

**Use this form to register your organisation to use MHRA Portal or RamaXL.**

I am an existing subscriber of:

Note: Fields marked '\*' are mandatory

MHRA Portal

RamaXL Product Licensing

I wish to apply for:

MHRA Portal Account  State the number of additional user bundles you require (one bundle is equal to five users) \* :

RamaXL Product Licensing  State the number of additional user bundles you require (one bundle is equal to five users) \* :

## Section 1: Organisation and Director Information

### 1.1 Director Details

**Enter organisation director's personal details in the fields below:**

Title \* :

Forename \* :

Middle Name:

Surname \* :

**Enter organisation director's residential address in the fields below:**

Address Line 1 \* :

Address Line 2:

Address Line 3:

City \* :

County / State:

Postcode / Zip \* :

Country \* :

Residential Tel \* :

**Enter details for a referee from your organisation:**

Referee's Full Name \* :

Contact Telephone No \* :

## 1.2 Organisation Details

**Enter the organisation name and department for which the director represents:**

Organisation Name \* :

Division / Department \* :

**Enter the registered address of the organisation:**

Address Line 1 \* :

Address Line 2:

Address Line 3:

City \* :

County / State:

Postcode / Zip \* :

Country:

Company Registration No \* :

**Enter director's business address if different to above:**

Address Line 1:

Address Line 2:

Address Line 3:

City:

County / State:

Postcode / Zip:

Country:

Tel \* :

Fax:

Email \* :

## Section 2: Organisation Administrator Information

(Organisation administrators are able to add and remove other users from MHRA Portal and RamaXL)

### 2.1 Administrator 1

**Please enter personal details for administrator 1:**

Title * :	<input type="text"/>
Forename * :	<input type="text"/>
Middle Name:	<input type="text"/>
Surname * :	<input type="text"/>
Business Tel * :	<input type="text"/>
Business Fax:	<input type="text"/>
Business Email * :	<input type="text"/>
Employee No.	<input type="text"/>

**Please enter business address for administrator 1 if different from section 1.2:**

Address Line 1:	<input type="text"/>
Address Line 2:	<input type="text"/>
Address Line 3:	<input type="text"/>
City:	<input type="text"/>
County / State:	<input type="text"/>
Postcode / Zip:	<input type="text"/>
Country:	<input type="text"/>

## 2.2 Administrator 2

### Please enter personal details for administrator 2:

Title * :	<input type="text"/>
Forename * :	<input type="text"/>
Middle Name:	<input type="text"/>
Surname * :	<input type="text"/>
Business Tel * :	<input type="text"/>
Business Fax:	<input type="text"/>
Business Email * :	<input type="text"/>
Employee No.	<input type="text"/>

### Please enter business address for administrator 2 if different from section 1.2:

Address Line 1:	<input type="text"/>
Address Line 2:	<input type="text"/>
Address Line 3:	<input type="text"/>
City:	<input type="text"/>
County / State:	<input type="text"/>
Postcode / Zip:	<input type="text"/>
Country:	<input type="text"/>

### Section 3: Inter-Company Information

The information you provide below will help MHRA to configure MHRA Portal and RamaXL correctly for your organisation.

Are you aware of a group of companies that your company is a member of?

Yes

No

If the answer to the above question was "Yes" please state your parent company name:

Please add any further information relevant to your application in the box provided below:

### Section 4: Form Submission

Click the button below to generate a reference number for your application, the reference number will be sent to you by email:

**Note:** Please note that if you save this form and then reopen it, you will need to generate the reference number again and enter the new reference number into the field below.

Enter your reference number below:

Reference number:

I accept MHRA Portal [Terms and Conditions](#)

## 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 the 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 MHRA 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 the 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 standard.

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.

## **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.

## **Additional Digital Workspaces**

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

## **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 the 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:**

## MHRA RamaXL Terms and Conditions

Use of RamaXL is governed by both the terms and conditions applicable to MHRA Portal (the “**MHRA Portal**”) (the “**Portal Terms and Conditions**”) and the terms and conditions set out below (“**RamaXL Terms and Conditions**”). In the event of any inconsistency between MHRA Portal Terms and Conditions and the RamaXL Terms and Conditions, the RamaXL Terms and Conditions shall apply to the extent of such inconsistency.

In consideration of the payment by the company of a registration fee of £7,750, and an annual fee of £15,500 (excluding VAT), MHRA grants the company, its Portal Group (as set out on MHRA Portal Registration Form unless the company notifies MHRA otherwise) (“**RamaXL Group**”), administrators and authorised users a non-exclusive, non-sublicensable, revocable, non-transferable, limited right and licence (the “**Licence**”) to access RamaXL for the period of one (1) year from the date of these RamaXL Terms and Conditions subject to these RamaXL Terms and Conditions.

If at any time the company wishes one or more sets of up to five (5) additional users to have access to RamaXL, 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 £6,700 (excluding VAT) to the company per set of five (5) additional users. On receipt of the relevant payment amount, MHRA shall provide access to RamaXL to the additional users and the Licence shall be deemed to have been extended to such users. 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 the second paragraph of these RamaXL Terms and Conditions and, unless the company notifies MHRA otherwise in advance, annually thereafter, for the annual fee; and
- at the end of the one (1) year period referred to in the third paragraph of these RamaXL Terms and Conditions 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 RamaXL for the number of its additional users (where applicable) that have previously been granted access to RamaXL,

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 the MHRA to access RamaXL are only granted to the company for its (including its RamaXL Group's, administrators' and authorised users') use of RamaXL. 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 RamaXL except MHRA's customer support staff as necessary.

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

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

Nothing in these RamaXL 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.

RamaXL 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 RamaXL will always be accurate, complete or current or that access to RamaXL 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, RamaXL.

MHRA may at any time revise these RamaXL Terms and Conditions by posting a revised version of these RamaXL Terms and Conditions on MHRA Portal.

### **Data licence**

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### **Virus protection**

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### **Confidentiality**

The parties agree that, while these RamaXL Terms and Conditions are in effect and after these RamaXL Terms and Conditions expire or are terminated for any reason, each party will keep in strict confidence the information about the affairs, businesses, or operating methods that it holds pertaining to the other ("**Confidential Information**"). Except with the prior written authorisation of the other party, neither party may use or disclose any Confidential Information at any time to any person. Both parties agree not to copy or transcribe Confidential Information.

This clause does not apply to the Confidential Information listed below:

- Confidential Information that is, at the date when it is provided from one party to the other, already in the public domain or in the category of common knowledge;
- Confidential Information that is in the public domain other than as a result of a breach of these RamaXL Terms and Conditions;
- Confidential Information provided by any third party to a party, in respect of which Confidential Information the said third party has no express or implicit confidentiality obligations; and/or
- Confidential Information that is required by any applicable law or regulation to be disclosed to any institution or organisation.

### **Restrictions on use of data obtained by using RamaXL**

The company shall not, and shall procure that its RamaXL Group, administrators and authorised users will not, without the prior written consent of MHRA:

- (A) merge, interface or combine the whole or any part of the data accessed using RamaXL with any other data other than within its RamaXL Group;
- (B) assign, transfer, distribute, sell, lease, rent, sub-license, charge or otherwise deal in or encumber the whole or any part of the data accessed using RamaXL; or
- (C) use the whole or any part of the data accessed using RamaXL on behalf of, or download any such data to, or make any of it available to any third party (except as permitted by these RamaXL Terms and Conditions) outside of its RamaXL Group.

## Copyright

© Crown copyright 2005

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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>.

## Support

MHRA shall provide support in respect of RamaXL to the company, its RamaXL 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 RamaXL 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 RamaXL. Omission by MHRA to exercise any right under these RamaXL Terms and Conditions will not constitute a waiver of such right unless expressly stated by MHRA in writing.

BY ACCEPTING THESE RAMAXL TERMS AND CONDITIONS, THE COMPANY ACKNOWLEDGES THAT IT HAS READ THESE RAMAXL 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:**

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