Medicines & Healthcare products Regulatory Agency

Data Protection and Privacy Information

1. Introduction

You can read the <u>MHRA Privacy Notice</u> to find out in general terms the types of personal data we process and why; as well as information about your rights and how to raise concerns.

This privacy notice sets out the approach to the Innovative Devices Access Pathway (IDAP) that the MHRA will take to handle information appropriately and to comply with data protection legislation.

This privacy notice covers documents gathered and created during this consultation and anything in which information of any description is recorded, whether in paper or electronic form.

2. Legal requirements for information management and privacy

The IDAP complies with data protection legislation including the Data Protection Act 2018 and the UK General Data Protection Regulation (UK GDPR).

We rely on UK GDPR Article 6(1)(a) as our legal basis for processing your personal data. This allows us to process personal data as you have given consent to the processing of your personal data for the outlined purposes.

3. Lawful basis and purpose of processing personal information

The IDAP form will collect and use personal information for the purpose of identifying who the application belongs to and to contact this individual regarding IDAP pilot activities.

Individuals whose personal information is held by the MHRA for purposes of the IDAP have given their consent to use their information for the purpose of the

application. In the case of personal information, the purpose is to identify who the application belongs to and contact this individual regarding IDAP pilot activities.

There will be no other use of personal information.

4. Security and confidentiality

The IDAP Delivery Group will have access to data submitted in the application form for the purpose of selecting technologies for the IDAP pilot. This group consists of representatives from Health Technology Wales, the Department of Health and Social Care, the Medicines and Healthcare products Regulatory Agency, the National Health Service England, the National Institute for health and Care Excellence, and Scottish Health Technologies Group as well as Patient and Public Representatives. The MHRA IDAP Operations manager will ensure access is kept up to date by restricting access to the application form on a secure shared digital platform.

Those who have access are aware of their obligations and responsibilities when handling personal and confidential information. They are subject to employment, contractual and other professional obligations regarding confidential and official information, both during the IDAP process and afterwards.

The information that you enter on this form will be held on a secure shared digital platform.

All personal and confidential information is stored securely to prevent loss or inappropriate access.

5. Sharing information

The MHRA will hold the personal information you provide in this form and use it for the purpose of identifying who the application belongs to and to contact this individual regarding IDAP pilot activities.

Information will be shared with the following partners through a secure shared digital platform.

• Health Technology Wales,

- the Department of Health and Social Care,
- the Medicines and Healthcare products Regulatory Agency,
- the National Health Service England,
- the National Institute for health and Care Excellence,
- and Scottish Health Technologies Group
- Patient and Public Representatives on the IDAP Delivery Group
- External Clinical Experts

If any new partner is identified, we will contact yourself to inform you of this and check that you are happy for information to be shared with them.

We do not intend to share your personal data with any other third party other than our data processors who act only upon our instructions. We will handle any specific requests from a third party for us to share your personal data with them in accordance with data protection law. We will not sell your personal data.

Information from the IDAP process, including personal information, may be disclosed in accordance with the access to information regimes. These are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (DPA), the UK General Data Protection Regulation 2016 (GDPR) and the Environmental Information Regulations 2004.

The MHRA will process your personal data in accordance with the DPA and UK GDPR and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

The partners will adhere to relevant institutional confidentiality and non-disclosure agreements.

6. Retention and destruction of documents

Information will be held by the MHRA for 15 years. Other partners in the IDAP do not store information.

7. Rights

You have several rights which are outlined in the MHRA Privacy Notice: https://www.gov.uk/government/publications/mhra-privacy-notice. For greater detail on when they apply please refer to the <u>Information Commissioner's website</u> If you wish to exercise any of your rights, or have any questions or concerns, please contact our Data Protection Officer at <u>dataprotection@mhra.gov.uk</u>.