
**UK PHARMASCAN DATABASE
DATA INPUTTER AGREEMENT**

(1) THE SECRETARY OF STATE FOR HEALTH

AND

(2) THE COMPANY

.....
(the Data Inputter)

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: CATHERINE WHITE, BUSINESS MANAGER, UK PHARMASCAN, NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE, LEVEL 1A, CITY TOWER, PICCADILLY PLAZA, MANCHESTER, M1 4BD, UK. IF YOU HAVE ANY QUESTIONS, PLEASE PHONE THE UK PHARMASCAN HELPDESK NUMBER 0845 003 9183.

This is a legal agreement 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 (referred to as 'Us', 'Our', 'We' or 'Department of Health', 'DH').

And

[INSERT NAME OF COMPANY] (Data Inputter)

registered company number whose registered office address is at

.....

(referred to as 'You', 'Your', or 'Yourself' 'Your Company' which terms shall include Your Users)

Together referred to as “the Parties”

Please read this Agreement carefully before You sign. By signing and/or exercising any of the rights granted hereunder you accept the following terms and conditions, You agree to be bound by them, and You agree that this Agreement is legally enforceable. The signatory must have a senior position which provides the authority to act on behalf and to bind Your Company.

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 for pharmaceutical companies..
- D. The National Institute for Health & Clinical Excellence NHS Evidence 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. You will enter Your Data on to the Database regarding pre-launch information about potential products in Your development line which shall be provided on a voluntary basis in accordance with this Agreement and will contain some information which is “commercial in confidence”. It is noted however that from time to time you may be requested to provide at your own choice other information which may be requested by Data Accessors.
- F. In addition to Your Data, the Database will receive Data from other Data Inputters like Your Company. Your use of the Database will comply with the conditions set out in this Agreement which are the same as those signed up to by other Data Inputters.
- G. Under this Agreement, the Secretary of State will make Your Data available to various national and regional government health care organisations as Data Accessors under the terms of the Data Accessor Agreement set out for information in Schedule 1 and on the website: www.ukpharmascan.org.uk
- 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
 - multidisciplinary 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. In order to comply with national and international laws on Competition You will only have access to Your own Data as entered on the Database. Data Inputters will not be able to view any Data supplied by other Data Inputters
- K. Under this Agreement, the Secretary of State for Health shall procure that NICE shall provide You with a computer security certificate to be used in conjunction with a unique email address and password to facilitate the secure access to and the use of the Database in accordance with the terms and conditions of this Agreement.
- L. It will be up to You to review Your Data on a regular basis to ensure that it is relevant and as accurate as possible (other than Data that has been moved to the accessible archive)
- a. As soon as possible after one of Your products listed receives marketing authorisation and is launched on the UK market You must mark this fact on the record for that product. Ninety days later the record for that product will automatically be moved to the accessible archive; and
 - b. As soon as You decide to withdraw a potential product from the pipeline You should also amend the Database record to indicate this. Ninety days after the record is marked any information about that product will be moved to the accessible archive
- M. The archive is accessible to You and it is possible for You to reinstate previously archived Data on pipeline products should you decide to go back to working on any candidate product at any time. The accessible archive will also be visible to Data Accessors to enable them to check on the status of Your pipeline products, it being acknowledged that information in the accessible archive will not be reviewed or updated by You.
- N. By entering into this Data Inputter Agreement there is no promised or dependent future commercial relationship made between any authorised user or any part of the NHS and any Data Inputter regarding purchase of potential products listed on the Database. This Database does not constitute any inducement to prescribe supply or recommend to buy or sell any particular medicine.

In consideration of the mutual covenants contained herein, and intending to be legally bound, the following terms and conditions are hereby agreed by You and Us regarding the Database Service:

1. DEFINITIONS AND INTERPRETATION

1.1 In this Agreement the following terms shall have the following meanings:

“Agreement” means this Data Inputter Agreement and Schedules;

“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;

- **“Your Data”** means all Data supplied by You for inclusion in the Database, as may be amended by You from time to time;
- **“Collected Data”** means all Data stored in the Database, which may be accessed by Data Accessors;

“Database” means the Horizon Scanning Database including the archive to be known as *UK Pharmascan*;

“Data Accessor(s)” means the individual or group of Horizon Scanning Bodies and NHS Organisations which shall be granted access to Data on the Database on the terms in the agreement set out in Schedule 1;

“Data Inputter(s)” means You and any 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 You;

“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: National Horizon Scanning Centre, National Prescribing Centre, All Wales Medicines Strategy Group, Scottish Medicines Consortium, “UKMi” (The United Kingdom Medicines Information Group) and The National Institute for Health and Clinical Excellence “NICE”;

“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, the Horizon Scanning Bodies and pharmaceutical industry plus an independent person and an independent Chair.

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

“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

1.2 References anywhere in this Agreement to any legislation, statutory provision, enactment, order, regulation or other similar legal obligation or instrument shall be construed to include the same as amended, modified, consolidated, re-enacted or replaced from time to time together with any orders, regulations, codes of practice, instruments or other subordinate legislation made under it

1.3 References anywhere in this Agreement to he/his, shall be deemed to be substitutable by she/hers and it/its.

1.4 Headings used herein are for the convenience of reference only and shall in no way affect the interpretation of this Agreement.

2. REGISTRATION AND PROVISION OF THE DATABASE

2.1 On submission by You of an initial application to be processed by the ABPI and subject to satisfactory security checks to ensure that You are an appropriate bona fide

organisation to provide Your Data into the Database, You will be permitted limited access to the Database on the terms and conditions in this Agreement. For the avoidance of doubt, whilst Your application is being processed, You will be permitted limited use of the Database, for the purpose of accessing and inputting Your Data.

- 2.2 In order to access and use the Database and also certain features of the Website, You shall designate a Champion User to register a login identity. The Champion User shall designate not more than four (4) other Standard Users at any one time. 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 total number of Users exceed five (5). All Users shall be required to have an appropriate company email address linking them to You. No User shall select or use a login identity with the intent of impersonating another person and all Users shall keep passwords confidential and shall not allow any other person to use their login identity and password to access any part of the Database, Collected Data or restricted area of the Website accessible only by logging in. Once Users have registered a login identity, they shall be provided with restricted access to the Database.
- 2.3 In the event that We, reasonably consider that You are making any illegal or unauthorised use of the Database, Collected Data or the Website, or we consider that Your use of the Database or Website is in breach of this Agreement, We reserve the right to take any action that We reasonably deem necessary, including freezing, deactivating or terminating without notice Your use of the Database and the Website, and in the case of illegal use, instigating appropriate dispute resolution or legal proceedings.
- 2.4 Subject to the usage limits in clause 2.2 and system capacity, We shall use reasonable endeavours to provide You with access to Your Data as inputted by You to the Database via the URL www.ukpharmascan.org.uk and when available by Your downloading reports generated by You to show Your Data.
- 2.5 We may suspend the Website and the provision of the Database and/or Collected Data for any technical reason whatsoever, including but not limited to repairs, planned maintenance or upgrades, and shall not be liable to You for any such suspension. Where possible we will notify you in advance of any suspension and its anticipated duration. We will also notify you when work has been completed and or if any remedial work may be required to Your Data as a result. We will use reasonable endeavours to minimise the duration of any suspension.
- 2.6 We reserve the right to make reasonable changes to the Database (with the exception of Your Data), including changes to proforma applications requesting collection of Your Data, the form in which Your Data is reported and/or Your Data is made available to Data Accessors of the Website, or to discontinue and/or modify any aspect or feature of the Database. All changes other than technical changes will only

be made subject to recommendation by the Oversight & Governance Committee and will be made effective after written notice has been given to You, from the date set out in the notice.

- 2.7 These terms and conditions of use and the general privacy policy of the Website shall be displayed on the Website and shall apply to Your use of the Website.
- 2.8 Whilst We would strongly encourage You to provide Data for the purposes set out in recitals A to E, We agree and acknowledge that nothing in this Agreement places on You any obligation so to do.

3. DATA AND PROPRIETARY RIGHTS

- 3.1 You shall own and retain all Intellectual Property Rights in Your Data as submitted and updated by You and in all reports generated through use of the Database based on Your Data. You remain in sole control of Your Data on the Database whether or not marked as provided in confidence. It is Your sole responsibility to ensure that all of Your Data on the Database is accurate and up to date at the time of input. You are not required to keep up to date any information in the accessible archive.
- 3.2 Subject to clause 3.1, all Intellectual Property Rights in the Database shall be owned by the Secretary of State for Health. You acknowledge that the inclusion of Your Data in the Database does not give You, and shall not convey, any title to or part-ownership of any rights in the Database.
- 3.3 You hereby grant the Department of Health a non-exclusive, revocable, royalty free licence to store, use and copy Your Data as inputted by Your Permitted Users to the Database through the Website only for the purpose of providing the Database and for Your Data to be used in accordance with the requirements and decisions of the Oversight and Governance Committee as notified to You, and by Data Accessors in accordance with the provisions of the Data Accessor Agreement.
- 3.3.1 Horizon Scanning Bodies will be able to see all fields as entered by You
- 3.3.2 NHS Organisations will be able to see only specific fields entered by You. These fields will only be visible following the regulatory submission for any particular pipeline product
- 3.4 We hereby grant You a non-exclusive, non-transferable, revocable, royalty free licence for You acting through your Permitted Users only to access the Database through the Website for the purposes of storing, accessing and uploading Your Data and reviewing, downloading, updating and modifying Your Data. For information a list of all possible fields to populate with Your Data can be seen on the training manual through the Help section of the Website. Please apply to NICE for an excel spreadsheet proforma which will assist you in collecting Your Data within your company. Your Users will then enter Your Data directly on to the Database.

3.5 For the avoidance of doubt, the licences set out in this clause 3 shall not extend to the provision of Your Data to other Data Inputters (and vice versa).

3.6 The licences granted by You pursuant to this clause 3 of this Agreement are subject to the Data Accessors complying with all the conditions set out in the Data Accessor Agreement.

4. DATA ENTRY, RETRIEVAL & CHECKING BY YOU

4.1 You will be able to download and print out reports of Your Data compiled from the entries you have submitted.

4.2 The Secretary of State for Health shall procure that NICE shall use reasonable skill and care in the provision of the Database. The Secretary of State does not warrant the continued availability of the Database or that the Database will be uninterrupted or error free.

4.3 The Secretary of State for Health shall procure that NICE shall make a history log as part of the Database functioning of all dates of activity by Your Users for each field in which You have supplied Your Data for inclusion in the Database. This is so that the date of last field update or review can be monitored by NICE to ensure effective use of the Database. NICE is not responsible for, and will not be, monitoring the accuracy of any Data submitted by You.

4.4 In the event that the history log shows that You have not updated or reviewed Your Data either as a whole or within in any particular field that You have populated within the last period of at least one (1) month, the Secretary of State shall procure that NICE shall inform Your Champion User of this fact. If after 3 monthly reminders no action to confirm Your Data has been taken, NICE shall inform the ABPI representative of this information. The purpose of NICE contacting the ABPI is for its representative to then contact you to remind you to do so.

4.5 Only Your Users will be able to make additions or changes to the fields populated for Your Data, and apart from any technical maintenance function required to be reserved by NICE in its function as the IT builder and administrator of the Database no other employees or representatives of NICE, ABPI or DH or any Data Accessor or other Database Inputter shall be able to alter Your Data entered into the Database whether or not on Your request or instruction.

4.6 Given the changing nature from day to day of Collected Data inputted for storage by various Data Inputters, please note that it will not be possible for the Secretary of State for Health or NICE acting on his behalf, to reproduce or check the accuracy of any Data report made by any Data Accessor on any particular date.

4.7 Your Data that relates to a product that either:

4.7.1 Has launched on the UK market, or

4.7.2 You have decided to discontinue work on

Shall be updated by you on the record as soon as possible after the decision has been made. Ninety days after the record has been marked as either launched or discontinued the record will be automatically moved to the accessible archive. It is possible for You to reinstate any stored Data from the archive should You decide to continue to work on a candidate product following an earlier discontinuation or when working on a new indication or dosage indication for an existing product now on the market. The accessible archive will also be visible to Data Accessors to enable them to check on the status of Your pipeline products. We acknowledge that once Data is moved to the archive will not be reviewed or updated by You.

4.8 Neither the Secretary of State, DH nor NICE acting on behalf of the Secretary of State, DH nor ABPI is willing or able to be joined in any disputes or litigation between You and any other Data Inputters or between you and any Data Accessors to act as a witness to such in order to verify the accuracy of any Data inputted by You or the accuracy of any Data reports created by Data Accessors.

5. CONDITIONS OF USE

5.1 Except as expressly permitted under this Agreement, the licences granted to You pursuant to clause 3 of this Agreement are subject to You complying (and ensuring compliance by Your Users) with all the conditions set out in this Agreement. You shall ensure that all Users undertake to agree to the terms set out in this Agreement.

5.2 Other than in respect of Your Data, You shall not (nor may You permit Your Users to) attempt to access, review, download, store, and/or archive the Collected Data from another Data Inputter.

5.3 Except for Users, You must not (nor may You permit others to) use any other Collected Data held on the Database other than Your Data in any manner not expressly authorised by this Agreement.

5.4 When a User ceases to be employed by You, or is no longer under contract to you or is no longer authorised by You to access the Database, You shall ensure that their login identity and security certificate to access the Database is cancelled or changed such that the individual is prevented from accessing the Database using the same login details without being an authorised User. The Champion User should apply to NICE to create a new security certificate for any replacement User taking over the vacant position.

5.5 You shall promptly notify NICE acting as agent on behalf of the Secretary of State for Health if You suspect or become aware of any infringement or breach of the Intellectual Property Rights in Collected Data which might have occurred as a result

of other parties gaining access to Collected Data. You shall give all reasonably required assistance in pursuing any such breach or infringement.

- 5.6 The Secretary of State for Health shall procure that NICE shall promptly notify You if it suspects or becomes aware of any infringement or breach of the Intellectual Property Rights in Your Data which might have occurred as a result of other parties gaining access to Your Data. If it becomes clear that a Data Accessor is not complying with the terms of its agreement the Department of Health through the Oversight & Governance Committee will take action to ensure compliance and in the absence of compliance will restrict or remove access to the Database for any offending Data Accessor.
- 5.7 You shall in supplying Your Data to the Database:
- 5.7.1 not at any time conduct Yourself in a manner which would reflect unfavourably on NICE or the Department of Health's good name and reputation;
 - 5.7.2 not by Yourself or with others participate in any illegal, deceptive, misleading or unethical practices including, but not limited to, disparagement of Collected Data or NICE or other practices which may be detrimental to the Collected Data, NICE or the public interest;
 - 5.7.3 not describe Yourself or allow Yourself to be described as an agent of the Department of Health or of NICE or representative or to act as such in any way; and
 - 5.7.4 use Your reasonable endeavours to ensure that You use adequate technological and security measures, including without limitation such reasonable measures as We may recommend from time to time, to ensure that Your Data are secure from unauthorised use or access and are only used in accordance with the terms of this Agreement.
- 5.8 In supplying the Database to You and to Data Accessors We shall:
- 5.8.1 use Our reasonable endeavours to ensure that We use adequate technological and security measures to ensure that Your Data is secure from unauthorised use or access and are only used in accordance with the terms of this Agreement; and
 - 5.8.2 only provide access to Your Data to Data Accessors as listed from time to time by the Oversight & Governance Committee; and
 - 5.8.3 only provide Your Data to Data Accessors in accordance with the terms of this Agreement and the Data Accessor Agreement; and
 - 5.8.4 use Our reasonable endeavours to ensure compliance by the Data Accessors with the Data Accessor Agreement, it being acknowledged that it is not possible under the NHS Act 2006 for the Data Accessor Agreement to be a legally binding contract, including to recommend to the Oversight & Governance Committee to remove or deny continuing access to Your Data

for any Data Accessor who does not comply with the Data Accessor Agreement.

6. INTELLECTUAL PROPERTY RIGHTS ACKNOWLEDGEMENT

- 6.1 There are appropriate acknowledgements of confidentiality on certain fields of data to be supplied and of database right ownership in the Database and copyright in the format of the Website
- 6.2 You must not (nor may You permit others to), tamper with or remove any copyright, trade mark, trade mark symbols, or other proprietary notices or terms of use contained within the Website, Collected Data or Database as a whole.
- 6.3 You must not under any circumstances use or apply for registration of any trade mark in respect of Our trade names or registered or unregistered trade marks or any part of them, nor use or apply to register any trade mark similar to or likely to be confused with any of them, nor register any domain name which is the same as, similar to or likely to be confused with any of Our trade names or registered or unregistered trade marks or domain names.

7. TERM AND TERMINATION

- 7.1 This Agreement shall commence on the Effective Date and continue in effect unless terminated by either Party on the provision of not less than thirty (30) calendar days' written notice to the other unless any other part of this clause 7 applies:
 - 7.1.1 In the event that the Secretary of State determines that the Database should cease to operate he will do so on notice and the Database will cease to operate in its entirety from the date given in the notice
 - 7.1.2 In the event that the You have applied to terminate this Agreement under this clause 7.1 Your Data will be placed in the accessible archive and marked as "archived" to put Data Accessors on notice that it may not remain accurate.
- 7.2 If We reasonably suspect that Collected Data not owned by You, is being used by You in breach of this Agreement, We may elect to terminate this Agreement forthwith on notice in writing. In such case Your Data will be placed in the accessible archive and marked as "archived" to put Data Accessors on notice that it may not remain accurate.
- 7.3 If You reasonably suspect that Your Data is being used in breach of this Agreement, You may elect to terminate this Agreement forthwith on notice in writing. In such circumstances You may apply to NICE to delete Your Data immediately from the Database.
- 7.4 If We make changes to this Agreement, or to any element of the Database in accordance with Clauses 2.6 or 19 and You do not find such changes acceptable, then

You may terminate this Agreement on giving notice in writing, effective from the date of expiry set by You in the notice. In such case Your Data will be placed in the accessible archive from that date and marked as “archived” to put Data Accessors on notice that it may not remain accurate.

- 7.5 If either Party breaches this Agreement in any material respect, and either fails to remedy the same on being given ten (10) working days’ written notice of the breach and requiring it to be remedied, or such breach is incapable of remedy, then the other Party may terminate this Agreement forthwith on notice in writing to the other. In such case Your Data will be placed in the accessible archive and marked as “archived” to put Data Accessors on notice that it may not remain accurate.
- 7.6 If We reasonably suspect that the Database has not been used by You, for a period of twelve (12) months, We may ask the ABPI to contact You to discuss Your ongoing requirements in respect of the Database and Collected Data and thereafter. In such case Your Data will be placed in the accessible archive and marked as “archived” to show that it may not remain accurate.
- 7.7 Upon any termination date being notified by either Party of this Agreement the rights and licences granted to You and Us herein shall forthwith terminate and You shall cease all use of the Database, and We will immediately terminate your access to the Database. At any time after termination You may request NICE to delete Your Data from the archive and NICE shall not unreasonably refuse such request.
- 7.8 Clauses 1, 2.3, 3.1, 3.2, 4.8, 5.5 and clauses 6, 8, 9, 11, 12, 15 and 21 in their entirety, shall survive any termination of this Agreement.

8. REPRESENTATIONS AND WARRANTIES

- 8.1 We warrant that We are authorised to enter into this Agreement with You.
- 8.2 We do not make any warranties express or implied, as to the accuracy, adequacy, quality or fitness for any particular purpose of the Database or of Data provided by You or of any reports that may be downloaded from time to time by You or Data Accessors and all such warranties or representations, whether express or implied, to the contrary are expressly excluded to the fullest extent permitted by law
- 8.3 To the fullest extent possible by law, we hereby exclude all liability for actions omissions and the economic effects of all decisions made by Us with respect to Your Data as is collected within the Database.
- 8.4 You warrant that Your Data inputted by You via Your Users will be accurate and up to date as at the time of input. You will not be in breach of this warranty where Your Data has been placed in the accessible archive.

- 8.5 We and You exclude, to the fullest extent permissible by law and except as expressly stated in this Clause 8, all warranties, conditions, representations or terms, whether express or implied by common law, statute or otherwise including, but not limited to, any regarding the accuracy, compatibility, fitness for purpose, performance, satisfactory quality or use of Your Data or Collected Data contained within the Database and any services We provide to You under or in connection with this Agreement.
- 8.6 We warrant that We will at all times comply with any relevant laws that might affect the subject matter of the Database and this Agreement.
- 8.7 You warrant that You and your Permitted Users shall comply at all times with any relevant laws that might affect the subject matter of this Agreement.
- 8.8 In addition to this representation of compliance You and We hereby Agree that
- (a) this Agreement and the activities undertaken by You in relation to providing Data for inclusion on the Database do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine;
 - (b) None of the support provided by You in entering Data into the Database is dependent on or related to any past, or present commercial relationship between You and any Data Accessor or NICE or DH or any business or other decision(s) that the Data Accessors or NICE or DH may have made or may make in future relating to the use of Your intended products or any other existing products placed by You on the market as available for sale;
 - (c) In providing Your Data to the Database there is no dependent or promised future commercial relationship made between You and any particular Data Accessor, or DH or NICE regarding potential products for which You provide Your Data; and
 - (d) You shall not offer, pay or authorise the offer or payment of any money or the giving of anything of value or the doing of any other thing in order to exert any improper influence on any healthcare professional or other government official. If You breach this clause, We shall be entitled to end this Agreement immediately, without prejudice to any rights that may have accrued before termination.

9. LIMITATION OF LIABILITY

- 9.1 Nothing in this Agreement shall have the effect of excluding or limiting the liability of either Party for:
- 9.1.1 death or personal injury to the extent it results from negligence, or that of Your or Our employees or agents in the course of their engagement hereunder; or
 - 9.1.2 fraud.
- 9.2 Subject to Clause 9.3, We accept no responsibility or liability whether in contract, tort (including negligence) or otherwise for any loss or damage of whatsoever nature

arising from any use of the Database, Your Data or from any delay, interruption or failure of any electronic transmission of Collected Data to Data Accessors or to You.

9.3 Subject to Clause 9.1, neither Party shall be liable to the other in contract, tort (including negligence) or otherwise for any direct, indirect, special or consequential losses or damages, (including but not limited to any loss of profits, loss of business or loss of contracts) provided that neither this Clause 9.3 nor any other provision of this Agreement shall prevent either Party from recovering all amounts lawfully due in respect of all infringements and breaches of Intellectual Property Rights or confidentiality by either Party, or any third party who gains unauthorised access to Collected Data.

9.4 Additionally both Parties agree and acknowledge that whilst the Database may be used in combination with any web application and other third party software, neither Party bears any liability, howsoever arising, for any loss, damage or cost that arises from a failure of the Database to integrate with any third party software in use by either Party.

9.5 Given the commercially sensitive nature of the Data and the potential commercial implications for You of an unauthorised release of Your Data, We understand that such a disclosure may cause irreparable harm to You for which damages would be inadequate compensation. Accordingly We acknowledge that any breach of Confidentiality may result in You applying for injunctive relief.

10. EVENTS OUTSIDE ANYONE'S CONTROL

10.1 Neither Party shall be responsible for any delay or failure in carrying out obligations under this Agreement if the delay or failure is caused by circumstances beyond the reasonable control of the affected Party. In such circumstances the affected Party shall notify the other of any such likelihood as soon as possible. The affected Party shall be allowed a reasonable extension of time to carry out its obligations in these circumstances.

11. FREEDOM OF INFORMATION ACT

11.1 In the event of receipt by Us of any Freedom of Information Request the Parties agree to use their best endeavours to deal with the request urgently:

11.1.1 the DH shall where appropriate consult the Data Accessors about whether the FOI Request should be transferred to any of them to respond. The request would be suitable to be answered by DH 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 any Data Accessor(s) to respond to the FOI Request DH will procure that the Data Accessor(s) shall contact all affected Data Inputters;

- 11.1.2 either the DH or Data Accessor(s) as appropriate will send a copy of the text of the request (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 You) before responding to the FOI Request, in order to check whether any of the information requested may be confidential or commercially sensitive. You shall have 5 working days from receipt of that notice to provide comments. You should provide comments to DH or the Data Accessor as appropriate on an urgent basis and in any event within the 5 working days provided for. If You have not responded within the initial period of 5 working days either DH or the relevant Data Accessor(s) as appropriate can respond to the request without Your comments.
- 11.1.3 The DH or the relevant Data Accessor(s) as appropriate shall consider representations made by You in relation to disclosure of Your Data on the grounds of such Data being confidential or damaging to its commercial interests (pursuant to s41 and s43 of FOIA 2000 respectively). The DH and or the relevant Data Accessor(s) as appropriate has the sole right to decide whether the information requested shall be disclosed
- 11.1.4 If the DH or the relevant Data Accessor(s) as appropriate decides not to accept all of Your representations, then two clear working days before the final response is due to be sent the DH or the relevant Data Accessor as appropriate will inform You of what is intended to be disclosed 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 the Data Inputter.
- 11.4 You acknowledge that the Department of Health and Data Accessors are subject to the Freedom of Information Act 2000 ("FOIA") and the Environmental Information Regulations ("EIR") and shall (at Your own expense) assist and cooperate with the Department of Health and/or Data Accessors to enable the Department of Health and Data Accessors comply with these requirements.

12. DATA PROTECTION AND CONFIDENTIAL INFORMATION

- 12.1 Both Parties to this Agreement shall comply in all respects with all current data protection legislation, including (without limitation) the Data Protection Act 1998 and any orders made or codes of practice issued under it and the Privacy and Electronic Communications (EC Directive) Regulations 2003 (the 'Data Protection Legislation').
- 12.2 If You provide Us with any personal data (as defined in the Data Protection Legislation), regarding the identity of Users, You warrant that such data was obtained and is supplied to Us in compliance with the Data Protection Legislation.

12.3 The Secretary of State for Health shall procure that NICE shall process all such personal data which You provide in relation to the Database only to the extent necessary to enable Us to meet Our obligations under the Agreement. In addition, the Secretary of State shall procure that NICE may pass such personal data to organisations who are engaged by NICE in connection with the provision of the Database and who may need access to such personal data to enable them to perform services, and who shall be bound by a written agreement containing terms regarding the processing of personal data and obligations of confidence.

12.4 We shall exercise all appropriate security and other measures to prevent unauthorised access to or accidental or unauthorised alterations, disclosure, destruction or loss of personal data supplied by You.

12.5 The Secretary of State for Health shall procure that NICE shall at all times during this Agreement and after its termination:

12.5.1 use all reasonable endeavours and the same level of care as it exercises in protecting its own information of a confidential nature to keep confidential all Data and Confidential Information (including without limitation, personal data of Permitted Users) supplied to NICE in connection with the Database as Confidential Information and not to disclose any Confidential Information except as permitted under this Agreement to be disclosed to Data Accessors in accordance with the provisions of the Data Accessor Agreement in the form set out in Schedule 1

12.5.2 not use any Confidential Information for any purpose other than the performance of Our obligations under this Agreement.

13. ASSIGNMENT, SUBCONTRACTING AND SUBLICENSING

13.1 Except as provided in the Agreement, neither Party shall licence, assign, transfer, contract or novate its rights and/or obligations under this Agreement, without the prior written consent of the other, not to be unreasonably withheld or delay, save that We shall be entitled to assign, transfer or novate the benefits and obligations of this Agreement to any government body to which Our activities or functions have been transferred. You expressly agree to the assumption of Our obligations under this Agreement by that entity.

14. PARTNERSHIP, JOINT VENTURE AND AGENCY EXCLUDED

14.1 Nothing in this Agreement or any circumstances associated with it or its performance gives rise to any relationship of agency, partnership or employer and employee between You and Us.

15. ENTIRE AGREEMENT

15.1 The Parties agree that this Agreement and any documents referred to in it constitute the entire agreement and understanding between the Parties concerning the subject matter of this Agreement.

15.2 This Agreement supersedes all understandings, representations and agreements made between the Parties concerning such subject matter. Without prejudice to any other Clause in this Agreement, any attempt by You to submit alternate terms and conditions, either as part of a purchase order or otherwise, subsequent to the Parties entering into this Agreement, is hereby rejected. However, neither Party seeks to exclude or limit liability for any fraudulent misrepresentations.

16. WAIVER

- 16.1 The waiving (which must be in writing and signed by an authorised representative of the relevant Party) on any occasion by either Party of any particular right under this Agreement does not mean that other rights shall be waived.
- 16.2 If a Party has a right arising from the other Party's failure to comply with an obligation under this Agreement and delays in exercising or does not exercise that right, such delay in exercising or failure to exercise is not a waiver of that right or any other right.

17. SEVERABILITY

- 17.1 Each term of this Agreement is a separate term and is intended to stand alone. Should any provision of this Agreement be held to be invalid or unenforceable, such provision shall be severed from the remainder of this Agreement, which shall continue to be valid and enforceable to the fullest extent permitted by law. In respect of such severed provision, the Parties shall negotiate in good faith and shall each use their reasonable endeavours to agree the terms of a mutually satisfactory provision to be substituted for the invalid, illegal or unenforceable provision which as nearly as possible validly gives effect to their intentions as expressed in this Agreement.

18. FURTHER ASSURANCE

- 18.1 The Parties shall do and execute all such further acts and things as are reasonably required to give full effect to the rights given and the transactions contemplated by this Agreement.

19. NOTICES

- 19.1 The Champion User shall be proactive in:
- 19.1.1 reporting all IT errors to NICE
 - 19.1.2 informing NICE of all concerns with the general format of the Database as and when they arise or are identified by Users
- 19.2 The Secretary of State for Health shall procure that NICE on behalf of the O&GC may from time to time contact You through Your 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.
- 19.3 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

- 19.4 Any notice required to be given for the purposes of this Agreement shall be given in writing by sending the notice by either by email, prepaid first class post, recorded delivery, or by delivering it by hand.
- 19.5 Any notice sent by email shall be deemed to have been served on the next business day following sending. All notices sent by email shall be confirmed by sending a written notice by post or hand.
- 19.6 Any notice sent by first class post or recorded delivery shall be deemed to have been served two (2) business days after posting.
- 19.7 Any notice delivered by hand shall be deemed to have been served on the same day if received before 12 noon on a business day, or on the next business day if received after 12 noon.
- 19.8 Notwithstanding the provisions in this Clause 19 regarding notices, the parties may communicate by email and by telephone on non-contractual matters.
- 19.9 For the avoidance of doubt, nothing in this Clause 19 is intended to prevent You from contacting O&GC directly to discuss aspects of this Agreement, or from preventing either You or Us from applying to a court for determination of issues, however We and You agree and acknowledge that both parties are encouraged to seek to resolve disputes informally via the O&GC.

20. CONTRACTS (RIGHTS OF THIRD PARTIES) ACT 1999

- 20.1 Save as agreed in this Contract a person who is not a Party to this Agreement has no right under the Contracts (Rights of Third Parties) Act 1999 to enforce or enjoy the benefit of any terms of this Agreement.

21. JURISDICTION AND GOVERNING LAW

- 21.1 This Agreement shall be governed by and construed in accordance with English law and the parties submit to the exclusive jurisdiction of the English courts in respect of any proceedings issued by either party in connection with this Agreement.

**This agreement is SIGNED
for and on behalf of
the Secretary of State for Health
by:**

**SIGNED for and on behalf of
YOUR COMPANY**

.....
by:

Name:

Name:

Job Title:

Job Title:

Date:

Date:

SAMPLE

SAMPLE

**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: CATHERINE WHITE, BUSINESS MANAGER, UK PHARMA SCAN, NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE, LEVEL 1A, CITY TOWER, PICCADILLY PLAZA, MANCHESTER, M1 4BDUK. IF YOU HAVE ANY QUESTIONS, PLEASE PHONE THE UK PHARMA SCAN HELPDESK NUMBER 0845 003 9183.

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 & Clinical Excellence NHS Evidence 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 :
- v. has a legitimate and clearly stated purpose for evaluating medicines

- vi. is responsible for providing the NHS (or parts of the NHS) with information on new medicines
- vii. has:
 - o a proven track record in critically evaluating new medicines
 - o evidence synthesis skills and the ability to synthesise information into a fair, accurate and balanced summary
 - o a proven track record in presenting data in a user friendly format; and
 - o multi-disciplinary expertise within the group, or as a minimum outputs which are subject to multidisciplinary peer review with incorporation of appropriate comments.
- viii. has, where appropriate:
 - o policies and processes in place for liaising with manufacturers during compilation of their evaluations; and
 - o 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.

SAMPLE

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: National Horizon Scanning Centre, National Prescribing Centre, All Wales Medicines Strategy Group, NHS Quality Improvement Scotland (Scottish Medicines Consortium), “UKMi” (The United Kingdom Medicines Information Group) and The National Institute for Health and Clinical Excellence “NICE”;

“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	SIGNED for and on behalf of YOUR ORGANISATION
by: by:
Name:	Name:
Job Title:	Job Title:
Date:	Date:

SAMPLE