Minister for Health and
Minister for Ambulance Services
Member for Woodridge

Queensland Government

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147–163 Charlotte Street Brisbane 4000
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**Website** www.health.qld.gov.au

17 JUN 2016

MI211570

Dr Geoffrey Guy
Founder and Chairman
GW Pharmaceuticals
1 Cavendish Place
London W1G 0QF
UNITED KINGDOM

Dear Dr ~~Guy~~ Geoffrey,

I would like to take this opportunity to thank you for agreeing to enter into this Memorandum of Understanding (MoU) with Queensland Health. The Queensland Government appreciates that GW Pharmaceuticals is the world leader in the field of cannabinoid-based pharmaceutical research and development. I have been greatly impressed by the professionalism of the GW Pharmaceuticals team in dealing with the complexities that this type of research and drug development presents.

Queensland Health looks forward to working with GW Pharmaceuticals to implement the activities developed in the MoU especially the 'Centre' at the Lady Cilento Children's Hospital. This is an exciting prospect and builds a platform to undertake a range of research projects into the future. This Centre will enable Queensland Health to contribute to the world-wide body of research into cannabinoid therapeutics for the benefit of not only Queenslanders but others more broadly.

The staff at the Lady Cilento Children's Hospital are excited about the prospect of using cannabinoid-based prescription medicines to improve the lives of the young Queenslanders in their care.

I am very thankful for the opportunities this agreement offers, particularly for those children afflicted by treatment resistant conditions, and for researchers in Queensland to gain skills in this rapidly developing area. Queensland Health look forward to an ongoing collaboration with GW Pharmaceuticals.

Should you require any further information in relation to this matter, I have arranged for Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Prevention Division, Department of Health, on telephone (+61) 7 3234 1138 or (+61) 412 172 539, to be available to assist you.

Yours sincerely

**CAMERON DICK MP**
**Minister for Health**
**Minister for Ambulance Services**

# Memorandum of Understanding between the Queensland Government and GW Pharmaceuticals

## Queensland Government Cannabis/Cannabis Derived Products Clinical Trial Initiative

### Parties:

The parties to the Memorandum of Understanding (MOU) are the State of Queensland acting through Queensland Health (Qld Health) and GW Research Ltd, a wholly owned subsidiary of GW Pharmaceuticals Plc. (GW Pharmaceuticals).

### Preamble:

Qld Health is seeking to develop a better understanding of the potential for cannabinoid-based pharmaceutical products to alleviate symptoms and/or treat a range of debilitating or terminal illnesses.

As part of this, Qld Health is funding research into the use of cannabinoid-based pharmaceutical products for the treatment of patients in Queensland with serious illness, including childhood epilepsy.

GW Pharmaceuticals is a UK-based biopharmaceutical company dedicated to developing and commercialising a portfolio of novel cannabinoid-based prescription medicines to meet patient needs in a wide variety of indications, including products showing promise in clinical trials for treatment of paediatric epilepsy, through a focused research and development program that is built upon high quality scientific evidence generated in accordance with internationally recognised legal and ethical standards in order to provide patients with unmet medical needs a viable treatment option.

This MOU sets out how the parties wish to collaborate for the above purposes.

## About Qld Health:

Qld Health is the public health agency of the Queensland Government. Qld Health is responsible for public sector health services in Queensland delivered through 16 Hospital and Health Services including the Lady Cilento Children's Hospital (LCCH). Children's Health Queensland (CHQ) Hospital and Health Service is the body responsible for the Lady Cilento Children's Hospital.

All organisations which form part of Qld Health are under the control and direction of the Minister for Health and Minister for Ambulance Services

The CHQ provides tertiary level care to children at a single site in South Brisbane. This site coordinates the care for all children with severe epilepsy across Queensland. In so doing the CHQ collectively treats approximately 1000 children across the State on an ongoing basis for severe epilepsy.

Qld Health has established the Medicinal Cannabis Team within the Chief Health Officer and Healthcare Regulation Branch. This team is developing strategies and approaches to support medicinal cannabis research, implement training and the development of greater understanding of the potential uses of medicinal cannabis in Queensland and more broadly. The Centre will draw on local and international sources to advance our formal understanding of medicinal cannabis, educate the community and support innovation.

## About GW Pharmaceuticals:

GW Pharmaceuticals is a global leader in cannabinoid-containing medicines and is developing a portfolio of prescription only medicines for a number of neurological indications, including for the treatment of childhood epilepsy.

GW Pharmaceuticals works closely with scientific collaborators at academic institutions across the world with the aim of identifying new research pathways and developing valuable intellectual property. GW Pharmaceuticals' research is increasingly featured in high status peer-reviewed scientific journals.

## Nature and effect:

The parties agree that this MOU sets out the principles by which they wish to collaborate.

The parties agree that nothing in this MOU is intended to create binding or legal obligations on either party.

This MOU will take effect from the date of signing by the parties and will operate for three years (**term**) unless terminated or extended under the terms of this MOU.

## Aims:

The aim of this MOU is to formalise collaboration between Qld Health and GW Pharmaceuticals to facilitate research into the clinical use of cannabinoid-based prescription medicines.

## Qld Health aim:

- To conduct further research into using cannabinoid-based -medicines for the management of severe drug-resistant childhood epilepsy and to enable a safe supply of a pharmaceutical-grade product for these children.
- To support research into the evidence based therapeutic use of cannabinoid-based medicines for certain conditions by setting up the Centre for Clinical Trials in Rare Neurodevelopmental Disorders ("Centre"),

## GW Pharmaceuticals aim:

- To provide a wide pool of patients with serious unmet medical needs with treatment options based upon cannabinoid-containing prescription pharmaceuticals developed based on sound scientific evidence and in accordance with Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and Good Manufacturing Practices (GMP).
- To progress bringing to market in Australia a proven cannabinoid-based prescription medicines to mitigate severe drug-resistant childhood epilepsy.
- To respond to opportunities and form partnerships to progress investigator-led trials of products that show clinical promise, where Queensland-based clinicians express an interest in leading such trials.

## Advisory Committee:

An Advisory Committee will be established to oversee the operation of all aspects of this MOU. It will be typically constituted of two representatives from Qld Health and two representatives from GW Pharmaceuticals. The Committee will meet three times a year which can be by teleconference or as otherwise agreed.

## Investigator-led trials:

GW Pharmaceuticals is developing a portfolio of new cannabinoid-based prescription medicines with potential applications that may align with Qld Health priorities and could be trialled in Queensland through investigator-led trials, where Queensland-based clinicians express an interest in leading such trials. As investigator-led initiatives, these trials would have to be assessed and approved by GW Pharmaceuticals' IIT committee.

Qld Health can facilitate linkages with clinical research networks in Queensland, for example, the Centre for Palliative Care Research and Education, (CPRCRE) and Queensland Paediatric Networks.

## Queensland Participation in Other Trials Led by GW Pharmaceuticals

GW Pharmaceuticals may plan to run clinical trials in children with developmental disorders and other conditions, based on positive outcomes from the observational trials undertaken through the "Centre". These further trials would be developed and negotiated by the Advisory Committee. These would be sponsored trials and the LCCH would be the likely site for these trials, GW Pharmaceuticals would be responsible for costs as well as all standard procedures associated with industry trials.

## Intellectual Property:

Qld Health acknowledges that GW Pharmaceuticals has a commercial interest in protecting the intellectual property in its products.

Nothing in this MOU will affect ownership of any intellectual property rights. Investigator-led studies in connection with this MOU are not intended or expected to result in any intellectual property rights being assigned to investigators, Qld Health, the Lady Cilento Children's Hospital (LCCH) or a Hospital and Health Service.

Should performance of any activities under the MOU by or on behalf of Qld Health and/or CHQ (including by any investigator) result in the generation of any intellectual property rights relating to the cannabinoid-based medicinal products under investigation, Qld Health will ensure that ownership of such intellectual property rights is assigned to GW Pharmaceuticals.

GW Pharmaceuticals shall have access to and the right to use the clinical trial data and the trial database for each Activity specified below in obtaining and maintaining regulatory approvals for its products.

## Announcements:

Any announcements by either party concerning the Activities 1,2, or 3 will be approved five business days in advance with both parties agreeing on content of such announcements.

## Specific activities investigating treatment for severe childhood conditions:

The following Activities proposed initially under this arrangement:

- Activity 1: Establish the Centre at CHQ to undertake clinician led observational studies using a cannabinoid-based investigational medicinal products across a range of childhood developmental disorders
- Activity 2: An expanded access treatment protocol using Epidiolex for a small number of patients with severe drug-resistant epilepsy
- Activity 3: An observational study for a small number of patients with severe drug-resistant epilepsy using Epidiolex and other cannabinoids

Each Activity will be designed implemented, and while the study is active, will be managed and overseen by the CHQ in accordance with Queensland regulatory approval and Children's Hospitals Queensland (CHQ) HREC Ethical approvals and Qld Health and GW Pharmaceuticals oversight. Each Activity shall be the subject of an independent agreement.

Prior to initiating each Activity Qld Health /CHQ and GW Pharmaceuticals shall agree upon the data plan for the Activity, the data communication/externalisation strategy and timetable.

For each Activity Qld Health shall be responsible for obtaining all necessary import licences and custom clearances for importing the Activity drug into Australia. In addition, for all Activities Qld Health shall bear all import and custom taxes, risk and title in the Activity drug shall transfer to Qld Health upon delivery, and following delivery Qld Health shall be responsible for ensuring the Activity drug is stored in accordance with GW Pharmaceuticals' instructions.

For each Activity GW Pharmaceuticals will be responsible for obtaining all necessary export approvals for the Activity drug and for delivering the Activity drug DAT (INCOTERMS 2015) to a named terminal in Queensland. Delivery will be made DAT (INCOTERMS 2015) to a named terminal in Queensland.

Safety data will be reported regularly to the Advisory Committee (consisting of Qld Health and GW Pharmaceuticals), while interim and final results will be published in peer reviewed journals. Safety data will also be reported to GW Pharmaceuticals in accordance with all applicable laws and regulations, to be detailed in a standalone pharmacovigilance agreement to be provided by GW Pharmaceuticals, in order to allow GW Pharmaceuticals to comply with its reporting obligations inside and outside Australia.

Qld Health funding for the Activities will include the following costs for three years from the signing of this MOU:

- Coordinating Centre personnel for services such as Project Managers, Regulatory Staff, Developmental Psychology Support, Statistical Personnel, scientific writing and protocol development.
- Research data collection devices and programs to ensure that the highest integrity of data is collected and maintained.
- Preparing and filing regulatory approvals such as Human Research Ethics Committees (to ensure human subject protection) and Therapeutic Goods Administration (TGA) approvals, at each clinical site.
- Research procedures (e.g. safety and efficacy measurements not covered by insurance) as well as biological sample processing and storage for all patients.
- Research staffing costs (i.e. Investigators and Coordinating Personnel) at all sites
- Travel and supply costs for the clinical site and coordinating centre.

## Activity 1: Establish the Centre to undertake a range of observational studies using cannabinoid-based medications for children with developmental disorders.

Establish the Centre at the CHQ to undertake clinician led observational studies across a range of childhood developmental disorders, possibly including (but not exclusively) Angelmans Syndrome, Rett Syndrome, and Fragile X syndrome. Other syndromes may be included as indicated or identified as being potentially responsive to cannabinoid therapies.

In consultation, the GW Pharmaceuticals clinical team and the Centre will determine the type and range of conditions and syndromes to be explored with the various cannabinoid-based medicines e.g. Epidiolex only or a combination Epidiolex and other cannabinoids in some instances or CBDV.

### Qld Health/CHQ will:

- Act as a sponsor of the trial
- Manage the approval process for import of the drug
- Design the trials in the various syndromes or conditions for patient sub-populations, for review, comment and approval by GW Pharmaceuticals' IIT Committee.
- Undertake structured observational trials following clear protocols in each identified condition and document safety, indications/markers of improvement to gather evidence towards possible broader GW Pharmaceuticals sponsored Randomised Controlled Trials (RCT's) if the observational studies show promise.
- Undertake pharmacokinetic measurements in the target populations in line with protocol

- Liaise with other Australian and International centres for the various syndromes or conditions and develop reliable outcome measures.
- Publish and disseminate results in the peer-reviewed literature through mutually agreed publication review and approval process

### GW Pharmaceuticals will:

- Supply drug free of charge to CHQ from mid-2016 until the product receives TGA registration on the Australian Register of Therapeutic Goods (ARTG), or for a period to be determined by all parties.
- Notify Qld Health of any safety signals suggesting use of medication should cease or be modified in particular groups.
- Receive safety data in accordance with agreed protocols.
- Notify Qld Health if any clinical trials show additional groups may benefit from access to the drug.

## Activity 2 – Expanded access treatment protocol using Epidiolex® for a small number of patients with severe drug-resistant childhood epilepsy

CHQ will hold an expanded access treatment protocol using Epidiolex® for a small number of patients with severe drug-resistant childhood epilepsy.

Import of medication: there are two options whereby access to Epidiolex can be provided within Australia through a special access arrangement:

i) The Special Access Scheme (SAS) of the TGA: Qld Health has previous experience importing an unregistered product on a limited basis within the terms and conditions of the SAS.
ii) An access-style clinical trial, subject to a formal protocol, National Health & Medical Research Council Ethics Committee approval and a Clinical Trials Notification in accordance with requirements of the TGA.

In both cases, the product is required to be imported to an identified pharmacy or pharmacies for distribution on a jurisdiction-wide basis and must be distributed on a named patient basis.

The most appropriate mechanism will be agreed in discussions between Qld Health and GW Pharmaceuticals.

### Qld Health/CHQ will:

- Establish access criteria specifying age range, type of epilepsy syndromes and previous medication history, this will be based on the protocol developed in NSW
- Manage the approval process for import of the medication

- Collect relevant safety data and transmit to GW Pharmaceuticals

### GW Pharmaceuticals will:

- Supply drug free of charge to CHQ from mid-2016 until the product receives TGA registration on the ARTG, or for a period to be determined by all parties.
- Notify Qld Health of any safety signals suggesting use of medication should cease or be modified in particular groups.
- Notify Qld Health if any clinical trials show additional groups my benefit from access to the drug.

## Activity 3: An observational study for patients' severe drug-resistant epilepsy using Epidiolex and other cannabinoids

The CHQ will run an observational study for a small number of patients with severe drug-resistant epilepsy using Epidiolex and other cannabinoids.

### Qld Health/CHQ will:

- Act as a sponsor of the trial
- Manage the approval process for import of the drug
- Design the trial with patient sub-populations and present the protocol to GW Pharmaceuticals' IIT Committee for review, comment and approval.
- Undertake observational trials in treatment resistant epilepsy sub-populations and document indications/markers of improvement to gather evidence towards possible broader GW Pharmaceuticals sponsored RCT's if the observational studies show promise
- Undertake pharmacokinetic measurements in target population in line with protocol
- Liaise with other Australian and International centres for the various syndromes or conditions to develop suitable measures
- Collect relevant safety data and transmit to GW Pharmaceuticals
- Publish and disseminate results in the peer-reviewed literature through mutually agreed publication review and approval process

### GW Pharmaceuticals will:

- Supply drug free of charge to CHQ from mid-2016 until the product receives TGA registration on the ARTG, or for a period to be determined by all parties
- Notify Qld Health of any safety signals suggesting use of medication should cease or be modified in particular groups
- Notify Qld Health if any clinical trials show additional groups my benefit from access to the drug

### Continued Supply under for all Activities

Continued supply of cannabinoid-based investigational medicinal products will cease in the event the Australian TGA approves a marketing authorisation application in respect of the investigational medicinal product. In this event, Qld Health will make local decisions regarding any ongoing funding of these patients.

## Termination and Extension:

This MOU may be terminated at any time by either party by notice to the other party or extended beyond the expiry of the term by the written agreement of the parties.

Upon termination, each party must cease to hold itself out as connected with the other party.

## General

Any rights and obligations of the parties under this MOU may be not assigned, changed or otherwise dealt with. An amendment of this MOU must be in writing and signed by the parties.

This MOU may be executed in counterparts and by way of electronic exchange. All counterparts together will be taken to constitute one instrument.

A notice to or by a party to this agreement must be in writing addressed as shown below:

i) If given to Qld Health by GW Pharmaceuticals, addressed and forwarded to the Chief Health Officer at the following address:
   Address: Queensland Health, GPO Box 48, Brisbane, Qld, 4001
   Email: MCTeam@health.qld.gov.au
   Or as otherwise notified in writing by Qld Health; and
   if given to GW Research by Qld Health, addressed and forward to the Chief Executive Officer at the following address:
   Address: Sovereign House, Vision Park, Histon, Cambridge, CB249BZ
   Or as otherwise notified in writing by GW Pharmaceuticals

Signed for and on the behalf of Qld Health by:

Cameron Dick MP

(name)

Minister for Health and Minister for Ambulance Services

(position)

.....

(Signature)

.....

(Date) 17 June 2016

In the presence of:

ANIKA HUME

(Name of Witness)

.....

(Signature)

Signed for and on the behalf of GW Pharmaceuticals by:

Dr Geoffrey Guy

(Name)

Chairman

(Position)

.....

(Signature)

.....

(Date) 7/6/16

In the presence of:

K J Dumas

(Name of Witness)

.....

(Signature)

Queensland Government

The State of Queensland acting through Queensland Health

[via the department's Central Pharmacy]

GW Research LTD

# Supply Agreement

for the Supply of Epidiolex®

# Contents

# Parties

**The State of Queensland acting through Queensland Health (QH)** ABN 66 329 169 412 of 147-163 Charlotte Street, Brisbane, in the State of Queensland, 4000, Australia

**and**

**GW Research Limited** (**GW**), incorporated in England and Wales with company number 03107561 whose registered address is, Sovereign House, Vision Park, Chivers Way, Histon, Cambridge CB24 9BZ, United Kingdom

# Background

A The Queensland government is seeking to develop a better understanding of the potential for cannabis and/or cannabis-derived pharmaceutical products to alleviate symptoms or potentially treat a range of debilitating or terminal illnesses.

B As part of its efforts to treat these illnesses, the government of Queensland has funded research into the use of cannabis-derived pharmaceutical products for the treatment of patients in Queensland with serious illness, including childhood epilepsy.

C GW is developing a portfolio of cannabinoid medicinal products to meet patient needs in a wide variety of indications, including products showing promise in clinical trials for treatment of paediatric epilepsy.

D On 17 June 2016, GW's parent company, GW Pharmaceuticals plc, entered into a Memorandum of Understanding with the government of Queensland setting out the terms whereby it and GW wish to collaborate on three separate activities.

E This Supply Agreement addresses the manner in which GW will supply QH with the drug Epidiolex® for the purpose of the second activity described in the Memorandum of Understanding. Specifically, this Activity is an expanded access treatment protocol using Epidiolex® for a small number of patients with severe, drug-resistant childhood epilepsy.

# Agreed terms

## 1 Interpretation

### 1.1 Definitions

In this Agreement:

**Activity** means the expanded access treatment protocol using Epidiolex® for a small number of patients with severe drug-resistant childhood epilepsy.

**Agreement** means this Supply Agreement and all schedules, appendices and any document attached to it.

**Authorised Prescriber** means a medical practitioner authorised by the Therapeutic Goods Administration (**TGA**) who must be:
(i) a medical practitioner engaged in clinical practice in a hospital and who has been endorsed by the ethics committee of the hospital for the purpose of the Activity; or
(ii) a medical practitioner treating patients outside a hospital setting who has obtained endorsement from an appropriate ethics committee for the purpose of the Activity.

**Business Day** means any day Monday to Friday (inclusive) on which the major clearing banks in London, England and Brisbane, Australia transact business.

**Commencement Date** means the date specified in **Item 2** of **schedule1**.

**Compassionate Access Scheme (CAS)** means the name used by the Queensland government that applies to the supply of Epidiolex® to Authorised Prescribers.

**Confidential Information** means information that is by its nature confidential, is designated by a party as confidential, or that a party knows or ought to know is confidential and includes:

(a) data or personal information created, collected or captured by QH in connection with this Agreement;

(b) 'confidential information' about any patients as defined in section 139 of the *Hospital and Health Boards Act 2011* (Qld); and

(c) information concerning the business or affairs of QH, and information concerning the business or affairs of GW or any other member of its Group, including information relating to GW's operations, processes, plans, product information, market opportunities and customers,

but does not include information which:

(d) is or becomes, without breach of confidentiality, public knowledge; or

(e) forms part of a party's general skill and knowledge.

**Delivery Date** means the date or period specified in **Item 6** of **schedule 1** for the delivery of the Product.

**Delivery Site** means the location for delivery of the Product.

**Forecast** means QH's anticipated supply needs of the Product for the six (6) calendar quarters following the date of the Forecast, which, as at the Commencement Date, is specified in **Item 14** of **schedule 1**.

**Group** means, in relation to a company, that company, its subsidiaries, a holding company, and/or any of its subsidiaries.

**Initial Period** means the date or period specified in **Item 3** of **schedule 1**.

**Product** means the unapproved, developmental pharmaceutical product described in **Item 1** of **schedule 1**.

**Product Specifications** mean the manufacturing and quality control specifications prepared by GW for the Product as they are set out in **Item 4** of **schedule 1**.

**Project Manager** means the persons described in **Item12** of **schedule 1**.

**Standard Operating Procedures** means the written procedures, protocols or manuals of GW that describe tasks and assign role responsibilities relating to the manufacture of Product..

**Storage and Transport Specifications** mean the minimum standards and requirements that have been specified for the storage and transport of the product.

**Technical Agreement** means the agreement between the parties attached at Appendix A that includes the Product Specifications, the Storage and Transport Specifications, and the requirements for manufacturing, packaging, quality control testing, and release of the Product—including procedures for managing the recall of the product and other issues in relation to the Product at the location where the Product is stored.

**Terminal** means the first designated Delivery Site of the Product in Australia.

## 1.2 Construction

Unless expressed to the contrary, in this Agreement:

(a) words in the singular include the plural and vice versa;

(b) any gender includes the other genders;

(c) if a word or phrase is defined its other grammatical forms have corresponding meanings;

(d) "includes" means includes without limitation;

(e) no rule of construction will apply to a clause to the disadvantage of a party merely because that party put forward the clause or would otherwise benefit from it;

(f) a reference to:

(i) a person includes a partnership, joint venture, unincorporated association, corporation and a government or statutory body or authority;

(ii) a person includes the person's legal personal representatives, successors, assigns and persons substituted by novation;

(iii) any legislation includes subordinate legislation under it and includes that legislation and subordinate legislation as modified or replaced;

(iv) an obligation includes a warranty or representation and a reference to a failure to comply with an obligation includes a breach of warranty or representation;

(v) a right includes a benefit, remedy, discretion or power;

(vi) time is the local time in Brisbane;

(vii) "$" or "dollars" is a reference to Australian currency;

(viii) writing includes any mode of representing or reproducing words in tangible and permanently visible form, and includes fax transmissions;

(ix) this Agreement includes all schedules, appendices and annexures to it; and

(x) a clause, schedule, appendix or annexure is a reference to a clause, schedule, appendix or annexure, as the case may be, of this Agreement;

(g) if the date on or by which any act must be done under this Agreement or is not a Business Day, the act must be done on or by the next Business Day; and

(h) where time is to be calculated by reference to a day or event, that day or the day of that event is excluded.

## 1.3 Headings

Headings do not affect the interpretation of this Agreement.

# 2 Project Management

## 2.1 Role of Project Managers

The parties will appoint Project Managers who will serve as the liaison and point of contact between them. A Project Manager will have the authority to represent its respective organisation in all day to day matters that relate to the supply and distribution of the Product.

QH and GW will each appoint the individual identified in Item 13 of schedule 1 as its Project Manager and may, from time to time, replace or remove the Project Manager by giving written notice to the other Party.

## 2.2 Liaison—monthly reporting by QH

The QH Project Manager must, not less than once per calendar month, send an email to the GW Project Manager to update and report on the following matters:

(a) the anticipated start date of the Activity;

(b) the Activity initiated, completed or continuing to be performed;

(c) Details of progress of the Activity;

(d) the anticipated completion date of the Activity;

(e) the number of patients enrolled in the Activity;

(f) the volume of stock of each Product held by QH or its agent, Link Medical Products Pty Ltd (**Link Healthcare**);

(g) the volume of stock of each Product at each clinical site;

(h) the volume of stock with each Authorised Prescriber and

(i) the volume of Product delivered to each Authorised Prescriber during the prior calendar month (if any).

## 2.3 Liaison—Quarterly Reporting by QH

The QH Project Manager must, not less than once per calendar quarter, provide GW an updated Forecast that covers the next six (6) calendar quarters or until expiry of the Term (whichever is sooner).

## 2.4 Liaison—Quarterly Meetings of Project Managers

The Project Managers will meet by telephone not less than once each calendar quarter to:

(a) discuss the status of the Activity;

(b) discuss QH's Product needs;

(c) finalise the Forecast, and

(d) review the operation of this Agreement.

Dates of meetings will be agreed between the Project Managers not less than twenty one (21) days prior to the quarterly meeting.

The first meeting of the Project Managers will take place no later than fifteen (15) days after the Commencement Date.

Project Managers may request special meetings by providing the other Project Manager with reasonable, written notice of the request.

### 2.5 QH's Forecast of Product Requirement

In accordance with **Item 14** of **Schedule 1**, QH agrees to provide GW with a quarterly update to its Forecast of Product supply requirements.

# 3 Term and termination

### 3.1 Term of Agreement

This Agreement will commence on the Commencement Date and continue until the end of the **Initial Period**.

### 3.2 Termination

(a) Without prejudice to its other rights or remedies, either party may terminate this Agreement immediately on written notice to the other party if the other party is:

(i) In material breach of any of its obligations under this Agreement and either that breach is incapable of remedy or the party has failed to remedy the breach within thirty (30) Business Days of being notified of the breach; or

(ii) becomes insolvent or is otherwise subject to an order or a resolution for its liquidation, administration, winding-up; or

(iii) is subject to any proceeding or equivalent bankruptcy proceeding in any jurisdiction.

(b) Termination of this Agreement shall not affect any rights, remedies, obligations or liabilities of the parties that have accrued up to the date of termination, including the right to claim damages in respect of any breach of the Agreement which existed at or before the date of termination.

# 4 Product Provision to QH

### 4.1 Compassionate Access Scheme

GW has agreed to provide QH with the Product for use exclusively for the Activity in accordance with:

(a) the terms and conditions of this Agreement;

(b) an amount of the Product that the parties reasonably estimate to be required to complete the Activity, and at a cost described in Item 12 of schedule 1;

(c) all applicable federal and state regulatory requirements;

(d) the Standard Operating Procedures;

(e) the Product Specifications; and

(f) the Transport and Storage Specifications applicable to GW.

### 4.2 Product Ownership, Authorisations and Shipment

GW warrants that it is the sole owner of the Product and will:

(a) obtain all licenses, permissions and authorisations necessary for the exportation of the Product to Australia at its own expense;

(b) deliver not more than once per calendar quarter, the Product in a quantity specified in the Forecast, subject to GW being required to deliver no greater volume of a Product, in aggregate, than it reasonably believes is necessary to complete the Activity;

(c) deliver all shipments of Product on a DAT Basis (**Delivery at Terminal**) to a named Terminal in New South Wales;

(d) arrange for shipping and insurance of each shipment of Product to Delivery at Terminal at its own expense where title and risk of loss or damage to the shipment of Product will remain with remain with GW. Title and risk of loss or damage will then transfer to QH;

(e) Ensure that the Product is properly packed and secure for delivery in good condition;

(f) Notify QH's Project Manager of the anticipated Delivery Date for each shipment of Product;

(g) Notify QH's Project Manager of the date on which a delivery is dispatched from its manufacturing facility and the named Terminal in New South Wales where it will be delivered.

## 4.3 Product collection, inspection, handling, storage and distribution

QH, or its agent, will, as described in the Technical Agreement at Appendix A to the Agreement:

(a) obtain all licences, permissions and authorisations required for the importation of the Product in accordance with terms of this Agreement;

(b) take responsibility following delivery at Terminal, for ensuring the Product is stored in accordance with the applicable Storage and Transport Specifications;

(c) handle, store and distribute the Product in accordance with the terms of the Technical Agreement; and

within three (3) days of Delivery at the Terminal in New South Wales:

(d) carry out a visual inspection of the delivery;

(e) verify that the identity, quantity, packaging and labelling correspond to the relevant Forecast;

(f) verify that the certificate/s of analysis for the shipment states that the Product conforms in all material respects to the Product Specifications;

(g) verify that the shipment appears in good condition;

(h) verify that the temperature of the shipment has remained consistent with the requirements specified in the Storage and Transport Specifications by examining the data logger information.

If, after conducting its inspection, QH, or its agent, considers that the shipment is defective, QH will promptly notify GW in writing and specify reasons in accordance with the requirements of the Technical Agreement.

QH is responsible for the allocation of each pack of Product to the relevant facility where Authorised Prescribers are undertaking the Activity.

QH or any of its employees or agents, shall not directly or indirectly, at any time during or after the Term:
(i) use any quantity of Product supplied by GW pursuant to this Agreement for any purpose which is not an Activity, or
(ii) adulterate, alter, over-sticker or otherwise amend the packaging or labelling of any quantity of Product.

# 5 Recalls

Recalls, withdrawals and corrections will be managed in accordance with the Technical Agreement in Appendix A.

# 6 Confidentiality

## 6.1 Duty not to disclose

Each party will ensure that it does not:

(a) disclose Confidential Information of the other party ('**Disclosing Party'**);

(b) use Confidential Information of a Disclosing Party for any purpose other than the performance of this Agreement,

in breach of any laws and without the prior, written approval of the Disclosing Party.

## 6.2 Exceptions to nondisclosure

A party ('**Recipient Party**') that receives Confidential Information of the other party may only disclose the other party's Confidential Information:

(a) to its employees, officers, agents, consultants or subcontractors who need to know such information for the purposes of carrying out the Recipient Party's obligations under this Agreement; or

(b) to the extent required or authorised by law or by a lawful requirement of any government, governmental body, authority or agency;

(c) if required to do so in connection with legal proceedings; or

(d) for public accountability reasons, including a request for information by Parliament, or a Parliamentary Committee, or a Minister.

# 7 Intellectual property rights

## 7.1 Ownership

The parties agree that nothing in this Agreement or the performance of an obligation under this Agreement transfers or affects a party's ownership in its intellectual property.

## 7.2 Warranty

(a) GW warrants to QH that, at the Commencement Date, (a) it is not party to any litigation pursuant to which a third party is claiming that the process by which GW manufactures Product or the formulation in which the Product is dispensed infringes or otherwise misuses such third party's intellectual property, and (b) to its knowledge there are no granted patents to which GW does not have rights which cover the the process by which GW manufactures Product or the formulation in which the Product is dispensed in the countries in which its Product manufacturing and formulation activities are conducted (each a "**Relevant Third Party Patent**").

(b) GW undertakes to notify QH of (a) any Relevant Third Party Patent it becomes aware of which may be infringed by the supply of Product by GW to QH under the terms of this Agreement, and (b) any litigation instituted against GW pursuant to which a third party calims that the process by which GW manufactures Product or the formulation in which the Product is dispensed infringes or otherwise misuses such third party's intellectual property.

# 8 Insurance and Liability

## 8.1 Liability and indemnity

(a) QH shall, to the extent authorised by applicable law, indemnify, defend and hold harmless GW, its affiliates and its and their employees from any and all liabilities, claims, actions, or suits resulting from:

(i) a breach of this Agreement by QH;

(ii) the negligent, unlawful, or fraudulent acts or omissions of QH, its employees or its agents pertaining to the activities of QH to be performed under this Agreement.

(b) Notwithstanding any other provisions of this Agreement, except the remainder of this clause, GW (including its affiliates) aggregate liability to QH shall not exceed GW's cost of manufacturing and supplying the Product supplied.

(c) Nothing in this clause shall have the effect of excluding or otherwise restricting, or limiting the amount of, GW's (including its affiliates) liability for:

(i) personal injury (including sickness) or death caused by its negligent, unlawful, or fraudulent acts or omissions; or

(ii) any other liability that cannot be excluded or limited by law.

## 8.2 Insurance policies

Each Party must maintain with a reputable insurer during the Term:

(a) professional indemnity insurance; and

(b) public and product liability insurance,

adequate to cover its liability to the other party in relation to this Agreement.

8.3 Each party will, upon request in writing at any time by the other party, produce evidence (in the form of certificates of currency) to the other party that these insurances have been effected and maintained.

# 9 Notices

## 9.1 General

A notice, demand, certification, process or other communication relating to this Agreement must be in writing, in English and may be given by an agent of the sender.

## 9.2 How to give a communication

In addition to any other lawful means, a communication may be given by being, sent by email to the party's Project Manager's current email address in Item 13 of Schedule 1.

# 10 General

## 10.1 Legal and other costs

Except as expressly stated otherwise in this Agreement, each party must pay its own legal and other costs and expenses of negotiating, preparing, executing and performing its obligations under this Agreement.

## 10.2 Compliance

Each party must comply with all applicable laws and standards in relation to performance of its obligations under this Agreement.

## 10.3 Amendment

This Agreement may only be varied or replaced by a document executed in writing by both parties.

## 10.4 Waiver and exercise of rights

(a) A single or partial exercise or waiver by a party of a right relating to this Agreement does not prevent any other exercise of that right or the exercise of any other right.

(b) A party is not liable for any loss, cost or expense of any other party caused or contributed to by the waiver, exercise, attempted exercise, failure to exercise or delay in the exercise of a right.

## 10.5 Governing law and jurisdiction

(a) This Agreement is governed by and is to be construed in accordance with the laws of Queensland and Australia.

(b) In the event of a dispute arising out of, or relating to, this Agreement, including any question regarding its existence, validity or termination, the parties shall first seek to resolve the dispute through the Project Managers of each party. If any dispute is unable to be resolved at this level, attempts must be made to resolve the dispute with senior officers within each party.

(c) If the parties are unable to resolve the dispute pursuant to Clause 10.5(b), either party may commence mediation proceedings to resolve such dispute. the jurisdictional location for commencing any such mediation shall be in either Brisbane, Australia, or London, England under the London Court of International Arbitration (LCIA) Mediation Rules available at the following website: http://www.lcia.org/Dispute_Resolution_Services/LCIA_Mediation_Rules.aspx, .

## 10.6 Assignment

(a) A party must not assign or deal with any right under this Agreement without the prior written consent of the other parties.

(b) Any purported dealing in breach of this clause is of no effect unless assignment is necessary by reason of legislative requirement.

## 10.7 Counterparts

This Agreement may consist of a number of counterparts and, if so, the counterparts taken together constitute one document.

## 10.8 Entire understanding

(a) This Agreement contains the entire understanding between the parties as to the subject matter of the agreement.

(b) All previous negotiations, understandings, representations, warranties, memoranda or commitments concerning the subject matter of this Agreement are merged in and superseded by this Agreement and are of no effect. To the extent such prior understandings, representations, warranties, memoranda or commitments cover subject matter in addition to that which address by this Agreement, such prior understandings, representations, warranties, memoranda or commitments shall continue in effect except to the extent it addresses the subject matter of this Agreement. Neither party is liable to the other party in respect of those matters.

(c) No oral explanation or information provided by a party to the other:

(i) affects the meaning or interpretation of this Agreement; or

(ii) constitutes any collateral agreement, warranty or understanding between the parties.

## 10.9 Relationship of parties

This Agreement is not intended to create a partnership, joint venture or agency relationship between the parties.

## 10.10 Negation of employment

This Agreement is not intended to create an employer/employee relationship between the parties.

## 10.11 Cooperation

The parties will cooperate with one another and their employees, agents and contractors, and act reasonably and in good faith at all times to comply with any obligations under the Agreement.

## 10.12 Force majeure

(a) If a party is prevented or delayed in performing an obligation by Force Majeure, and promptly acts to mitigate or remove the Force Majeure and its effect, then the obligation is suspended during, but for no longer than, the period the Force Majeure continues and any further period that is reasonable in the circumstances.

(b) In this clause "**Force Majeure**" means an event beyond the reasonable control of the affected party, which occurs without the fault or negligence of the affected party but, in the case of the GW, does not include acts or omissions of the GW's officers, employees, agents and contractors or other customers.

## 10.13 Subcontracting

Neither party will subcontract its obligations under this Agreement without obtaining the prior approval of the other party.

**EXECUTED BY THE PARTIES** as follows:

**SIGNED** for and on behalf of THE STATE OF QUEENSLAND ACTING THROUGH QUEENSLAND HEALTH

ABN 66 329 169 412 )

…… )
*(signature of duly authorised person)*

by ) **Michael Walsh**
**Director-General**
**Queensland Health**

a duly authorised person, in the presence of: ) ……/……/……
) *(date)*

…… ) ……
*(name of witness)* *(signature of witness)*

**SIGNED** for and on behalf of ) ……
GW RESEARCH LIMITED ) *(signature of duly authorised person)*
by )

.....
*(printedt name)*

.....
*(position)* )

a duly authorised person, in the presence of: ) ……/……/…….
*(date)*

…… ) ……
*(name of witness)* *(signature of witness)*

# Schedule 1

| | | |
|---|---|---|
| **Item 1** | Product | Epidiolex® 100 (2 x 100 mL) ROW<br><br>Epidiolex® 100 mg/mL pack containing 2 x 100 mL bottles of CBD in sesame oil, oral solution, for the Rest Of World (ROW) only (excluding the US). Packs will be assembled and stored as bulk stock from which packs will be selected and shipped as required to each intended or a third party for distribution. |
| **Item 2** | Commencement Date | The date the last party executes the Agreement |
| **Item 3** | Initial Period | The period starting on 1 December 2016 and ending on to the earlier of, (i) 30 November 2020 and (ii) the date on which Epidiolex® is placed on the Australian Register of Therapeutic Goods. |
| **Item 4** | Product Specifications | Description: Epidiolex® 100 mg/mL pack containing 2 x 100 mL bottles of CBD in sesame oil, oral solution, for the Rest Of World (ROW) only (excluding the US). Packs will be assembled and stored as bulk stock from which packs will be selected and shipped as required to each intended or a third party for distribution.<br><br>Model No: FT0095 / GA0077 V4.<br><br>Value: 2 x 100 mg/mL per pack<br><br>Local Narcotics Schedule: S4 |
| **Item 5** | Terminal | Sydney International Terminal |
| **Item 9** | Party responsible for Delivery to theTerminal | GW |
| **Item 10** | Party responsible for Delivery from the Terminal to QH | QH through an agreement with Link Healthcare |
| **Item 11** | Party responsible for Inspecting Product at Terminal | QH through an agreement with Link Healthcare |
| **Item 12** | Payments | Under the Compassionate Access Scheme, GW is providing the Product to QH completely free of charge for the purpose of the Activity |
| **Item 13** | Project Managers | **GW:**<br><br>Louise Harris |

<table>
<tr>
<td></td>
<td></td>
<td>
Address:<br><br>
Team Lead CTS<br>
Kent Science Park, Sittingbourne,<br>
Kent, ME98AG, UK<br>
Tel: 01-7-9543-4068<br>
Email: @gwpharm.com<br><br>
QH:<br><br>
Dorothy Vicenzino<br>
Address:<br><br>
PO Box 2368 Fortitude Valley BC<br>
Qld 4006, Australia<br>
Tel: 61-07-3328 -9219<br>
Email:<br>
Dorothy.Vicenzino@health.qld.gov.au
</td>
</tr>
<tr>
<td>Item 14</td>
<td>Forecast at 1 May 2016</td>
<td>
<table>
<tr><th>Calendar Quarter</th><th>Number of Bottles of Epidiolex®</th></tr>
<tr><td>1</td><td>226</td></tr>
<tr><td>2</td><td>270</td></tr>
<tr><td>3</td><td>270</td></tr>
<tr><td>4</td><td>270</td></tr>
<tr><td>5</td><td>270</td></tr>
<tr><td>6</td><td>270</td></tr>
</table>
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# APPENDIX A
# Technical Agreement

The State of Queensland acting through Queensland Health

[via the department's Central Pharmacy]

GW Research LTD

# Technical Agreement

**for the Supply of Epidiolex®**

# Parties

**The State of Queensland acting through Queensland Health (QH)** ABN 66 329 169 412 of 147-163 Charlotte Street, Brisbane in the State of Queensland, Australia

**and**

**GW Research Limited** (**GW**), incorporated in England and Wales with company number 03107561 whose registered address is, Sovereign House, Vision Park, Chivers Way, Histon, Cambrdige CB24 9BZ, United Kingdom

## TABLE OF CONTENTS





| Initialled by GW | KS | Initialled by QH | |
|---|---|---|---|

## 1. SCOPE

A. This agreement supplements and forms part of the Supply Agreement that this agreement is appended to, and defines the technical responsibilities of the parties for the quality assurance, quality control, storage and distribution of the Epidiolex® (Product) to Authorised Prescribers under the Queensland government's Compassionate Access Scheme, including as required based on the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP)for Medicinal Products - 15 January 2009, PE 009-8, (except for Annexes 4, 5 and 14) https://www.tga.gov.au/publication/manufacturing-principles-medicinal-products, Australian code of good wholesale practice for medicines in schedules 2, 3, 4 and 8 https://www.tga.gov.au/publication/australian-code-good-wholesaling-practice-medicines-schedules-2-3-4-8, and Access to unapproved therapeutic goods, Authorised prescribers October 2004 https://www.tga.gov.au/sites/default/files/access-authorised-prescriber-guidelines.pdf.

B. The responsibilities outlined in this Technical Agreement will not be varied by either party unless agreed to by the parties in writing.

## 2. DEFINITIONS

The following list contains definitions used in this Technical Agreement:

**2.1** **'Approved Contractor'** means the sub-contractor described in Appendix D.

**2.2** **'Authorised Prescriber'** means an authorised medical practitioner by TGA in Australia to become an 'Authorised Prescriber' who must be:

- a medical practitioner engaged in clinical practice in a hospital and who has been endorsed by the ethics committee of the hospital; or
- a medical practitioner treating patients outside a hospital setting and who has obtained endorsement from an appropriate ethics committee.

The Authorised Prescriber Scheme is the mechanism by which Epidiolex under the CAS will be supplied to investigators.

**2.3** **'Compassionate Access Scheme' (CAS)** is the name which Queensland are applying to the Epidiolex Supply Programme for Authorised Prescribers.

**2.4** **'Certificate of Analysis' (CoA)** is a certificate detailing the results of analysis of a particular batch of Product, usually against a particular specification, signed and dated by a competent person in the Quality Department.

**2.5** **'Certification of Release' or 'Certificate of GMP Compliance'** is a manufacturing and/or testing declaration that a particular batch of Epidiolex (Cannabidiol Oral

| | | | |
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| **Initialled by GW** | KS | **Initialled by QH** | |

Solution) has been made (and tested) in compliance with a cited set of GMP guidelines with or without deviation and signed and dated by a Qualified Person.

**2.6** **'Clinical Trial'** is defined as any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.
The terms clinical trial and clinical study are synonymous.

**2.7** **'Compassionate Access Scheme' (CAS)** has the same meaning as in the Supply Agreement.

**2.8** **'Controlled Drug'** for the purpose of this agreement, has the same meaning as in the United Kingdom's *Human Medicines Regulations 2012* [SI 2012/1916]

**2.9** **'Designated Agent'** means any sub-contractor of QH, who has sufficient knowledge, staff and training to be able to carry out the sub-contracted services to the necessary and required standards.

**2.10** **'Drug Distribution Warehouse' (DDW)** means a site covered by a Wholesale Dealer's Licence or local equivalent carrying out one or more activities relating to procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public.

**2.11** **'End of the Clinical Trial or Study'** means the point at which the Product is licensed by TGA or is no longer manufactured or available.

**2.12** **'Expiry Date (or Expiration Date)'** means the date after which the Product should no longer be used. The expiry date designates the time during which the material is expected to remain stable and within established shelf life specifications if stored under defined conditions, and after which it should not be used. Note: When shelf life is described in the MM/YYYY format, the last day of use is the last day of the month described.

**2.13** **'Export Licence'** means the licence required by the exporter of Controlled Drugs when moving Controlled Drugs to an importing country from an exporting country.

**2.14** **'Good Distribution Practice' (GDP)** (for the Product) means that part of Quality Assurance which ensures that products are consistently stored, and distributed to the quality standards appropriate to their intended use and as required by the Clinical Trial Authorisation or product specification file.

**2.15** **'Good Manufacturing Practices' (GMP)** means the following:

i) Australian GMP Guidance based on PIC/S Guide to Good Manufacturing Practice (GMP) - 15 January 2009, PE 009-8, (except for Annexes 4, 5 and 14)
ii) TGA Guidelines on Manufacturing standards for overseas manufacturers

iii) European Commission Eudralex Volume IV – GMP guidelines (Current)

**2.16** **'Import Licence' and 'Export Licence'** means the licences required by the importer and exporter of Controlled Drugs when moving Controlled Drugs to an importing country from an exporting country.

**2.17** **'Investigational Site'** means the location of the Authorised Prescriber or nominee to where the Distribution Warehouse will supply the Product.

**2.18** **'Manufacturer's/Importer's Authorisation for IMPs'** (MAI(IMP)) means a licence issued by the United Kingdom's Medicines & Healthcare products Regulatory Agency (MHRA) following satisfactory inspection of the site by MHRA inspectors, giving permission for the licensed site to manufacture, assemble, test, store and release the Product.

**2.19** **'Narcotic'** means Narcotics are defined as substances that either stimulate or dull an individual's senses, and that ordinarily become habit-forming (i.e., addictive) when used over time.

**2.20** **'Narcotics Schedule'** means the local classification of a Controlled Drug.

**2.21** **'Out of Specification (OOS), Out of Trend (OOT) and Out of Expected (OOE) Results'** OOS Results mean Quality Control results which do not comply with specification. An OOS investigation is normally carried out in order to establish if there is a non-product related reason why the results were out of specification and a process for evaluating and retesting the batch in a structured way to determine if there is a Quality failure in the test procedures or in the product.

Also included within the same definition are Out Of Trend results which are defined as results not being within an established trend and Out of Expected results which are results which are not what was predicted or expected. Both undergo an investigation similar to, but may not be as extensive as Out of Specification results.

**2.22** **'Packaging Components'** means items to contain or label a product, e.g. in this agreement particularly secondary packaging such as cool containers, shipping outers/cases etc.

**2.23** **'Product'** means Epidiolex® also known as Cannabidiol Oral Solution which is an Unlicensed or Unregistered Medicine.

**2.24** **'Product Specifications'** means the finished product specification referenced in the Certificate of Analysis.

**2.25** **'Product Specification File' (PSF)** means a reference file containing all the information necessary on the Product so as to inform the drafting of detailed written instructions on processing, packaging, quality control testing, batch release and shipping in relation to the Product and its use in a clinical trial. Some of this detail has informed the requirements to be met in the Storage and Transport Conditions.



| Initialled by GW | KS | Initialled by QH | QP |
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2.26 **'Quality assurance'** is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

2.27 '**Qualified Person' (QP)** means the persons described in Article48 of *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use*, who by virtue of their qualifications and experience are able to certify in a register the release of medicinal products for commercial or clinical use in accordance with their registered details and specifications, the details of which are to be notified by GW to QH.

2.28 **'Recall'** means the withdrawal of a medicinal product or in this context, the Product, from the market or clinic as a result usually of either a quality defect or an unacceptable safety issue.

2.29 **'Responsible Person'** means the designated person at the Drug Distribution Warehouse who is responsible for ensuring that the requirements are met for Good Distribution Practice, and the EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use Guideline 2013/C 343/01.

2.30 **'Routine GMP Controls'** refers to the management of post-release GMP issues such as product quality complaints and recalls.

2.31 **'Storage and Transport Specifications'** mean the specifications applicable to the storage and transport of the Product which are included in the checklist of responsibilities contained in Appendix A to this Agreement

2.32 **'Supply Agreement'** means the agreement between GW and QH that governs the terms of supply of the Product.

2.33 **'Terminal'** means the first designated Delivery Site of the Product in Australia and is the point at which Delivery at Terminal is made. The Terminal address is specified in Appendix C to this Agreement.

2.34 **'TGA'** means Therapeutic Goods Administration, the regulatory body in Australia responsible for conducting assessment and monitoring activities on therapeutic goods to ensure they are of an acceptable standard and that access to therapeutic advances happens in a timely manner.

2.35 **'Wholesale Dealer's Licence'** means a licence granted pursuant to regulation 18 of the United Kingdom's *Human Medicines Regulations 2012* [SI 2012/1916] or the local regulation equivalent. A **'Wholesale Distribution Authorisation'** has a corresponding meaning. The licence covers all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public.

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| **Initialled by GW** | KS | **Initialled by QH** | QR |

2.36 **'Unlicensed or Unregistered Medicine'** means a medicine, or dosage form of a medicine, that has not been evaluated nor approved by the TGA in Australia and is not entered on the Australian Register of Therapeutic Goods.



| | | | |
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| Initialled by GW | KS | Initialled by QH | QR |

## 3. GENERAL TERMS AND CONDITIONS

### 3.1 SUPPLY and RELEASE OF PRODUCT

3.1.1 The supply of the Product is governed by the Supply Agreement. The terms of delivery and passing of risk and title of the Product are dealt with in the Supply Agreement but for the purposes this agreement, the point at which risk and title pass in the Product from GW to QH is the point at which the Product is delivered at the Terminal. For ease of reference in this Agreement, the flow diagram relating to the supply of Product is in Appendix E.

3.1.2 GW agrees that its Qualified Person is responsible for sampling and Product inspection prior to the release of the labelled generic packs of Product to QH and for the Routine GMP Controls (such as complaints and Recalls of the Product) to be carried out by GW, following release to QH.

3.1.3 QH will use its best endeavours to ensure that only eligible patients of the CAS Authorised Prescribers are prescribed the Product.

3.1.4 QH agrees to use its best endeavours to ensure the correct labelling of each pack for dispensing to the patient of each Authorised Prescriber at the relevant hospital pharmacy.

3.1.5 QH will use its best endeavours to ensure that delivery will only be made to the sites as specified in Appendix C. Should additional time be required in an emergency, GW should be consulted to determine whether it impacts on the stability of the Product.

### 3.2 COMPLIANCE WITH PRODUCT SPECIFICATIONS AND STORAGE AND TRANSPORT SPECIFICATIONS

3.2.1 GW and QH each agree to comply with the terms of this Agreement and each of their respective obligations regarding storage and transit requirements arising under the Storage and Transport Specifications.

3.2.2 GW agrees to ensure that the Product complies with the Product Specifications and the agreed standards and procedures specified in the Product manufacturing, packaging and release activities contained in the checklist of responsibilities attached to this Agreement in Appendix A.

3.2.3 GW will supply or ensure that QH has access to all applicable documents including those listed in Appendix F that are required to be provided by GW as supporting guidance to help QH to achieve regulatory compliance. GW will provide a data sheet or Safety Data Sheet (SDS) to assist in case of spillage.

### 3.3 USE OF SUB-CONTRACTORS

| | | | |
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| Initialled by GW | KS | Initialled by QH | QR |

QH will not subcontract its obligations in this Agreement without first seeking written consent from GW. GW's consent will not be unreasonably withheld. QH acknowledges that it is responsible for the obligations it proposes to delegate to the Approved Contractor or any other contractor it may sub-contract to during this Agreement.

Sub-contractors agreed to by both parties are listed in Appendix D

## 3.4 ANTI-BRIBERY/ANTI-CORRUPTION LAWS

GW and QH agree to comply with their respective anti-bribery and anti-corruption laws.

## 3.5 GENERAL PRODUCT DATA

The parties acknowledge that the Product is an Unlicensed or Unregistered Medicine and therefore not subject to any regulatory authority authorisation.

The Product is classified as a Schedule 4 poison in the Commonwealth Poisons Standard (SUSMP) issued under the *Therapeutic Goods Act 1989* (Cth) and the *Health (Drugs and Poisons) Regulation 1996* (Qld), and is subject to regulation regarding its use and supply, accordingly.

## 3.6 VARIATION OF THE CONTENT IN THIS AGREEMENT

3.6.1 The parties will obtain written approval from the other party for any variation to obligations and responsibilities described in this Agreement prior to implementation, including any changes to the Storage and Transport Specifications.

3.6.2 The parties will not unreasonably refuse to implement any new standards, specifications or procedures at the written request of the other party.

## 3.7 RESPONSIBILITIES FOR SURVEILLANCE FOR SAFETY REPORTING

In relation to the Product, safety reporting to the regulatory authorities will be detailed in the letter to Authorised Prescribers issued by the TGA.

## 3.8 RESPONSIBILITY FOR UNLICENSED MEDICINE SAFETY AND EFFICACY

In relation to the effects on the safety and efficacy of the Product of the storage, distribution and handling of the Product by QH or its agent, this is the responsibility of QH provided both parties have used their best endeavours to comply with the Technical Agreement and the Study Protocol.

## 3.9 RESPONSIBILITIES FOR RESPONDING TO CUSTOMER COMPLAINTS

GW will investigate and respond to customer complaints. QH will ensure all customer complaints that QH is made aware of are notified to GW promptly using form GE-GXP-023.

| | | | |
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| **Initialled by GW** | KS | **Initialled by QH** | |

### 3.10 CONTRACTOR CLOSE DOWN

If QH or their agent terminates the Supply Agreement, GW has the right to request the return of all unused Product which has been maintained under GDP conditions and is still within the controlled supply chain.

## 4. DESIGNATED CONTACTS

**4.1 MINOR QUALITY ASSURANCE MATTERS** - e.g. documentation, reconciliation, traceability

| | |
|---|---|
| At GW | Qualified Person or<br>Quality Assurance Personnel |
| At QH | RESPONSIBLE PERSON or<br>Project Manager |

**4.2 SERIOUS QUALITY ASSURANCE MATTERS** - e.g. customer complaints, product Recall.

| | |
|---|---|
| At GW | QP or DIRECTOR OF QUALITY |
| At QH | RESPONSIBLE PERSON or<br>Project Manager |

Signatures, initials and contact details of approved release signatories are in Appendix H.



| | | | |
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| **Initialled by GW** | KS | **Initialled by QH** | |

## 5. EFFECTIVE DATE:

**Effective from Date of Final signature**

**DATE OF CONTRACT REVIEW:**

**Three years from date of final signature**

| | QH | GWR |
|---|---|---|
| Signature | MWalsh | Karen Stoddart |
| Name | Michael Walsh | Karen Stoddart |
| Position | Chief Executive | Global Director of Quality |
| Company | Queensland Health | GW Research Ltd |
| Date | 20-12-2016 | 12th December 2016 |



| Initialled by GW | KS | Initialled by QH | |
|---|---|---|---|

## 6. TECHNICAL AGREEMENT CHANGE HISTORY

| Technical Agreement Ref. | Effective Date | Significant Changes | Previous TA Ref. |
|---|---|---|---|
| QH-GW Technical Agreement | Date of Final Signature | N/A | First Issue |
| | | | |
| | | | |



| | | | |
|---|---|---|---|
| Initialled by GW | KS | Initialled by QH | |

## CONTENTS OF APPENDICES



All appendices will be reviewed by both parties on a regular basis or as changes occur. The Parties agree that this will not constitute a variation of the agreement but rather changes to each separate Appendix may be confirmed with each other in writing.

**NB: All amendments to specified data in Appendices will be updated via document control and the issue of current procedures.**



| | | | |
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| **Initialled by GW** | KS | **Initialled by QH** | |

## Appendix A

(for the Product described in Appendix B)

| CHECKLIST OF RESPONSIBILITIES<br>*(according to specifications regarding **Product** Manufacturing, Packaging & Release and Storage and Transport Specifications)* | | | | |
|---|---|---|---|---|
| **Product Manufacturing, Packaging & Release** | | | **GW** | **QH** |
| (a) | | Will adhere to the EMA Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3) (2011/C 73/01) Transmissible Spongiform Encephalopathy agents – TSE and any other specific requirements of regulations relating to Medicinal products containing or using in the manufacturing process materials of animal and/or human origin http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003700.pdf | X | |
| (b) | | Will provide assistance to GW regarding labelling of Product to ensure regulatory compliance | | X |
| (c) | | Will obtain written QH approval for Product labels and packaging to ensure regulatory compliance | X | |
| (d) | | Will ensure Qualified Person releases each batch of product prior to export | X | |
| (e) | | Will maintain the Product Specification File for the Product | X | |
| (f) | | Will supply Primary and Printed Packaging compatible with the Product | X | |
| (g) | | Will supply syringes and bottle stoppers compatible with the Product | X | |
| (h) | | Will inform QH in writing of the flight number, quantity and timing of impending shipments of Product to the Terminal | X | |
| (i) | | Will ship Product only to the airport Terminal described in Appendix C. | X | |



| Initialled by GW | KS | Initialled by QH | |
|---|---|---|---|

<table>
<tr><th colspan="3"></th><th>GW</th><th>QH or agent</th></tr>
<tr><td colspan="3">1. Compliance with GDP</td><td></td><td></td></tr>
<tr><td>(a)</td><td></td><td>Will ensure safe, GDP compliant storage of Product up until the point at which it is delivered at the designated Terminal (Delivery at Terminal Incoterms 2015 http://www.one-ill.com/downloads/incoterms%202015.pdf )</td><td>X</td><td></td></tr>
<tr><td>(b)</td><td></td><td>Will ensure safe, GDP compliant storage of Product from time of pick-up from designated Terminal (Delivery at Terminal) until Product is provided to the receiving pharmacy</td><td></td><td>X</td></tr>
<tr><td colspan="3">2. Distribution</td><td></td><td></td></tr>
<tr><td>(a)</td><td></td><td>Will ensure Product is transported from the Terminal to the Drug Distribution Warehouse, and from the Drug Distribution Warehouse to the relevant pharmacies (Central Pharmacy, QH) in such a manner as to ensure that the Product's identity and ownership are not changed, and in accordance with Good Distribution Practices</td><td></td><td>X</td></tr>
<tr><td>(b)</td><td></td><td>Will supply, on request, documented confirmation that the Product transported to the relevant pharmacy has been maintained at the appropriate temperature</td><td></td><td>X</td></tr>
<tr><td colspan="3">3. Required Temperature for Storage and Transport</td><td></td><td></td></tr>
<tr><td>(a)</td><td></td><td>Will ensure the following temperatures are maintained when the Product is stored and when in transit (the 'Temperature Requirements')
<table>
<tr><th>Product</th><th colspan="2">Temperature Requirements</th></tr>
<tr><th></th><th>Storage</th><th>Transport</th></tr>
<tr><td>Epidiolex® (100 mg/mL CBD Pure Oral Formulation)</td><td>Do not store above 30°C. Do not refrigerate or freeze</td><td>Do not transport above 30°C. Do not refrigerate or freeze</td></tr>
<tr><td colspan="3">For any Products considered Narcotics, storage must comply with the local laws for that substance.</td></tr>
</table></td><td>X</td><td>X</td></tr>
</table>

| Initialled by GW | KS | Initialled by QH | |
|---|---|---|---|

| | | | GW | QH or agent |
|---|---|---|---|---|
| (b) | | Will ensure distribution only to pharmacies described in Appendix C. | | X |
| **4.** | | **Buildings and Facility where the Product is stored after delivery to the Terminal** | | |
| (a) | | Will ensure validation and management of the temperature units and mapping of the storage area and that the validated state is maintained including via periodic review | | X |
| (b) | | Will ensure security of the facility in accordance with local regulations for storage of Schedule 4 products | | X |
| (c) | | Will ensure the facility is compliant with a GDP grade level pest control program as per the EU Guidelines on Good Distribution Practice (**GDP**) of Medicinal Products for Human Use Guideline 2013/C 343/01; | | X |
| **5.** | | **Equipment and Utility Services** | | |
| (a) | | Will ensure the product is transported in insulated containers designed and qualified to maintain the temperature requirements | | X |
| (b) | | Will ensure security of the transport vehicles is in accordance with local regulations for the transport of Schedule 4 products | | X |
| **6.** | | **Systems Validation** | | |
| (a) | | Will ensure validation of computerised systems used to manage the temperature and security at the Drug Distribution Warehouse | | X |
| (b) | | Will ensure safe storage of the Product from the point it is delivered at the Terminal until delivery of the Product to the pharmacy or until the point at which it is destroyed | | X |



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| **Initialled by GW** | KS | **Initialled by QH** | |

| | | | GW | QH or agent |
|---|---|---|---|---|
| (c) | | Will ensure that the storage and transport of the Product is undertaken in accordance with all relevant regulatory requirements, and in accordance with:<br>• theAustralian code of good wholesale practice for medicines in schedules 2, 3, 4 and 8 https://www.tga.gov.au/publication/australian-code-good-wholesaling-practice-medicines-schedules-2-3-4-8, ,<br>• the EU Guidelines on Good Distribution Practice (**GDP**) of Medicinal Products for Human Use Guideline 2013/C 343/01; and<br>• the EU Directive 2011/62/EU | | X |
| (d) | | Will pay special attention to those aspects dealing with temperature-controlled environments and Narcotics restrictions and will take into consideration all applicable Environmental, Health and Safety standards and good record keeping standards for storage and transport in Australia. i.e. the EU Guidelines on Good Distribution Practice (**GDP**) of Medicinal Products for Human Use Guideline 2013/C 343/01; | | X |
| (e) | | Will ensure that the Product is stored for no longer than eighteen (18) months.<br>When the shelf life is described on the Product in the MM/YY format, the last day of use is the last day of the month described. | | X |
| (f) | | Will ensure that all Products are delivered to the Terminal safely, and are transported and stored according to these Storage and Transport Specifications and that safe transport and storage of the Product will be maintained until Delivery at Terminal. | X | |
| (g) | | The Storage and Transport Specifications contained throughout this table must be maintained throughout the distribution chain. | X | X |
| (h) | | Will ensure that no third party under QH's control other than the Approved Contractor and its approved courier may open any container or carton without prior and specific agreement with GW. | | X |

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|---|---|---|---|
| **Initialled by GW** | KS | **Initialled by QH** | |

| | | | GW | QH or agent |
|---|---|---|---|---|
| (i) | | Will make all necessary declarations concerning the Product and the Manufacturer's License required for the Product | X | |
| **7. Regulatory Requirements** | | | | |
| (a) | | Will maintain a Wholesale Dealer's License (or local equivalent) current for the duration of the Compassionate Access Scheme and make all necessary declarations concerning the Wholesale Dealer's License. | | X |
| (b) | | Will comply with all applicable regulatory requirements and laws relevant to the obligations under this Agreement | X | X |
| (c) | | Will in the event of a termination of this Agreement, return all unused Product which has been maintained under GDP conditions and is still within the controlled supply chain. | | X |
| (d) | | Will maintain the appropriate Regulatory and/or Ethics approvals during the CAS | | X |
| (e) | | Will obtain required Export licenses and permits | X | |
| (f) | | Will obtain required Import licenses and permits | | X |
| **8. Organisation and Personnel required** | | | | |
| (a) | | Will ensure the assignment and availability of a Responsible Person at the depot of the agent | | X |
| (b) | | Will ensure that staff at the Drug Distribution Warehouse engaged in GDP activities are appropriately trained to undertake the GDP activities | | X |
| (c) | | The Responsible Person will seek advice from the Qualified Person at GW, as necessary, on issues relating to the safe and secure storage and distribution of the Product, and on any returns of the Product prior to destruction. | | X |
| (d) | | Will ensure that a technical or quality agreement is in place with sub-contractors, including the Approved Contractor, who are GDP compliant and associated with the Product covered by this Agreement. | | X |

| | | | |
|---|---|---|---|
| **Initialled by GW** | NS | **Initialled by QH** | QH |

| | | GW | QH or agent |
|---|---|---|---|
| (e) | Will ensure that the Qualified Persons of GW are part of the Technical or Quality Agreement Review and Approval process for all QH GMP and GDP Approved Contractors. | | X |
| (f) | Will maintain overall Product supply chain accountability for the Compassionate Access Scheme | X | X |
| **9. Process Controls** | | | |
| (a) | Will supply Product only to patients of Authorised Prescribers | | X |
| (b) | Will supply Products in accordance with flow diagram in Appendix E. | X | X |
| (c) | Will record distribution of Product by batch to enable Recall of Product from all entities to which distribution has been undertaken as part of the Agreement | | X |
| (d) | Will produce, and use, their general procedures, as agreed by the parties, and as appropriate to each part of the supply of the Product under the Activity. Specific procedures relating to the Product will be written by QH or their Designated Agent. | X | X |
| **10. Product Retains** | | | |
| (a) | Will retain a representative sample of each Product batch, together with records and specifications relating to packaging of the Product exported to QH for two (2) years after the completion of the CAS, or the finalisation of any relevant study reports, whichever is later. | X | |
| (b) | Will retain the samples required to comply with regulatory requirements for retained samples. Any other samples required will be requested by GW from QH in writing. QH is not required to keep any samples. | X | |
| (c) | Will keep retained Product for responding to complaints. | X | |



| Initialled by GW | KS | Initialled by QH | |
|---|---|---|---|

| | | GW | QH or agent |
|---|---|---|---|
| **11. Receipt (at airport Terminal)** | | | |
| (a) | Will receive and inspect Product from GW in accordance with GDP procedures | | X |
| (b) | Using Form CL-GCP-091 will inform GW within 24 hours of inspection should any defects be found. | | X |
| (c) | Will check and review data from delivery transportation temperature monitoring devices. | | X |
| (d) | Will send the transportation temperature monitoring device download to GW. | | X |
| (e) | Will ensure written receipt of acceptance of delivery conditions is given to QH, to allow release of product to hospital pharmacies | X | |
| (f) | Prior to releasing Product to hospital pharmacies, will ensure written receipt of acceptance of delivery conditions by GW | | X |
| **12. Quality Assurance** | | | |
| Deviations/Non-Conformance Events | | | |
| (a) | Will report any deviations from agreed procedures to GW in writing, particularly in relation to GDP, temperature monitoring, and labelling activities. | | X |
| (b) | Will report to GW in writing any GDP deviations to procedures and processes, relating to the Product, by QH or its designated agent, which have a material effect on the quality of the Product | | X |
| (c) | Will inform QH of any quality issue which could adversely impact the batches of Product supplied to QH. | X | |
| Destruction | | | |
| (d) | Will destroy returned and out of date product in accordance with local regulations for destruction of medicinal products in the presence of a Responsible Person | | X |



| | | | |
|---|---|---|---|
| **Initialled by GW** | KS | **Initialled by QH** | QH |

| | | | GW | QH or agent |
|---|---|---|---|---|
| Information & Records | | | | |
| (e) | | Will maintain records of temperature monitoring and shipment for at least five (5) years, including temperature calibration certificates. At the end of this time, subject to legislative requirements, including under the *Public Records Act 2002* (Qld), QH will offer all records relating to temperature monitoring and shipment of the Product to GW for retention, unless by mutual agreement they are transferred to GW for archiving prior to the 5 years. | X | X |
| (f) | | Will provide documents listed in Appendix F to QH | X | |
| (g) | | Will provide documents listed in Appendix G to GW | | X |
| (h) | | Will ensure all records are kept to ensure complete traceability of the Product and its distribution | | X |
| (i) | | Will maintain all GMP and GDP records up until the transfer of ownership of the Product at the airport Terminal | X | |
| (j) | | Will maintain records at least for the period required by local legislation | X | X |
| | | Note: data from any clinical trial associated with this Agreement must be kept for at least fifteen (15) years after the completion of the clinical trial, or until the 25th birthday of the youngest participant, whichever is later, Australian Privacy Principles | | |
| (l) | | Will maintain appropriate records, and make these available to the regulatory authorities as required and GW on reasonable request. | | X |
| (m) | | Will ensure that in case of emergencies relating to the technical details of the Product or related products, GW's Qualified Person will immediately provide specific details to QH. | X | |



| Initialled by GW | KS | Initialled by QH | |
|---|---|---|---|

| | | | GW | QH or agent |
|---|---|---|---|---|
| Customer Complaints, Defects, Theft, Diversion, Adverse Occurrences | | | | |
| (n) | | Will ensure that the applicable Recall procedures are implemented if a complaint leads ultimately to a Recall of the Product. | X | X |
| (o) | | Will ensure that assistance is provided to GW for any recall required as per the GW recall or defect procedure. | | X |
| (p) | | Will notify GW immediately, and subsequently provide the notification in writing, of any instance where there is a discrepancy found between the quantities detailed on the paperwork and the physical amount of Product. GW will also be notified immediately, as above, of any loss of Product by theft or damage. | | X |
| (q) | | Where a defect is noted, or quality complaint received, QH will supply the necessary information on the storage and delivery conditions from arrival at the Terminal up until the identification of the defect. | | X |
| (r) | | Will complete and report to QH the results of any defect investigations within twenty (20) business days, with assistance from QH, where appropriate | X | |
| (s) | | Will manage defect investigations or complaints arising from transportation and storage once the Product has been accepted by QH, with assistance from GW as appropriate. | | X |
| (t) | | Will accept returned Product on behalf of GW, where there is evidence of a defective Product on delivery, or Product associated with a complaint has been returned. | | X |
| (u) | | Will inform GW within 24 hours in writing of the details of any customer complaint received by QH concerning the Product and will return any Product associated with the complaint to GW, forthwith if requested. | | X |



| Initialled by GW | KS | Initialled by QH | |
|---|---|---|---|

| | | | GW | QH or agent |
|---|---|---|---|---|
| (v) | | Will maintain complaint samples returned under the required conditions as far as reasonably possible until a written instruction to investigate or destroy has been received by QH from GW. | | X |
| (w) | | Will report any adverse occurrences that may affect the Product to GW contacts. E.g. product impact /crushing/water damage. | | X |
| **13. Recalls** | | | | |
| (a) | | Will maintain at all times a **Recall Procedure** to be immediately implemented on the sole instructions of GW or their nominated Responsible Person or Qualified Person. | | X |
| (b) | | Will initiate both urgent and non-urgent Recalls and communicate this to QH. | X | |
| (c) | | Will conduct the recall of Product according to GW Recall Procedures, if instructed or requested to do so either by GW or by the local regulatory agency or other authorised government agency | | X |
| (d) | | Will implement non-GW Recall Procedures ONLY in the event that prior instructions cannot be reasonably obtained in a timely manner from GW, and if required to do so by the local regulatory authority or other authorised government agency. | | X |
| **14. Product Returns to GW** | | | | |
| (a) | | From time to time additional samples of finished Product may be requested by GW from the Drug Distribution Warehouse, e.g. in response to testing for customer complaints. These samples are not to be unnecessarily withheld by QH. | | X |
| (b) | | Will ensure the necessary export arrangements are made for the return to GW of complaint or Recall samples | X | X |
| (c) | | Will obtain verification of GW's import license prior to exporting product | | X |

| | | | |
|---|---|---|---|
| **Initialled by GW** | KS | **Initialled by QH** | |

| | | | GW | QH or agent |
|---|---|---|---|---|
| **15. Audits** | | | | |
| (a) | | Will provide reasonable access to facilities, equipment, procedures and records to allow GW to confirm satisfactory compliance with the Transport and Storage Specifications contained in this table. | | X |
| **16. Regulatory Inspections/Notifications** | | | | |
| (a) | | Will inform the other party in writing of any deficiencies noted during an inspection by a Licensing Authority Inspector which relates to, or impacts upon, the Product storage and distribution. | X | X |



| Initialled by GW | KS | Initialled by QH | |
|---|---|---|---|

## Appendix B – the Product

| Investigational Medicinal Product | GW Ref | Current Version Reference* | Local Narcotics Schedule [Health (Drugs and Poisons) Regulation 1996 (Qld)] |
|---|---|---|---|
| Epidiolex® (100 mg/mL CBD Oral Solution) | s.73 - Irrelevant information (commercial)* | | S4 |

## The Product Specifications

*Future updates to Product Specification versions will be provided to QH via the GW Document control process as they are issued.

Manufacturing of the Product has been in accordance with the Product Specifications and with GMP and all applicable internal processes of GW applicable to the Product.

s.73 - Irrelevant information (commercial)



| Initialled by GW | KS | Initialled by QH | |
|---|---|---|---|

## Appendix C

### Site Addresses for Storage and Collection with target Delivery Times

| Activity | Site/Address/Contact details (General) | Site Licence Reference No: | Delivery Times |
|---|---|---|---|
| **Delivery at Terminal** | Airport (Terminal) | | |
| **Collection** | Point of entry into country (local customs) Airport (Terminal) | | |
| **Main Storage** | LINK Healthcare, | | from customs to Main Storage – same day |
| **Pharmacies** | Queensland Health (QH) Central Pharmacy | | from Main Storage to QH Central Pharmacy – same day |
| **Pharmacies** | Lady Cilento Children's Hospital (LCCH) Pharmacy<br><br>Level 2, Lady Cilento Children's Hospital<br>501 Stanley Street, South Brisbane Qld 4101<br><br>61 (07) 3068 1900 | | from Main Storage to LCCH Pharmacy – same day |
| **Other Sub-Contactors** | N/A | | |

NB: Delivery times restricted to working days and delivery addresses being available to receive delivery.



| Initialled by GW | KS | Initialled by QH | |
|---|---|---|---|

## Appendix D

### Approved QH Agent and Sub-Contractor List

| Study Number | Agent/Sub-Contractor Name and Address | Contact Details | Service Provided |
|---|---|---|---|
| CHQ001 | Link Medical Products Pty Ltd ACN: 010 971 516, | RA and QA Manager<br>@linkheathcare.com<br><br>Supply Chain Manager<br>@linkhealthcare.com.au | Storage and distribution |



| Initialled by GW | KS | Initialled by QH | |
|---|---|---|---|

## Appendix E

## Flow Diagram for Supply of Epidiolex to Individual Patients

| Flow Chart | Responsibilities |
|---|---|
| s.73 - Irrelevant information (commercial) | |



| | | | |
|---|---|---|---|
| Initialled by GW | KS | Initialled by QH | AI |

## Appendix F

### Documents Supplied by GW

- Appropriate Export Licences for each delivery/event (all cross borders to be covered)
- Safety Data Sheets for each product listed in Appendix B
- Certificate of Release for the Product
- Certificate of Analysis for the Product
- Changes to standing instructions or agreements
- Faxes or e-mails relating to Import Licences required
- Faxes or e-mails relating to impending shipments
- Instruction relating to authorisation for picking and distribution of medication packs
- Complaints Form: GE-GXP-023
- Patent Safety Summary Sheet
- Patient Administration Instructions

**Good Warehousing Practices**

- Guidelines on Good Distribution Practice of Medicinal Products for Human Use (Guideline 2013/C 343/01)



| | | | |
|---|---|---|---|
| **Initialled by GW** | KS | **Initialled by QH** | |

# Appendix G

## Complaints Form: GE-GXP-023

GW pharmaceuticals

**IMP Complaint Notification Form**

**Sign and email to [redacted]@g-pharm.com and [redacted]@gwpharm.com**
**or fax to +44 (0)1795 475349 within 24 hours of notification of product complaint**

If complaint is also linked to a Serious Adverse Event the form **must** also be emailed to [redacted]@gwpharm.com or faxed to +44 (0)1223 233319

- A **Photocopy** of the form is to be filed in Investigator / Pharmacy Site File
- The **Original** signed form should be posted to the GW CTS Department (with any returned sample)

**INVESTIGATOR CENTRE TO COMPLETE**
(Please complete all relevant areas of this form)

| | | |
|---|---|---|
| GW Protocol: | Date of Complaint | |
| Site Address: | Patient No. | |
| | Time Point (visit, period, vial / bottle no.) | |
| | Date Dispensed (if applicable) | |
| Site No.: | GW PRN (if known) | |
| | Pack no. | |
| Tel: | Product Name (if known): | |

**Is the complaint also linked to a Serious Adverse Event or Adverse Event?** ☐ YES ☐ NO

**If YES, please tick appropriate box and attach copies of the SAE or AE form:** ☐ SAE ☐ AE

**Complaint Details:**

Investigator / Staff Name: ☐Dr ☐Mr ☐Mrs ☐Miss / Ms ☐Other

Name (print): Signature: Date:

**Faxed / Email to GW Pharma Ltd (tick box and date)** Fax: ☐ Email: ☐ Date:

**For CRA/Monitor Use:**

- Complaint samples should be returned to GW within **20 working days.**
- If it is not possible to return the complaint sample, include a more detailed description, and digital photography to illustrate the complaint sample.
- Where complaint IMP is being shipped with other returned IMP the CRA/CRM **must** inform the CTS Department and highlight the complaint IMP packs within the consignment.

**Sample(s) Returned to CTS Department** ☐ YES Quantity: Units: Date Sent:

**CRA / Monitor Details:**

Name: Signature: Date:



Page 1 of 1 Form No. GE-GXP-023-V6

| | | | |
|---|---|---|---|
| Initialled by GW | KS | Initialled by QH | AJ |

## Appendix H

### Documents Supplied and Used by QH

**Procedures and Records covering:**

- Distribution Reports on request by GW
- Procurement, ordering and purchasing
- Receipt and checking of deliveries including counterfeits
- Storage and stock rotation
- Cleaning and maintenance of the medicines storage area (including pest control)
- Specification, maintenance and recording of storage temperatures
- Specification, maintenance and recording of transit temperatures
- Security of Product on site and in transit
- Controlled Drugs Log
- Removal of expired and damaged stock from usable stock
- Destruction of returns and expired Product
- Records (including orders, returns and Recalls)
- Complaints handling
- Recall
- Duties of the Responsible Person
- Records of building management temperatures
- Records of transit temperatures as agreed with GW for specific sites/studies
- Calibration records for thermometers and probes used in the storage and transport of the Product
- Records relating to pest control monitoring
- Stock reports as agreed
- Patient Authorisation Form
- Authorised Prescriber Form
- Patent Safety Summary Sheet (generated by GW used by Authorised Prescribers )
- Patient Administration Instructions (generated by GW used by Authorised Prescribers)

**Documents:**

- Importation licences
- Pharmacy order form



| | | | |
|---|---|---|---|
| **Initialled by GW** | KS | **Initialled by QH** | AL |

## Appendix I

### Signatures, Initials and Contact Details of Approved Signatories

| GW | | | |
|---|---|---|---|
| Position | Name | Signature | Initial |
| Site Head of Quality/QP | Steven Stuart[1] | | |
| QA Manager/QP | Scott Smith[1] | | |
| Contract QP | Robert (Bob) Lambert[1] | | |
| Technical Director | Peter Gibson | | |
| Head of Clinical Trials Supplies | Liz Brooks | | |
| Global Director of Quality/QP | Karen Stoddart | | |

| Contact Details: | e-mail | Phone |
|---|---|---|
| Steven Stuart | [redacted]@g-pharm.com | |
| Scott Smith | [redacted]@g-pharm.com | |
| Bob Lambert | [redacted]@g-pharm.com | |
| Peter Gibson | [redacted]@g-pharm.com | |
| Liz Brooks | [redacted]@g-pharm.com | |
| Karen Stoddart | [redacted]@gwpharm.com | |
| Pharmacovigilance | [redacted]@gwpharm.com | |
| Complaints | [redacted]@gwpharm.com | |

[1]Qualified Persons from GW responsible for post release QP responsibilities.

| QH | | | |
|---|---|---|---|
| Position | Name | Signature | Initial |
| Executive Director, Chief Medical Officer and Healthcare Regulation Unit | Dorothy Vicenzino | | |
| Director Central Pharmacy QH | Graham Cook | | |
| Director Medicinal Cannabis Unit | Gregory Perry | | |
| | | | |

| Contact Details: | e-mail | Phone |
|---|---|---|
| Dorothy Vinzino | Dorothy.Vicenzino@health.qld.gov.au | 07 3328 9219 |
| Graham Cook | Graham.Cook@health.qld.gov.au | 07 3120 8561 |
| Gregory Perry | Gregory.Perry@health.qld.gov.au | 07 3328 9152 |

[2]Responsible Person for QH

| Initialled by GW | | Initialled by QH | |
|---|---|---|---|