

Supplemental Privacy Notice

Introduction

We, the University of Glasgow, are contacting you because you have been a participant in the IRONMAN Study (the “**Study**”), which was co-sponsored by us, the University of Glasgow and Greater Glasgow Health Board (commonly known as NHS Greater Glasgow and Clyde). As part of this Study, information about you was collected and processed by the University of Glasgow and NHS Greater Glasgow & Clyde as joint data controllers.

We have previously let you know about how your information was used in the conduct of the Study in the Study documentation, including the privacy information available on the IRONMAN Study website <https://www.ironmanstudy.co.uk>.

We now wish to inform you about a new use of certain information about you that forms part of the results of the Study.

Data sharing with Pharmacosmos A/S

Pharmacosmos A/S, located at Roervangsvej 30, DK-4300 Holbaek, Denmark (“**Pharmacosmos**”) is a pharmaceutical company, which produces Monofer®, the iron preparation used in the Study. Pharmacosmos wishes to use clinical data generated in the Study to develop and seek authorisation for new treatments for patients.

We have agreed to share the necessary clinical data with Pharmacosmos for this purpose.

What personal information will be shared?

Pharmacosmos will receive certain information relating to your state of health that is contained in the clinical data. This includes information created in the course of the Study and may also include medical information from your NHS records which we obtained in the conduct of the Study.

The information being shared with Pharmacosmos is in what is known as “pseudonymised” form, which means that it will not, on its own, allow Pharmacosmos to identify you directly. Please note that Pharmacosmos will not have access to your name, address, telephone number, email address, date of birth or NHS or Community Health Index number.

What will Pharmacosmos do with your information?

Pharmacosmos will only use your pseudonymised information for the following purposes:

- (i) analysis of the Study results and submission of the results to the competent regulatory authorities for the authorisation of medicinal products in the European Union (“EU”), the United States of America (the “US”) and other countries; and
- (ii) the development of medicinal products and seeking regulatory approval for placing new treatments for patients on the market.

Pharmacosmos will be a separate data controller of your personal information for these purposes, and will process it in strict compliance with the requirements of applicable data protection laws, including the requirement to keep your information secure and confidential. The information will be pseudonymised at all times, as well as being encrypted and/or otherwise protected when stored in secure databases or transferred using secure channels.

Who will Pharmacosmos share your information with?

As mentioned above, Pharmacosmos will review and analyse the clinical data and may use it in regulatory submissions to the European Medicines Agency (“EMA”), the competent regulatory authority in the EU, the U.S. Food and Drug Administration (“FDA”) and equivalent regulatory authorities in other countries.

Pharmacosmos will only ever hold information about you in pseudonymised form and so will provide pseudonymised information to the regulatory authorities.

The regulatory authorities may as part of their processes, conduct an inspection of University of Glasgow and NHS Greater Glasgow & Clyde to ensure that the IRONMAN Study was conducted in a compliant manner. This is as noted in the existing Study information (noted in the Study information (<https://www.ironmanstudy.co.uk>). As part of such inspection, the regulatory authorities may review the clinical data held by the University of Glasgow and/or NHS Greater Glasgow & Clyde in more detail, including accessing identifiable personal information relating to you.

The regulatory authorities are bound by strict professional secrecy obligations and will not disclose any of your personal data to third parties.

Pharmacosmos may also share the clinical data with other third parties in connection with its regulatory submissions, such as with regulatory consultants working with Pharmacosmos. Any such sharing will be governed by strict processing agreements in strict compliance with applicable data protection laws.

Pharmacosmos will not, in any event, make public the pseudonymised personal information with which it is provided nor share it with any other third parties, save as explained above.

Legal basis for sharing your information with Pharmacosmos

Under the UK General Data Protection Regulation (UK GDPR), we are using the following legal bases for the sharing your personal information with Pharmacosmos:

- Article 6(1)(f) that it is in legitimate interests of Pharmacosmos to seek regulatory approval for new treatments for patients; and
- Article 9(2)(i) (for special category information such as information relating to your health) processing is necessary for reasons of public interest in the area of public health, such as ensuring high standards of quality and safety of medicinal products.

The lawful bases that Pharmacosmos will rely on for processing your pseudonymised personal information are:

- Article 6(1)(f) that it is in legitimate interests of Pharmacosmos to seek regulatory approval for new treatments for patients; and
- Article 9(2)(i) (for special category information such as information relating to your health) processing is necessary for reasons of public interest in the area of public health, such as ensuring high standards of quality and safety of medicinal products.

How long will Pharmacosmos keep your information for?

Pharmacosmos will keep the clinical data that contains your pseudonymised personal information for as long as it is necessary to do so for the purposes of development, regulatory submissions and approval of new treatments in the EU, the US and other countries and for compliance with regulatory and legal obligations.

The applicable laws in the various jurisdictions may require Pharmacosmos to retain the clinical data, for as long as any treatments authorised using the clinical data are available and used to treat patients, as well as for an additional period afterwards.

Transfers outside the UK

Your pseudonymised information will be transferred to Denmark where Pharmacosmos is based. Denmark is part of the European Union, which the UK government considers to offer adequate protection to your personal information.

Pharmacosmos may also transfer your pseudonymised information to the US and/or to other countries where different data protection laws apply. These laws may not ordinarily offer the same protection of your personal information as the UK, but Pharmacosmos will make such transfers in strict compliance with all applicable data protection laws, including the UK GDPR using transfer mechanisms required by law and ensuring, at all times, the confidentiality and security of the clinical data.

What are your rights?*

You have the following rights in relation to your personal information:

- you can request access to the information we process about you at any time;
- if at any point you believe that the information we process relating to you is incorrect, you can request to see this information and may in some instances request to have it restricted, corrected or erased; and
- you have the right to object to the processing, however this is not an absolute right and will not be upheld if we can demonstrate compelling legitimate grounds for processing your personal information, like patient safety or for evidence to support legal claims.

If you wish to exercise any of these rights, please submit your request via the webform or contact dp@ gla.ac.uk.

You also have the right to complain to the ICO if you are unhappy with how we have used your information.

The ICO's address:

Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

Helpline number: 0303 123 1113

ICO website: <https://www.ico.org.uk>

The Data Protection Manager at Pharmacosmos can be contacted at:
dataprotection@pharmacosmos.com

For more details about Pharmacosmos' privacy policies please see:
<https://www.pharmacosmos.com/contact-us/privacy-notices>