DATED this

June 12th 2013

SERVICE AGREEMENT

between

THE IRISH MEDICINES BOARD,

Kevin O'Malley House,

Earlsfort Centre,

Earlsfort Terrace,

Dublin 2

- and -

THE PUBLIC ANALYST'S LABORATORY,

Seamus Quirke Road,

Galway

THIS SERVICE AGREEMENT is made between:

The Irish Medicines Board, established in Ireland pursuant to the Irish Medicines Board Act, 1995, having its principal place of business at Earlsfort Centre, Earlsfort Terrace, Dublin 2 (hereinafter referred to as 'the IMB'), and the Pharmaceutical Section of the Public Analyst's Laboratory, Galway, having its principal place of business at Seamus Quirke Road, Galway (hereinafter referred to as the 'OMCL', which stands for Official Medicines Control Laboratory).

1. Law

   This Agreement shall be governed by and construed in accordance with the Irish Medicines Board Act of 1995 (No. 29) and with the Irish Medicines Board Miscellaneous Provisions Act of 2006 (No. 3).

2. This Agreement shall be deemed to have come into force on **July 1st, 2013**. The Agreement will be jointly reviewed annually by both parties.

   This agreement can be terminated by either party with six months notice in writing, subject to the satisfactory completion or transfer of work that has been commenced prior to notification.

3. This agreement between the IMB and the Pharmaceutical Section of the Public Analyst Laboratory describes the manner in which the Pharmaceutical Section of the Public Analyst Laboratory, as the IMB-appointed OMCL for physico-chemical testing of human and veterinary medicinal products and active substances, shall provide analytical or other laboratory services to the IMB.

   Analysis shall be conducted in accordance with:

   i) ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories;
   ii) Applicable and relevant OMCL Network guidelines for the testing of medicinal products and active substances.

   The OMCL will be accredited by the Irish National Accreditation Board and comply with ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories. Such accreditation must be maintained and expanded in line with requirements and available resources. The OMCL will keep the IMB informed on the scope of their accreditation.

4. Having regard to the resources available to the OMCL, the IMB has specified the following matters to the OMCL who has agreed to those matters –

a) the objectives and targets for sample analysis it wishes the OMCL to meet, and the timeframe for achieving those targets and objectives, and

b) any other matters which the IMB considers necessary.

The matters referred to in (a) and (b) are set out in Schedule 1 of this Service Agreement.

5. The IMB reserve the right to conduct audits of the OMCL and/or any approved sub-contractor. The audit shall be carried out to investigate compliance with the principles and guidelines of ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories and with the applicable and relevant OMCL Network guidelines for the testing of medicinal products and active substances.

In advance of any audit, the IMB and the OMCL will agree such protocols and procedures as are necessary, including provisions with regard to notification, timing, audit criteria, scope, audit frequency and audit reports.

Mutual Joint Audits may also be carried out periodically by auditors from the European Directorate for the Quality of Medicines and Healthcare (EDQM) and the OMCL Network, subject to prior agreement of the OMCL and the IMB.

6. The terms agreed to by the IMB and the OMCL relating to confidentiality of information is set out in Schedule 2 of this Service Agreement.

7. No Assignment

This agreement is personal to the parties and no party shall assign this Agreement without the prior written consent of the other party.

8. Steps for Conflict Resolution

Any matter pertaining to the Service Agreement which becomes or is likely to become the subject of a disagreement between the OMCL and the IMB shall in the first instance be dealt with at a liaison meeting or a specially convened meeting.

Issues not resolved by the parties at this meeting may be referred to the Chief Executive of the IMB and the Public Analyst.

9. Amendments to this Service Agreement
The IMB and the OMCL will review and amend this Service Agreement by agreement in the event of changing circumstances.

To signify acceptance of the terms of this Service Agreement a duly authorized representative of each party shall sign and date each copy of the Service Agreement.

For and on behalf of the Public Analyst's Laboratory:

Name: ...RORY MANNION...

Title: ...PUBLIC ANALYST...

Signature: ...Rory Mannion...

Date: ...12-06-13...

For and on behalf of the Irish Medicines Board:

Name: ...PAT O'MAHONY...

Title: ...CHIEF EXECUTIVE...

Signature: ...Pat O'Mahony...

Date: ...07/07/13...

SCHEDULE 1

Objectives, targets, timeframes and other matters which the IMB considers necessary for sample analysis

1. Personnel:

Both the IMB and the laboratory will provide each other with a list of personnel who have the authority for the following actions.

IMB Personnel

1. Provide analytical protocols;
2. Authorise the laboratory to use sub-contractors;
3. Jointly agree significant changes to analytical protocols and any changes which may impact in more than a minor way the analytical request made by the IMB;
4. Provide samples for analysis;
5. Discuss results of investigations and failure investigations;
6. Request further work on samples where required;
7. Jointly authorise the use of reference materials other than those supplied by IMB or obtained by the laboratory from a compendial source or which are traceable to a compendial source.

Laboratory

1. Discuss and jointly agree significant changes to previously agreed analytical methodology, and authorise and justify (on the laboratory report) such changes to analytical methods;
2. Request and authorize samples for sub-contracting;
3. Carry out and provide details and results of investigations and failure investigations;
4. Authorise and / or otherwise certify results;
5. Jointly authorise the use of reference materials other than those supplied by IMB or obtained by the laboratory from a compendial source or traceable to a compendial source;
6. Develop and validate internal laboratory methods, where jointly agreed.

2a. Fee due.

The annual fee paid by the IMB for the analytical service will be agreed annually.

2b. Number of samples to be sent to the OMCL and tested per year:

The IMB will provide the OMCL with 90 samples per year and the OMCL shall analyse and report the results of the testing performed on 90 samples per year*.

*This number of samples to be analysed per year is contingent upon the type of analysis requested and the staff and equipment resources in the laboratory being maintained at a level appropriate to the requested service. In situations where more complex analyses are required by the IMB, the IMB and the laboratory will jointly agree, on a case by case basis, the numbers of samples to be tested in any one year and the level of testing per sample.

3. Analysis Requests

A sampling and analysis plan is prepared by IMB in conjunction with the OMCL. This plan is subject to change due to emerging issues resulting in unplanned and/or urgent samples. This document is maintained by the IMB and updates are sent quarterly to the OMCL.

In all instances where the analysis is to be performed, the IMB will provide to the OMCL an analysis request form with the sample, outlining the analysis to be conducted.

The IMB will also provide the OMCL with information on the status of samples with regard to being controlled or non-controlled, and on the hazardous nature of the samples, if such information is available.

4. Unsuitable samples

The OMCL will contact the IMB for further instructions before proceeding where there is doubt about the suitability of a sample for test, or where the sample does not conform to the description provided, or where the test required by the IMB is not specified in sufficient detail, or where the relevant reference standards or documentation are not available.

6. Storage of samples prior to, during and after completion of the analysis

All samples and reference material must be stored appropriately and in accordance with their labelled storage instructions, when available. The IMB will provide a description of any special storage conditions required for samples within the analytical protocol.

Unless otherwise agreed, for all work performed, the laboratory will retain samples for at least 6 months beyond the dispatch of the final report. The OMCL will be responsible for disposal of samples after the retention period is over.

7. Validation of analytical methods

In most cases the laboratory shall use the pharmacopoeial methodology (or will be provided with methods that have been appropriately validated). The laboratory shall verify (e.g. by confirming the suitability of the system) that it can operate standard methods prior to introducing the test.
In relation to the testing of enforcement samples, validation requirements will be discussed on a case-by-case basis.

8. Change Control

Any proposed changes to the methodology which are not covered by a compendial source, or by the analytical method requested to be used by the laboratory by IMB, and which are not of a minor nature, and which the laboratory wishes to instigate, shall be discussed in advance with the IMB Market Compliance Manager or designee, whenever possible, and a description of the changes should then be included in the laboratory report which is provided to the IMB.

9. Sub-contracting

Sub-contracting must not be used without the prior approval of the IMB. Any proposals to sub-contract any part of the proposed analysis must be made in writing to the IMB Market Compliance Manager. The subcontracting criteria as set down in ISO 17025 will be followed.

10. Retests

In the case of the results of the test failing to comply with the specification supplied, the OMCL shall follow its internal procedure for handling such results, and as part of this, the OMCL shall:

1. Carry out a test failure investigation;
2. If appropriate, retest the same sample;
3. If the sample fails this retesting, report the result immediately to the IMB Market Compliance Manager or designee, and prepare to discuss the data with IMB;
4. Have discussions to agree a programme of additional testing with the IMB Market Compliance Manager or designee.

11. Reference Materials, Standards, Reagents and Media

The laboratory shall ensure that all chemical consumables, which they procure and /or prepare, used for the agreed analysis are suitable for the use and whenever possible are traceable with regard to their purchase, quality, factorization and preparation.

Where non-compendial or company-sourced working standards are provided by IMB to the OMCL for use as reference materials, these will be accompanied by a Certificate of Analysis. No further qualification of the working standards will be required, unless specifically requested by the IMB or suggested by the OMCL, or in cases where the quality of the reference material is in question.

11. Instrument calibration procedures

All instruments and metrological devices (Weighing and Measuring) shall be appropriately and regularly calibrated meeting the requirements of ISO 17025 and the relevant OMCL guidelines. All standards used to perform these calibrations shall be fully traceable. In the case of equipment where a calibration method is described in the European Pharmacopoeia, i.e. spectrophotometers, etc., the calibration method used shall be fully equivalent to the compendial methods described.

12. Retention of records

Raw data and other records relating to the analysis performed will be retained for a minimum of five years after the completion of a survey or sample analysis, or for one year after expiry of the sample, whichever is longer.

13. Reporting of results

Results should be reported in a timely manner to the IMB; results may be reported by post, telephone, e-mail or facsimile, depending upon circumstances.

The results provided will be authorized by the laboratory manager or his/her approved deputy and sent to the IMB Sampling & Analysis group.

Results reported first by telephone, e-mail or facsimile must be followed by an original sent by post. The IMB is aware and agrees to the potential loss of confidentiality where transmission is by electronic means (e.g. e-mail, facsimile).

The results of the analysis shall be reported in a Certificate of Analysis meeting the requirements of ISO/IEC 17025:2005 and applicable OMCL Network

guidelines. This Certificate of Analysis will contain the OMCL and IMB sample reference numbers, a description of the label on the sample (if applicable), a sample description, the batch no (if applicable), the expiry date (if applicable), and the result(s) of the analytical test(s) performed. A brief description of, or a reference to, the analytical methods used, should also be stated, and details of the chromatographic conditions used, if applicable and if different from the analytical method, should be provided. A statement on whether the methods used were in-house, company, compendial or literature should be given.

Uncertainty of Measurement is not required to be reported on Certificates of Analysis issued by the OMCL, unless specifically requested by the IMB.

14. Review of Service Standards and Monitoring of Performance

Regular contact shall be maintained between the IMB and the OMCL. In addition, a minuted meeting should take place at least once a year with both parties in attendance. In the event that one or both parties have not attended the annual OMCL-EDQM (or similar) meeting, a second meeting should be held between both parties within the year.

15. Updating Information

The IMB and the OMCL shall review the Service Level Agreement annually, and when changes are required, a new or revised Service Level Agreement will be agreed.

SCHEDULE 2

Terms of the confidentiality agreement, under which the Pharmaceutical Section (the OMCL) of the Public Analyst's Laboratory will act as a contract testing laboratory to the IMB:

1. Purpose of the confidentiality agreement

   By this Agreement, each party confirms its willingness to make available to the other party valuable proprietary information relating to the analysis of samples and other materials sent for testing for the purpose of IMB market surveillance activities, subject to the OMCL/IMB undertaking to observe the terms of this Agreement.

2. Interpretation

   In this Agreement references to "Information" are references to information relating to analysis of samples and other materials sent for testing where such information has been supplied by one party and received by the other party.

3. Disclosure and Use

   3.1 Each party will treat the Information as secret and confidential.

   3.2 Neither party will directly or indirectly disclose the Information in whole, or in part, to any third party without the consent of the party who supplied the information. (This does not apply to the disclosure of confidential information to Irish National Accreditation Board (INAB) auditors when such auditors are auditing the OMCL, provided the INAB auditors have signed an appropriate confidentiality agreement with the OMCL.)

   3.3 The OMCL/IMB will use the Information exclusively for the purpose of analysis of samples and other materials sent for testing and, in particular, will not make commercial use of it without the permission of the other party given by the completion of a formal written agreement.

4. Exemptions

   The restrictions on use and disclosure under Clause 3.1 shall not apply to Information which:

4.1 is proven, by documentary evidence produced to the party who supplied the information, to have already been in the possession and at the free disposal of the receiving party before it was supplied to the receiving party.

4.2 is disclosed, to the receiving party without any obligations of confidentiality, after the date on which this Agreement comes into, or is deemed to have come into force, by a third party who has not derived it directly or indirectly from the party who supplied the information.

4.3 is in, or comes into, the public domain other than through a breach of this Agreement or of any undertaking given in pursuance of Clause 3.3 of this Agreement.

5. Confidentiality Measures

To secure the confidentiality attaching to the Information the parties shall:

5.1 keep all Information, and all further information generated from it, secure, retrievable and accessible to the appropriate authorities.

5.2 keep all documents and any other material bearing, or incorporating, any of the Information at their usual places of business namely the Public Analyst Laboratory, Seamus Quirke Road, Galway, and the Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.

5.3 not use, reproduce, transform or store any of the Information in any externally accessible computer or electronic information retrieval system, (excluding computer or electronic information retrieval systems which need to be externally assessed for the purposes of repair or maintenance), nor transmit it in any form or by any means whatsoever which involves the information going outside their usual places of business, excluding appropriate off-site document storage facilities. It is understood that appropriate confidentiality agreements and controls shall be in place with persons engaged in repair and/or maintenance activities for computers or electronic information retrieval systems which store such Information.

5.4 not make copies of the Information except to the extent that such copies are strictly required by the laboratory for the carrying out of its functions.

5.5 notify the other party promptly of the date of, and the circumstances involved in, any loss or unauthorized disclosure, of any documents, or other material comprised in, containing, or relating to the Information.

6. Exemption for statutory purposes

6.1 The IMB reserves the right to use the results of the analyses performed on its behalf, to produce reports and scientific papers for publication in appropriate journals to fulfill its role in protecting the public and animal health.

6.2 IMB may reproduce reports in full. However, where the information is to be used in part, a written letter of approval shall be sought from the laboratory in advance and in accordance with ISO/IEC 17025.

6.3 Where the reports and scientific papers are based on the work and results of the staff of the laboratory, their contribution shall be acknowledged, either by being co-authors if the contribution is substantial or otherwise by reference.

7. Inventions

If as a result of the Information being made available either party makes any invention, the other party will be notified immediately in writing. Any patents or other intellectual property rights in respect of such invention shall be applied for by, or assigned to the party who supplied the information, unless the parties agree otherwise by the completion of a formal written agreement.

8. Return of Information

All copies of the Information, or part of it, in whatsoever form it is held, shall remain the property of the party who supplied it and upon request the receiving party shall notwithstanding the termination of this Agreement, return, delete or destroy all such copies.

9. Summary

In discharging its statutory function, the Irish Medicines Board deals with highly confidential matters, including information on patients' reactions to drugs and pharmaceutical company formulations for medicines.

An employee, contractor or other person employed or working at the Public Analyst's Laboratory, Galway is prohibited from disclosing any confidential information obtained while working on behalf of the Irish Medicines Board. In addition, records / documentation must never be left in such a manner that unauthorized persons can obtain access to them and must be kept in safe custody at all times, even when no longer active.