SUPPLIER ROLE SPECIAL CONDITIONS OF CONTRACT FOR THE SUPPLY OF CHEMICALS, MEDICINES AND MEDICAL DEVICES - Version 4 (June 2022)

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.

Bona fides

Suppliers of medicines must supply Crown Agents with a full copy of their manufacturing or wholesaling licence, authorisation, or equivalent in English. In addition, their Good Manufacturing or Distribution Practice certificate, as applicable, must be provided. If the Supplier supplies controlled drugs then the UK Home Office Licence or equivalent must also be supplied in English. The scope of these licences must allow for the legal supply of the Goods required by Crown Agents.

Manufacturers and wholesalers must comply with Good Distribution Practice (GDP).

All premises used for the manufacture/distribution of the Goods to be supplied must hold a current License to operate as a Pharmaceutical Manufacturer/Distributor as proof that the site (including warehouse) and equipment used respect the conditions stipulated in an international quality certification system. If the original licence is not in English an official translation or notarised copy is required.

Details of the National Competent Authority or other Regulatory organisation that issued the original documents should be supplied. 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.

If new licences, authorisations or other relevant bona fides are updated these must be forwarded to Crown Agents for re-approval.

The Supplier and their licenced premises or contract manufacturing organisation or contract storage site must be open to visits from Inspectors appointed by Crown Agents.

Crown Agents reserve the right, to, at any time, request any data or other information required by us to meet our obligations to the UK Medicines and Healthcare products Regulatory Agency (MHRA).

The Supplier must inform Crown Agents of any issues, national regulatory alerts or restrictions placed on export of medicines or medical devices which could affect their ability to legally supply the required Goods as soon as they have been made aware of them.

Standards

- The Goods to be supplied must be manufactured in accordance with the standards of Good Manufacturing Practice (GMP or cGMP). The GMP standards shall have been accredited by:

1. a Stringent Regulatory Agent (SRA);
2. 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.
- The Goods must be able to be declared free from Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) .
- The Supplier must notify Crown Agents immediately of any changes to the Goods specification, expiry date, batch number, labelling, contra-indications, or quantity. The certificates or controlled documentation pertaining to the Goods which evidence the changes must be forwarded to Crown Agents for them to re-approve the Goods prior to their supply.
- 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 or UKCA (UK Conformity Assessed) marking or UKNI marking and Declaration of Conformity documentation as applicable, or equivalent. If the Supplier is not the manufacturer, they must have verified the documentation.
- 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).

Controlled Drugs (CDs)

Where applicable, the Supplier is wholly responsible for ensuring that the handling of the controlled drugs as identified in the contract, shall comply with all applicable statutory and regulatory requirements within the country of export and import. The certificates required to export CDs must be obtained and provided in advance to the importer to allow them time to obtain the relevant import documentation. Crown Agents must be sent copies of these certificates for their records.

Consideration must be given to the countries through which the CDs may pass during their transportation and any additional documentation which may be required by these countries. Where possible the most direct and shortest route should be taken to minimise the risk of delays, diversions, or theft of CDs. The logistics companies used must be approved to transport CDs and a suitable contract must be in place prior to the Goods being dispatched.

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 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,
- Batch number, date of manufacture, the expiry date in an uncoded form and any 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
- Batch number, date of manufacture, expiry date in an uncoded form
- 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 and labelling.

External packing to protect the Goods during transportation 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 they are packed and labelled with the requirements of the appropriate regulations governing the despatch by sea or air of hazardous cargo. The packaging must be appropriately labelled providing sufficient information to protect the handlers of the product in addition to the labelling requirements of the Goods.

The information shall be detailed on delivery notes and manifests in addition to the external packaging, and shall include the details of the identification of the container's contents and source, where applicable.

Wooden pallets (if any) should be marked, fumigated, or treated in another way according to the international phytosanitary legislation requirements.

Double stacking of pallets is often not advisable and corner protectors are often required in addition to pallet wraps which may be required to give protection to the Goods.

Special Storage and Transportation

The manufacturers advice, the Goods monograph, or marketing authorisation will detail the required conditions for transportation and storage of the Goods. These conditions must be adhered to, in order to ensure that the quality, integrity, expiry date and when required sterility of the Goods are maintained. Goods may be sensitive to temperature, and any of the following; humidity, light, shaking, tilting, and must be kept secure at all times.

Goods which have strict temperature requirements such as:

- controlled ambient (+ 15°C to + 25°C)
- cold chain fridge (+2°C to +8°C)
- frozen (the majority of frozen medicines require storage in the range of -15°C to -20°C but some require colder temperatures such as -60°C to -80°C)

will require the Supplier to consider validated active or passive packaging solutions or temperature controlled vehicles, or specialist validated containers to ensure that the required temperature conditions are maintained at all times during the transportation.

Where the Supplier considers despatch by air is desirable or essential owing to the nature of the Goods, or the urgency of the supply, the requirements of the airline, and any relevant documentation must be brought to the attention of Crown Agents in writing.

Where Goods are supplied under "D - Delivered" terms (Incoterms® 2020), the Supplier is responsible for everything, including packaging, documentation, export approval, loading charges, to the point of delivery. The Supplier must provide the risk assessments of the lane, the choice, qualification and validation of the packaging and the temperature data loggers, when required. Details of all the chosen approved transport providers and the specific transport arrangements from the Supplier's premises/warehouse through to the delivery at the Consignee's nominated warehouse must be supplied in advance to Crown Agents.

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. Copies of all the completed customs documentation with the correct product Commodity or "HS" Code, relevant temperature data, associated documents should be supplied to Crown Agents for all Goods in each shipment.

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 and delivery notes should be in the English language unless otherwise stated in the Contract. They must be dated and have the Supplier's full name and address. They must have an accurate description of the Goods including where applicable the pharmacopoeia title and initial letters of the pharmacopoeia standard, e.g. BP, as shown on the label. The full name of the medicinal product

including the form and the strength or the device(s). The quantity, expiry date and batch number of all of the Goods being supplied.

Product Recalls

Upon award of Contract, the Supplier must provide to Crown Agents the full name and contact details of the person responsible for recalls within their company. The Supplier shall be contractually responsible to notify Crown Agents in writing of any recalls within stated timeframes. If the Supplier is a manufacturer it may be the name of their Qualified Person (QP) or Head of Quality. If the Supplier is a wholesale distributor it may be their Responsible Person (RP). Out of hours contacts and deputies should be provided and when these contacts or their details change Crown Agents must be informed.

Deviations

In the case of serious deviations such as temperature or humidity during transportation, which could affect the Goods quality or integrity the Supplier's QP or RP should be contactable and must make themselves available to help with any investigation to determine if the Goods can be released into usable stock.

Record Keeping and Reports

The Supplier shall maintain records of:

- the quality and regulatory checks, such as the qualification and approval of their suppliers and Goods and their origin, if they are not the manufacturer.

- Copies and subsequent checks of relevant certificate of analysis and the CE/UKCA marks of devices and any third party verification.

- Evidence of checks that the Goods can be exported and will not cause a shortage in the UK or the relevant country the Goods are being exported from.

- Checks of the import documents, and recipient countries banned import list prior to exporting of the Goods to ensure they will be able to be imported .

- A full description of the Goods, the quantity, weight, the order number, batch number, expiry date, the commercial costs including the costs of storage and distribution must all be retained along with ancillary paperwork, literature, purchase orders, delivery notes and invoices proof of delivery and receipt, customs documentation and if relevant the Airway Bills.

- Evidence of temperature, and when required humidity data, including any deviations experienced by the Goods during storage or distribution, investigations and associated CAPAs must all be retained.

The controlled records, as with all GDP related documents, must be made available for future reference and audit purposes by Crown Agents, the End User, any relevant Regulatory Authority or their auditors or inspectors and must be retained for at least five years.

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

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:

a) Its identity, including its packaging and labelling, its name, or its composition, about any of the ingredients including excipients and the strength of those ingredients;
b) Its source, including its manufacturer, its country of manufacturing, its country of origin or its Marketing Authorisation holder; or
c) 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 UK or 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.