Goods are expected to maintain their stability. Notwithstanding the data contained in the monograph or marketing authorisation the Supplier shall provide Crown Agents with the results of any extended stability testing that has been undertaken by the manufacturer.

**Marking of Containers**

Each individual container, i.e. bottle, tin, vial, ampoule etc. shall be marked in English with the following:

Name of the Goods, including (unless inapplicable) the pharmacopoeia standard, e.g. BP

* Strength of the preparation (if applicable).

In addition, each individual container (or in the case of ampoules, the box containing them) shall bear the following information:

* The name and location of the manufacturer,
* The date of expiry if applicable, and
* Batch number, date of manufacture, expiry date in an uncoded formAny other marking specified in the Contract.

The following minimum information must be provided on all packs, boxes, cartons and intermediate containers:

* International Non-proprietary Name (INN)
* Dosage form
* Name and strength of raw material/active ingredients
* Number of units per box/packaging
* Conditions of storage and handling
* Directions for use, and any warnings or precautions that may be necessary
* Name and address of manufacturer
* Name and address of Supplier
* Any other marking specified in the Contract.

If labels are used, these shall be affixed with adhesive suitable for conditions in the country of destination.

**Inserts/Patient Information Leaflet/Package Leaflet**

The Supplier must make available the instructions for the use of the Goods (package leaflet) in the English Language. These must be inserted within each individual container or box holding either the bottle, tin, vial or ampoule etc.

**Individual Containers**

It is the Supplier’s responsibility to provide individual containers of a type suitable for the Goods concerned and closed in a manner capable of protecting the material during transit and appropriate storage under conditions prevailing in the country of destination. Where a particular form of packing is specified by Crown Agents, which the Supplier considers is unsuitable for the Goods**, this should be brought to the attention of Crown Agents in writing and an alternative suggested.**

On arrival at their ultimate destination, the Goods must be free from damage. Individual containers must be sealed in a manner that makes tampering with the pack during transit easily detectable. The Supplier shall be liable for all losses, damage or expenses due to insufficient or unsuitable packing. The Supplier shall also be liable for all losses due to discrepancies in quantities in intact containers even after delivery and storage in the country of destination. These discrepancies will be made good on a free of charge basis by the Supplier

**External Packing**

External packing will be required in accordance with Clause 7 Packing of the General Contract Conditions. Particular attention must be paid to Goods classified as “hazardous” to ensure that these are packed and marked to conform with the requirements of the appropriate regulations governing the despatch by sea or air of hazardous cargo.

All external packing shall include labels providing sufficient information on handling and storage precautions to ensure that the Goods are properly handled and secure at all times. The information shall be detailed on delivery notes and manifests if it cannot go on the external packaging, in addition to the details of the identification of the container’s contents and source, where applicable.

Wooden pallets (if used) shall be heat treated (HT) and marked accordingly in compliance with the International Standards for Phytosanitary Measures No. 15 (ISPM 15).

**Special Storage and Transportation**

For Goods which require compliance with temperature control (“cold chain” regime) during storage and transportation, the Supplier must ensure that such temperature control conditions are observed strictly at all time.

Where the Supplier consider despatch by air is desirable or essential owing to the nature of the Goods, this should be brought to the attention of Crown Agents in writing.

Goods that are or maybe classified as hazardous must be distributed via approved means at all times and must be packaged and labelled in accordance with relevant local and international standards.

Where Goods are supplied under DAP terms, the Supplier must provide detailed evidence of all transport arrangements from their premises/warehouse and at every stage through to final delivery to the Consignee’s nominated warehouse including, but not limited to, timely evidence of temperature control records for all Goods (including ambient products).

The Supplier will ensure that the Goods are transported to ensure maintenance within the storage requirements as set out in the relevant monograph or marketing authorisation. The Supplier should make available upon request records of temperature controls maintained throughout the distribution of the Goods or the results of relevant distribution lane risk assessments.

Regardless of the Incoterm of the Contract, the Supplier must provide documentary evidence (including date and time) of when the Goods left the Supplier’s premises and subsequent arrival at the named final destination. Proof of delivery is required irrespective of the Incoterm.

**Examination**

Crown Agents reserve the right to examine all Goods in course of manufacture and packaging and to take samples for independent analysis. The Supplier must provide all reasonable facilities for such examination to be made.

**Invoices**

Invoices should be in the English language unless otherwise stated in the Contract. The description of the Goods shown on the Supplier’s invoices and packing notes shall include (unless inapplicable) the pharmacopoeia title and initial letters of the pharmacopoeia standard, e.g. BP, as shown on the label. The expiry date and batch numbers must be indicated for all Goods being supplied.

**Product Recalls**

Upon award of Contract, the Supplier must provide to Crown Agents, in writing, the full name and contact details of their Quality Person (QP) for any product recalls. The Supplier shall be contractually responsible to notify Crown Agents in writing of any recalls within stated timeframes.

**Record Keeping and Reports**

The Supplier shall maintain complete and accurate records concerning the Goods supplied under the Contract, including any required by these Special Conditions of Contract. Without limiting this, the Supplier shall maintain complete and accurate records showing temperature controls maintained throughout the storage and distribution of the Goods and shall make such records available to Crown Agents, any End-User and any relevant National Competent Authority upon request.

The Supplier shall maintain a complete and accurate record of each delivery of the Goods, stating the full description, weight, quantity, measure, order number, batch number, expiry date of the Goods, name of manufacturer and origins of the Goods, cost of storage and distribution, any external quality control requirements and any other information required by Crown Agents, End Users or any relevant National Competent Authority. All ancillary paperwork and literature (including invoices) shall include the same information and be available for inspection by Crown Agents, End-Users or the relevant National Competent Authority upon request.

The Supplier shall also upon request provide all required assistance to enable Crown Agents to meet its reporting obligations to End-Users.

The Supplier shall maintain all records for five years.

**Suspected Substandard, Spurious, Falsely Labelled, Falsified and Counterfeit (SSFFC) Goods**

In the event that contractual documents provided for payment purposes indicate a risk of Spurious, Falsely labelled, Falsified or Counterfeit Goods, the Supplier is advised that Crown Agents (at their sole and absolute discretion) reserve the right to withhold payment for the Goods pending the satisfactory outcome of the investigation of the suspected falsification and the Goods should be segregated in a quarantine area pending the outcome of the investigation. The Marketing Authorisation holder or Manufacturer (if the Supplier is not the Manufacturer) is to confirm if the Chemicals, Medicines or Medical Devices batch is falsified and advise of arrangements for its disposal.

For the purposes of these Special Conditions of Contract, “Falsified Goods” means that any Chemicals, Medicines or Medical Device with a false representation of:

1. It’s identity, including its packaging and labelling, its name or its composition about any of the ingredients including excipients and the strength of those ingredients;
2. Its source, including its manufacturer, its country of manufacturing, its country of origin or its Marketing Authorisation holder; or
3. Its history, including the records and documents relating to the distribution channels used.

**Handling and Destruction of Falsified Goods**

In the event of confirmed falsified Goods, any shipments which have been exported and are refused entry by customs or are not to be onward despatched for any reason must not be returned to the EEA once they have been exported and must not be returned to saleable stock.

Goods for disposal shall be destroyed using an appropriately authorised waste disposal contractor and written proof of evidence of the destruction shall be provided to Crown Agents by the Supplier’s QP or Head of Quality for audit trail purposes.

**Liability**

The Supplier shall indemnify and keep indemnified Crown Agents and their End-User against all loss, damages, costs and expenses arising in respect of any product liability or similar claim for injury to person or property in connection with the Goods supplied under the Contract.