

**PV-related personal data**

|                     | <b>Data collected by the organisation</b>                                      | <b>Source of data</b>      | <b>Why data is processed</b>  | <b>Legal basis of processing</b>  | <b>Where data is stored</b>                                       | <b>Retention period</b>                                    | <b>Deletion/destruction arrangements</b>   | <b>Recipients of data</b>  |
|---------------------|--|----------------------------|---|---|---|--|--|----------------------------|
| Contact information | Patient's Name<br>Address<br>Telephone number<br>Fax number<br>Email address   | Reporter of adverse effect | To fulfil the data controller's legal obligation to collect, manage and report suspected adverse reactions associated with medicinal products | Article 6 (1) (c) - processing is necessary for compliance with a legal obligation to which the controller is subject | In individual files (in hard copy or electronic format, or both). | 10 years from end of calendar year in which report is made | Personal data will be deleted from live electronic systems and hard copies shredded at the end of the retention period.<br><br>Backup emails will be retained for 12 years before deletion and backups of all other electronic information will be destroyed after 30 days | Pharmacovigilance provider |
|                     | Reporter's: Name<br>Address<br>Telephone number<br>Fax number<br>Email address | Reporter of adverse effect | To fulfil the data controller's legal obligation to collect, manage and report suspected adverse reactions associated with medicinal products | Article 6 (1) (c) - processing is necessary for compliance with a legal obligation to which the controller is subject | In individual files (in hard copy or electronic format, or both). | 10 years from end of calendar year in which report is made | Personal data will be deleted from live electronic systems and hard copies shredded at the end of the retention period.<br><br>Backup emails will be retained for 12 years before deletion and backups of all other electronic information will be destroyed after 30 days | Pharmacovigilance provider |

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|                           | Healthcare professional's:<br>Name<br>Address<br>Telephone number<br>Fax number<br>Email address<br>Profession | Reporter of adverse effect | To assist with the data controller's legal obligation to collect, manage and report suspected adverse reactions associated with medicinal products | Article 6 (1) (f) - processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child. | In individual files (in hard copy or electronic format, or both). | 10 years from end of calendar year in which report is made | Personal data will be deleted from live electronic systems and hard copies shredded at the end of the retention period.<br><br>Backup emails will be retained for 12 years before deletion and backups of all other electronic information will be destroyed after 30 days | Pharmacovigilance provider |
| Other patient identifiers | Gender<br>Age<br>Medical record number   | Reporter of adverse effect | To fulfil the data controller's legal obligation to collect, manage and report suspected adverse reactions associated with medicinal products      | Article 6 (1) (c) - processing is necessary for compliance with a legal obligation to which the controller is subject  | In individual files (in hard copy or electronic format, or both). | 10 years from end of calendar year in which report is made | Personal data will be deleted from live electronic systems and hard copies shredded at the end of the retention period.<br><br>Backup emails will be retained for 12 years before deletion and backups of all other electronic information will be destroyed after 30 days | Pharmacovigilance provider |

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| <p>Health information</p> | <p>Pregnancy status (if applicable)</p> <p>Product information (strength, form dosage)</p> <p>Information about other medication taken</p> <p>Description of adverse event</p> | <p>Reporter of adverse effect</p> | <p>To fulfil the data controller's legal obligation to collect, manage and report suspected adverse reactions associated with medicinal products</p> | <p>Article 6 (1) (c) - processing is necessary for compliance with a legal obligation to which the controller is subject</p> <p>Article 9 (2) (i) - processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy</p> | <p>In individual files (in hard copy or electronic format, or both).</p> | <p>10 years from end of calendar year in which report is made</p> | <p>Personal data will be deleted from live electronic systems and hard copies shredded at the end of the retention period.</p> <p>Backup emails will be retained for 12 years before deletion and backups of all other electronic information will be destroyed after 30 days</p> | <p>Pharmacovigilance provider</p> <p>Medicines and Healthcare products Regulatory Authority (MHRA) but personal data is anonymised so that neither the reporter nor the patient can be identified.</p> |
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