



## MHRA Portal Terms and Conditions

MHRA website includes an internet-based hosted platform designed to enable pharmaceutical companies to carry out business with MHRA electronically through a central hub (“**MHRA Portal**”). A “**Digital Workspace**” is a portion of MHRA Portal that has been specially configured for a company so that certain companies can conduct their business with MHRA in a secure electronic environment.

Use of MHRA Portal is governed by the following terms and conditions (“**Terms and Conditions**”):

MHRA grants the company, its Portal Group, administrators and authorised users (as set out on MHRA Portal Registration Form) a non-exclusive, non-sublicensable, revocable, non-transferable, limited right and licence (the “**Licence**”) to access MHRA Portal and the Digital Workspaces in order to participate in the business being conducted through those Digital Workspaces subject to these Terms and Conditions. The company agrees and represents that it shall only, and that it shall procure that its Portal Group, administrators and authorised users will only, access and/or use Digital Workspaces and/or other resources on MHRA Portal to which it has been granted authorised access in accordance with these Terms and Conditions.

If at any time the company wishes one (1) or more sets of up to five (5) additional users to have access to MHRA Portal, it may notify MHRA using a user administration form, which is available on MHRA Portal. On receipt of such notice, MHRA shall invoice the amount of £1,000 (excluding VAT) per set of up to five (5) additional users to the company and shall grant such additional users access to MHRA Portal and the Licence shall be deemed to have been extended to such users for the period of one (1) year from the date on which MHRA provides such access. Unless the company notifies MHRA otherwise in advance (in which case any invoice amount will be revised accordingly), MHRA will automatically invoice the company at the end of the one (1) year period referred to in this paragraph and, unless the company notifies MHRA otherwise in advance (in which case any invoice amount will be revised accordingly), annually thereafter, for a further one (1) year's worth of access to MHRA Portal for the number of its additional users (where applicable) that have previously been granted access to MHRA Portal and, upon receipt by MHRA of such amounts, the Licence shall be deemed to have been extended accordingly.

The company understands and agrees that the Licence and the information provided to it by MHRA to access MHRA Portal are only granted to the company for its (including its Portal Group's, administrators' and authorised users') use of MHRA Portal. The company agrees to take all reasonable and prudent steps not to let any other person learn or use the information provided to it by MHRA to access MHRA Portal except MHRA's customer support staff as necessary.

**Specific attention is drawn to the notice concerning copyright, the limitations/exclusions of liability and the Privacy Statement.**

MHRA makes every attempt to ensure the accuracy and reliability of the information stored, served and accessed by using MHRA Portal.

Nothing in these Terms and Conditions will limit MHRA's liability for death or personal injury caused by its negligence, fraud or for any other type of liability that cannot be limited by law. MHRA, its employees, subcontractors, licensors and agents will not be responsible to the company or any other third party for any loss, however arising, from the use of, or reliance on this information, including but not limited to miscommunications or any errors. MHRA, its employees, subcontractors, licensors, and agents will not be liable for any special, incidental, indirect or consequential damages of any kind, or for any loss of use, data or profits, however those damages may arise and even if the parties had been informed of the possibility of the same.

MHRA Portal is provided "**as is**" without warranty of any kind, either expressed or implied, to the extent permitted by law. The company should not presume that the information displayed is error-free or that it will be suitable for any particular purpose.

MHRA does not guarantee or represent that the content and/or facilities available or accessible via the Portal will always be accurate, complete or current or that access to MHRA Portal will be uninterrupted.

MHRA assumes no responsibility for errors or omissions in any publications and services, or other documents, which may be referenced in, or linked to, MHRA Portal.

MHRA may at any time revise these Terms and Conditions by posting a revised version of these Terms and Conditions on MHRA Portal and the company agrees to be bound by all such revisions from the date they are posted.

#### **Data licence**

Solely for the purpose of MHRA supplying access to MHRA Portal, the company grants to MHRA a non-exclusive licence to use all data inputted by the company, its Portal Group, administrators and authorised users.

#### **Data capacity**

The company understands and agrees that the total amount of data memory at its disposal is one 0.2 gigabytes per user (the "**data capacity**"), save that, if the company purchases the right for any sets of up to five additional users to access MHRA Portal, the data capacity shall be increased by 0.2 gigabytes per additional user for one (1) year from the date on which such users are granted access to MHRA Portal. MHRA shall use its reasonable endeavours to notify the company as soon as reasonably practicable when the company is close to exceeding the data capacity. If the company exceeds the data capacity, irrespective of whether it has been notified in accordance with this paragraph, it agrees to be charged an administration fee of £200 and any excess data charges imposed on MHRA as a direct result of the company exceeding the data capacity. The company agrees that any amounts charged to it under this paragraph are a reasonable pre-estimate of loss arising in the event of it exceeding the data capacity and are not a penalty.

#### **Virus protection**

Though MHRA makes every reasonable effort to check and test material at all stages of production, it is always wise for the company to run an anti-virus program on all material downloaded from the Internet. MHRA cannot and does not accept any responsibility for any loss, disruption or damage to the company's (including its Portal Group's, administrators' and authorised users') data or computer system which may occur whilst using material derived from using MHRA Portal.

## **Privacy and Data Protection**

MHRA is a Data Controller as defined in the Data Protection Act 1998 (the “**Data Protection Act**”). The information received from the company (including in respect of its Portal Group, administrators and authorised users) is held by MHRA to enable the information to be used for any of MHRA's functions.

MHRA may get information about the company (including in respect of its Portal Group, administrators and authorised users) from others or MHRA may give information to them. If MHRA does so, it will only be as the law (including the Data Protection Act) permits, including to:

- check accuracy of information;
- prevent or detect crime; and/or
- protect public funds.

## **Confidentiality and security**

MHRA has a legal duty to protect the confidentiality of user information. MHRA takes every precaution to protect any information submitted via MHRA Portal, in accordance with legislation such as the Data Protection Act. Any data, which MHRA uses in its offices, is protected in accordance with Government standards.

Throughout the registration process, and also when the company is submitting information, any information received by MHRA is encrypted to protect confidentiality, and protected according to industry best practice. The company understands and agrees that it needs to have Microsoft Internet Explorer 5.0 or Netscape 7.1 (or, in each case, a later version) and to have 128 bit (or higher) encryption installed on the computer systems it uses to access MHRA Portal and Digital Workspaces for the information submitted by it to be successfully encrypted by MHRA.

## **Copyright**

© Crown copyright 2005

The material featured on MHRA Portal may either be subject to (i) a separate licence entered into by MHRA or (ii) Crown copyright protection.

The Crown copyright protected material (other than the departmental or agency logos) may not be reproduced in any format or medium without prior permission from MHRA. Authorisation to reproduce material which is not Crown copyright material must be obtained from the copyright holders or legal owners concerned. Crown copyright authority is delegated to MHRA. For further information on Crown copyright policy and licensing arrangements, see the guidance featured on Office of Public Sector Information's website at <http://www.opsi.gov.uk>.

## **Monitoring of e-mail**

MHRA may monitor electronic communications with MHRA (this includes any member of MHRA's staff). Any such monitoring will take place in accordance with the law.

## **Additional Digital Workspaces**

The company may request that an additional Digital Workspace be created for it at a cost of £500 (excluding VAT).

## **Registration**

To use MHRA Portal, the company must first complete MHRA Portal Registration Form.

The administrators named in MHRA Portal Registration Form (or such other individuals notified by the company to MHRA with reasonable notice of the changes required) are responsible on the company's behalf for providing and receiving all notices in respect of these Terms and Conditions, and for ensuring that the company and its authorised users comply with these Terms and Conditions.

### **Cookies**

A cookie is a piece of data stored locally on a user's computer and contains information about a user's activities on the Internet. Session cookies are used within MHRA Portal to identify a user within a session. A cookie is created upon successful user logon and is used to identify that same user whilst they are using MHRA Portal. The session cookies do not store any persistent information (no usernames or passwords are held). When the user logs off the cookie is destroyed.

### **Log Files**

When the company (including its Portal Group, administrators and authorised users) uses the Internet, it is assigned a unique address, known as an IP Address. MHRA uses IP Addresses to analyse trends, to administer MHRA Portal, track users' movements, and gather statistical information. IP addresses are not linked to personally identifiable information.

### **Links**

MHRA Portal may contain links to other sites, mainly those of other government departments, but also to those of third parties. MHRA is not responsible for the privacy practices within any of these other sites. MHRA encourages the company (including its Portal Group, administrators and authorised users) to be aware of this when using these links to leave MHRA Portal and to read the privacy statements on other websites which collect personally identifiable information. This privacy statement applies solely to information collected on MHRA Portal.

### **Support**

MHRA shall provide support in respect of MHRA Portal to the company, its Portal Group, administrators and authorised users during normal MHRA working hours on Monday to Friday (other than on bank holidays or privilege days). Contact details for accessing MHRA support are available on MHRA Portal.

### **Governing Law and Jurisdiction**

These Terms and Conditions are governed by and construed in accordance with the laws of England and Wales. The courts of England and Wales shall have exclusive jurisdiction over disputes between a company and MHRA arising out of the access or use of MHRA Portal. Omission by MHRA to exercise any right under these Terms and Conditions will not constitute a waiver of such right unless expressly stated by MHRA in writing.

BY ACCEPTING THESE TERMS AND CONDITIONS, THE COMPANY ACKNOWLEDGES THAT IT HAS READ THE TERMS AND CONDITIONS, UNDERSTOOD THEM AND AGREES TO BE BOUND BY THEM.

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### **For and on behalf of the Company**

**Full name of the Company (e.g. XYZ Limited):**

**Name of signatory:**

**Title:**

**Date:**