UK PHARMASCAN DATABASE

DATA ACCESSOR AGREEMENT

(1) THE SECRETARY OF STATE FOR HEALTH

AND

(2) THE ORGANISATION

……..

(the Data Accessor)

Please read this Agreement carefully before you sign. By signing you accept its terms and conditions, and agree to be bound by them.

PLEASE PRINT TWO COPIES OF THIS AGREEMENT. ONE COPY SHOULD BE SIGNED AND KEPT FOR YOUR RECORDS. THE OTHER SHOULD BE RETURNED TO NICE AT THE FOLLOWING ADDRESS:

CARRIE THOMSON, UK PHARMASCAN, NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE, LEVEL 1A, CITY TOWER, PICCADILLY PLAZA, MANCHESTER, M1 4BD, UK.

BACKGROUND

A. As part of the 2009 Pharmaceutical Price Regulation Scheme ("PPRS") agreement, the Department of Health ("DH") and the Association of the British Pharmaceutical Industry ("ABPI") have committed to the delivery of a single horizon scanning database, known as *UK PharmaScan*, containing pre-launch product information for potential new medicines.

B. All of the major horizon scanning bodies in the UK together with those companies who in the past have regularly provided them with pre-launch information have agreed that one common database of information would be helpful to avoid unnecessary duplication of effort.

C. An Oversight and Governance Committee ("O&GC"), operating on behalf of the Ministerial Industry Strategy Group, will oversee the maintenance of the Database and set the annual subscription fee for Data Accessors and the ABPI on behalf of pharmaceutical companies.

D. The National Institute for Health & Care Excellence Evidence Resources team "NICE" has developed and will host the database on behalf of the Secretary of State for Health. A common dataset for the Database was agreed by all interested parties. NICE will continue to maintain the Database.

E. The Database will be populated by individual pharmaceutical industry companies operating in the UK. The companies inputting data will be responsible for continuing to input new data and keeping their own data up to date on a regular basis until any data is placed in the accessible archive. For competition law purposes companies will only have access to their own data and must not be provided with any access at any time to other parts of the collected data on the Database. All data supplied for inclusion on the Database will remain owned by the company entering it onto the Database.

F. Data can be extracted from the Database in the format of reports downloaded from the website which must not be used or distributed to anyone else outside your organisation in this format for any purpose outside that set out in this agreement.

G. The Database will be hosted on a secure password protected website: www.ukpharmascan.org.uk, which will be the portal for accessing the information in the Database, via downloadable reports.

H. All the Horizon Scanning Bodies will have access to the *UK PharmaScan* secure website using personal log-in and passwords. In addition, some NHS Organisations which have arrangements in place to provide information and advice to the NHS on new medicines in the development pipeline will also be granted access. To prevent duplication between the work of these organisations and the horizon scanning bodies, these NHS Organisations will only have access to information on potential new medicines for which a marketing authorisation has already been requested (usually 12 months prior to market entry).

I. Any NHS Organisation will only be granted access to *UK PharmaScan* as a registered Data Accessor if it can demonstrate that it :

i. has a legitimate and clearly stated purpose for evaluating medicines
ii. is responsible for providing the NHS (or parts of the NHS) with information on new medicines

iii. has:
- a proven track record in critically evaluating new medicines
- evidence synthesis skills and the ability to synthesise information into a fair, accurate and balanced summary
- a proven track record in presenting data in a user friendly format; and
- multi-disciplinary expertise within the group, or as a minimum outputs which are subject to multidisciplinary peer review with incorporation of appropriate comments.

iv. has, where appropriate:
- policies and processes in place for liaising with manufacturers during compilation of their evaluations; and
- policies and processes in place for inviting comment from manufacturers on the factual accuracy of reports or findings.

J. The individual companies supplying data will continue to own the rights to control their data which they have put in the Database. This data may include some confidential information and commercially sensitive data. The Database contains certain levels of security to protect the security of this information. All users will need to respect and maintain this security when dealing with data downloaded as reports from the Database for use in providing advice on or when making decisions regarding uptake of potential new medicines.

K. As soon as a pipeline new medicine receives marketing authorisation and is launched, the Data Inputter will indicate this on the appropriate place in the data record. Ninety days after the product is marked as launched, the whole record for that product will automatically be moved to the accessible archive and will not continue to be updated.

L. Data Inputters may also decide to stop development of a potential product in the pipeline at any time. Again the Data Inputters will update the record to show this fact, and ninety days after this event all information on the whole record for that medicine will be moved to the accessible archive and the record will not continue to be updated.

M. The *UK PharmaScan* Database is funded in two stages:

1. Initial Development is funded by equal contributions from the Government and the ABPI for and on behalf of the UK pharmaceutical industry.

2. The running and maintenance costs for *UK PharmaScan* will be covered by a uniform annual subscription fee set by the Oversight and Governance Committee paid by each of the authorised users (known in this agreement together as Data Accessors) and ABPI.

N. In return for payment of the annual subscription fee Data Accessors will be permitted access to the data on the Database for their Champion and Standard Users. These Users will be able to create and download reports from the secure website for the purpose of providing information and advice to the NHS on new medicines and indications, in accordance with relevant good practice guidance on managing the introduction of new healthcare interventions.

O. By entering into this Data Accessor Agreement there is no promised or dependent future commercial relationship made between any authorised user or any part of the NHS and any company regarding purchase of potential products listed on the Database. This Database and the activities of the Data Inputters in populating the Database do not constitute any inducement to prescribe supply or recommend to buy or sell any particular medicine.

This agreement is made by and between

The Secretary of State for Health acting through the Department of Health whose principal place of business is Richmond House, 79 Whitehall, London SW1A 2NS

And

……..... ("the Data Accessor") *[Please add name of Organisation]*

of ……*[please add main address]*

Together known as the Parties.

The signatories to this agreement must have the authority to act on behalf of and to bind the Secretary of State and the Data Accessor respectively with respect to ensuring compliance with this Data Accessor Agreement.

On payment by the Data Accessor of the annual subscription fee set from year to year by the Oversight and Governance Committee, the Data Accessor shall be provided with access to the data collected by pharmaceutical companies entering data from time to time in the *UK PharmaScan* Database on the following conditions of use

DEFINITIONS AND INTERPRETATION

In this Agreement the following terms shall have the meanings set out below:

"Agreement" means this Database Accessor Agreement

"Champion User" means an individual within an organisation authorised to have access rights to the Database, who has the responsibility for providing access to Standard Users using a self-administration system on the website, and acting as the main point of contact for NICE in any communication between NICE or the O&GC with the organisation;

"Confidential Information" means any information of a confidential nature including commercially sensitive information which any Data Inputter has put into the Database and is marked as confidential information (but not including information stated as at the date of inputting to be confidential but which the Data Inputter subsequently puts in to the public domain) or which is obvious by its nature as being confidential (including, without limitation, personal data);

"Data" means any text, graphics, or other data, placed by Data Inputters onto the Database;

"Database" means the Horizon Scanning Database including its archive to be known as *UK Pharmascan*;

"Data Accessor(s)" means your organisation or any of the group of Horizon Scanning Bodies and NHS Organisations with responsibility for planning for the managed introduction of new

medicines which shall be granted access to Data on the Database;

"Data Inputter(s)" means any or all of the individual pharmaceutical companies who are registered to input Data on to the Database;

"Effective Date" means the date that this agreement is signed by the Data Accessor;

"Freedom of Information Request" or FOI Request means any request made under the Freedom of Information Act 2000 or the Environmental Information Regulations 2004 for information about the Database, the Data or any report containing Data;

"Horizon Scanning Bodies" refers to the following organisations: All Wales Medicines Strategy Group, National Horizon Scanning Centre, NHS England, Scottish Medicines Consortium, The National Institute for Health and Clinical Excellence "NICE" and "UKMi" (The United Kingdom Medicines Information Group);

"Intellectual Property Rights" means copyright, patent, trade mark, design right, database rights, trade secrets, know how, rights of confidence, broadcast rights and all other similar rights anywhere in the world whether or not registered and including applications for registration of any of them;

"NHS Organisations" means those organisations which have arrangements in place to provide information to the NHS on new medicines and new indications in development other than Horizon Scanning Bodies;

"**Oversight and Governance Committee**" or "**O&GC**" means the group reporting to the Ministerial Industry Strategy Group that will oversee the running of the Database and will include representatives of DH, NHS, ABPI, each of the Horizon Scanning Bodies and pharmaceutical industry plus an independent person and an independent Chair.

"Standard User" means an individual who has been given access to the Database by the Champion User working for or on behalf of an organisation with access rights.

"**User**" means either a Champion or a Standard User

"Website" means the portal through which the Database is accessible, located at: www.ukpharmascan.org.uk

1. In General

1.1 This Agreement will come into force from the date it is signed by the Data Accessor.

1.2 The Data Accessor shall use the Data contained in the Database only for the purpose of providing advice to the NHS regarding planning and providing support for the introduction into the NHS of new medicines and indications and precludes its use for any other purposes:

1.2.1 Horizon Scanning Bodies will be able to see all fields as entered by Data Inputters

1.2.2 NHS Organisations will be able to see only specific fields entered by Data Inputters. These fields will only be visible following the regulatory submission for any

particular pipeline product

1.3 The Data Accessor shall appoint a Champion User as the key point of contact for NICE and inform NICE of the contact details for The Champion User using the administration section on the Website. The Data Accessor shall keep NICE informed of any change of Champion User by updating the administration section on the Website as soon as possible following any change of responsibilities. There must at all times be a designated Champion User for the account.

1.4 The Data Accessor shall restrict access to the Database to the Champion User and any other authorised Standard Users registered by the Champion using the administration section on the Website. The Data Accessor shall be entitled to allocate no more than a total of 5 Users which is the present number permitted by the Oversight & Governance Committee. These Users will comprise a minimum of one Champion User and up to four Standard Users. A substitute Champion User can be designated to cover periods such as annual leave or sickness of the original Champion User, but at no time should the number of Users exceed five (5).

1.5 As part of the initial log-in process the first time each User accesses the database NICE will grant a security certificate for the specific computer that the User works from. It is not permitted to transfer this security certificate to use any other computer (whether or not networked to the original computer) to access the Database. Only one certificate per User will be granted at any one time.

1.6 This agreement is specific to the Data Accessor who shall not assign or transfer or attempt to deal with any of its rights or obligations under this agreement to any other third party. In particular it is forbidden to lend or transfer any log-in or password to another person who is not the person registered with NICE as a User for the Data Accessor.

1.7 The Data Accessor shall recognise that ownership of Data remains with the Data Inputters and that ownership of the Database belongs to the Secretary of State for Health on behalf of the Crown.

1.8 In the event of receipt by the Data Accessor of any Freedom of Information Request the Parties agree to use their best endeavours to deal with the request urgently. The Data Inputters have agreed likewise in their Data Inputter agreement with DH:

1.8.1 the Data Accessor shall where appropriate consult the Department of Health or where appropriate the relevant Devolved Administration about whether the FOI Request should be transferred to DH to respond. The request would be suitable to transfer to DH or where appropriate the relevant Devolved Administration only if relates to Data entered into the Database and not to reports drawn down from the Database by Data Accessors or information derived from those reports. In the event it is appropriate for DH or where appropriate the relevant Devolved Administration to respond to the FOI Request the DH will consider whether to procure that NICE will contact all affected Data Inputters;

1.8.2. alternatively if it is decided that the Data Accessor should respond, the Data Accessor will send to each affected Data Inputter a copy of the text (if not a copy

of the request itself) redacted so as to remove personal data relating to the requester plus the information to be considered for disclosure (again redacted to remove any information not relevant to the particular Data Inputter) before responding to the FOI Request, in order to check whether any of the information requested may be confidential or commercially sensitive. The Data Inputter shall have 5 working days to provide comments from the date the Data Inputter receives the copy of the FOI Request. All Data Inputters have agreed to provide comments to the Data Accessor on an urgent basis and in any event within the 5 working days provided for. If any Data Inputters have not responded within the initial period the Data Accessor can respond to the request without that particular Data Inputter's comments.

1.8.3 The Data Accessor shall consider representations made by any Data Inputter in relation to disclosure of their Data on the grounds of such Data being confidential or damaging to its commercial interests (pursuant to s41 and s43 of FOIA 2000 respectively or equivalent provisions under the Freedom of Information (Scotland) Act 2002). The Data Accessor has the sole right to decide whether the information requested shall be disclosed.

1.8.4 If the Data Accessor decides not to accept all of the representations of any relevant Data Inputter, then two clear working days before the final response is due to be sent the Data Accessor will inform that Data Inputter of what the Data Accessor intends to disclose in the final response by providing a copy of the information in the form that it is intended to be disclosed redacted so as not to include any information not relevant to that Data Inputter.

1.9 The Data Accessor and all Users shall recognise that Data is subject to change during the development of the relevant product and that therefore it is possible for Data Inputters to update Data about intended products in the development pipeline at any time during the operation of the Database. Data Inputters may decide to archive a potential product from the live Database where they decide to discontinue commercialisation. Similarly on receipt of marketing authorisation for a new product, the pre-launch pipeline information will be moved from the live Database. In both cases the information will be transferred to an accessible archive section of the Database to enable the Data Accessor to check any product information downloaded at an earlier time. Please note that it is not possible for Data Inputters to update data once it has been placed in the archive. It is the responsibility of the Data Accessor to check the Database for updates on information previously drawn down.

1.10 Given the changing nature of the Database Data Accessors may only download reports from the Database via the secure website and are not given permission to download or copy the entire Database over from the website to another computer or to alter any individual data records contained within the Database.

1.11 Accordingly, whilst the Data should be current on the date it is entered by a Data Inputter, Data Accessors should note that Data may not still be current following any report being drawn down from the Database.

1.12 To the fullest extent possible, neither NICE, the Secretary of State for Health nor any of the Data Inputters shall be liable for the consequences of advice given by the Data

Accessor or decisions made for and on behalf of by other NHS bodies about potential pipeline products as a result of downloading information from the Database.

1.13 Nothing in the agreement gives rise to any partnership or agency arrangement between NICE as the operator of the Database on behalf of the Secretary of State and the Data Accessor or any other third party relying on advice provided by the Data Accessor.

1.14 You may only use or process personal data contained in the Database regarding Champion Users of Data Inputters in accordance with the Data Protection Act to the extent necessary to enable the Data Accessor to work this Agreement.

2. Confidentiality and Dealing with Data

2.1 Some of the Data contained in the Database is confidential and/or commercially sensitive information belonging to the relevant Data Inputter. The Data Accessor and Users must not remove any identifying features from Reports of Data drawn down showing any Data which is entered by Data Inputters as confidential and/or commercially sensitive.

2.2 The Data Accessor shall use its best endeavours to ensure that all Data drawn down as reports from the Database by Users is used only for providing advice to the NHS regarding planning and providing support for the introduction into the NHS of new medicines and indications and for such other purposes as may be set out in this agreement. The Data Accessor shall use the same level of care to generally keep confidential and prevent any unauthorised use or disclosure of the Confidential Information, as it exercises in protecting its own information of a confidential nature.

2.3 The Data Accessor shall maintain a register of interests for all Users and ensure that all identified conflicts of interest are discussed and appropriately managed

2.4 The Data Accessor must only distribute advice documents for use by the NHS in a format which either

2.4.1 presents only non-confidential information, or

2.4.2 presents the Data in a format which has been further analysed by the User such that such confidential information is not able to be discovered from reading the document, or

2.4.3 clearly identifies any confidential information as such and places restrictions on readers as to the further non-disclosure of confidential information by the reader.

2.5 The Data Accessor shall be liable for all breaches of confidentiality by its employees or any persons who are not employees but who are providing services to the Data Accessor either on a self employed basis or through a personal service company or through some other form of consultancy.

2.6 The Data Accessor shall ensure that appropriate and effective administrative procedures are in place to

2.6.1 limit damage by managing any breaches of security or breaches of confidential information however they should occur and

2.6.2 report such instances to NICE as soon as is reasonably possible

2.7 Given the commercially sensitive nature of the Data and the potential commercial implications for a Data Inputter of an unauthorised release of the Data, the Data Accessor understands that such a disclosure may cause irreparable harm to Data Inputters for which damages would be inadequate compensation. Accordingly any breach of Confidentiality may result in an affected Data Inputter applying for injunctive relief against the Data Accessor.

3. Communication with NICE & the Oversight and Governance Committee

3.1 The Champion User shall be proactive in :

3.1.1 reporting all IT errors to NICE

3.1.2 informing NICE of all concerns with the general format of the Database as and when they arise or are identified by Users

3.2 The Secretary of State for Health shall procure that NICE on behalf of the O&GC may from time to time contact the Data Accessor through the Champion User to request participation in written consultation on the operation of the Database including any proposed amendments to the Database or these terms and conditions of use.

3.3 In most circumstances, contact with NICE (or the O&GC) will be via the helpline telephone number: 0845 003 9183, or via email to: contactus@ukpharmascan.org.uk

4. Intellectual Property Rights

4.1 All Intellectual Property Rights in the Database, the Website and Domain name and the trade mark UK PharmaScan are owned by the Secretary of State for Health.

4.2 The ownership and rights to control use of the Data contained in the Database are owned by the individual Data Inputter who entered it.

4.3 The Data Inputters have each agreed to provide Data to the Secretary of State for Health via UK PharmaScan and for that Data to be used by Data Accessors on these terms and conditions.

5. Termination

5.1 In the event that the Data Accessor no longer requires access to the Database it shall give at least 5 working days notice to NICE who will then remove the organisation as a Data Accessor from the date specified in the notice and will revoke all security certificates for the Users registered by the Data Accessor. Any fees paid for unused periods of the

current annual subscription will not be refunded.

5.2 If the O&GC reasonably suspects that the Data Accessor or anyone under its control has acted in breach of this agreement, the O&GC will give written notice to the Data Accessor of its intention to suspend or terminate this agreement as of the date specified in the notice. Any dispute by the Data Accessor regarding the contents of the notice may be resolved by contacting the O&GC using the procedure indicated in the notice. Should the O&GC decide as a result of any subsequent inquiry to cancel this agreement any fee paid for unused period of the current annual subscription will not be refunded.

5.3 If the Secretary of State for Health decides to cease operation of the Database it will write to give notice of this intention with a date for the intended termination of access to the Database. Any fees for unused periods of the current annual subscription will be refunded on a pro-rata basis.

5.4 The Data Accessor shall remain under all obligations to maintain confidentiality in any confidential or commercially sensitive information downloaded from the Database for a period of 10 years following termination of this Agreement unless and until any earlier time that any confidential information is made publicly available by the relevant Data Inputter.

5.5 In the event that access to the Database is terminated the Data Accessor will immediately take appropriate measures to:

i. destroy all hard copies of reports of Data downloaded from the Database containing confidential or commercially sensitive information; and

ii. delete all electronic copies of reports of Data downloaded containing confidential or commercially sensitive information from each of its Users computers; and

iii. retrieve any reports or advice currently being considered which contain confidential or commercial Data downloaded from the Database

unless either this information is now available within the public domain, or has been disclosed to the Data Accessor by the Data Inputter otherwise than through access to the Database.

6. Jurisdiction and governing law

6.1 This agreement is governed by English law and the parties agree to submit to the jurisdiction of the English Courts in respect of any proceedings that may be issued in connection with this agreement.

This agreement is SIGNED for and on behalf of the Secretary of State for Health **by:**  **Name**: Richard Carter **Job Title**: Head of Industry Sponsorship **Date**: 29 January 2014	**SIGNED for and on behalf of YOUR ORGANISATION** **……** **by:** Name: Job Title: Date: