

关于不良反应相关个人信息出境告知授权书

Notification and Authorization Letter for Cross-border Transfer of Personal Information Related to Adverse Reactions

为确保药品生产企业对药物上市后安全性的监测，我们（个人信息处理者：美纳里尼国际贸易（上海）有限公司）可能会将您在 400-880-5906 热线中向我们提供的个人信息向境外传输。为保护您的个人信息权益，我们准备了如下特别说明，供您参考。对重点内容，我们采用“**加粗**”的书写方式进行提示，希望您在阅读时特别关注。此外，在您向我们提供您的任何敏感个人信息前，您已慎重考虑并在此确认该等提供是适当的。

To ensure the post-marketing safety monitoring of pharmaceutical products by the pharmaceutical manufacturer, we (the Personal Information Processor: Menarini International Trading (Shanghai) Co., Ltd.) may transfer the personal information you provide to us via the 400-880-5906 hotline to locations outside the territory of the People's Republic of China. To protect your rights and interests regarding your personal information, we have prepared the following special instructions for your reference. For key content, we have used "**bold**" formatting for emphasis and request that you pay special attention to these parts when reading. Furthermore, before providing any of your sensitive personal information to us, you have carefully considered and hereby confirm that such provision is appropriate.

境外接收方 / Overseas Recipient: A. Menarini Asia-Pacific Holdings Pte. Ltd.

联系方式 / Contact Information: 电子邮箱 / Email: privacy@menariniapac.com

处理目的 / Purpose of Processing: 我们作为个人信息处理者需要将境内发生的个例不良反应发给境外接收方做医学评估（如不良反应严重性、和药物的相关性、是否是说明书中列出的不良反应等）。

As the personal information processor, we need to transmit Individual Case Safety Reports (ICSRs) occurring within the territory to the overseas recipient for medical assessment (e.g., seriousness of the adverse reaction, causality with the drug, whether it is an adverse reaction listed in the package insert, etc.).

处理方式 / Method of Processing: 通过 400 热线的电话收集不良反应数据，由我们的员工通过邮箱发送电子邮件传输至给境外接收方。境外接收方将对患者的信息进行医学评估，对报告者的信息进行简单的整理，并在实现目的所必须的内存存储前述患者和报告者的个人信息。

Adverse reaction data is collected via the 400 hotline, and our employees transmit this data to the overseas recipient via email. The overseas recipient will conduct a medical assessment of the patient's information, perform a simple collation of the reporter's information, and store the aforementioned personal information of the patient and the reporter for the period necessary to achieve the purpose.

个人信息种类 / Categories of Personal Information

如您为患者，我们将收集并向境外传输您的以下个人信息：

If you are a patient, we will collect and transmit the following personal information of yours to the overseas recipient:

患者姓名拼音首字母缩写 / Patient's name initials (in Pinyin)
患者不良事件发生时的年龄/ Patient's age at the time of the adverse event
患者出生日期/ Patient's date of birth
患者年龄组（是否为成年人） / Patient's age group (whether an adult)
患者性别/ Patient's gender
患者体重/ Patient's weight
患者民族/ Patient's ethnicity
不良事件病例信息，包括/ Adverse event case information, including: 1. 患者/消费者信息/patient/Consumer information 2. 平台处理方式（给到报告不良反应患者的处理方式） /platform handling method (the processing method provided to the patient reporting the adverse reaction) 3. 药物和产品信息（本次不良反应事件相关的药物产品信息） /drug and product information (drug product information related to this adverse reaction event) 4. 病例描述（患者发生不良事件的日期、患者不良事件结束的日期、发生在患者身上的不良事件、对发生在患者身上的不良事件的具体描述、每个发生在患者身上的不良事件的结果、患者的相关既往病史和现病史、患者的相关用药史、获知不良反应事件的日期） /case description (date of onset of the adverse event, date of resolution of the adverse event, the adverse event(s) occurred to the patient, specific description of the adverse event(s), the outcome of each adverse event, relevant past medical history and current medical history, relevant medication history, and the date the adverse reaction event was learned)
反映不良事件病例情况的照片（适用于通过在线聊天或社交媒体或电子商务平台收到的报告） /Photographs reflecting the adverse event case (applicable to reports received through online chat, social media, or e-commerce platforms)

如您为报告者，我们将收集并向境外传输您的以下个人信息：

If you are a reporter, we will collect and transmit the following personal information of yours to the overseas recipient:

报告者是否为医护专业人员，如是，其任职资格/ Whether the reporter is a healthcare professional; if yes, their professional qualifications
报告者名称（若适用）、姓名拼音首字母缩写/ Reporter's organization name (if applicable), name initials (in Pinyin)
报告者国家/ Reporter's country
报告者是否愿意进行随访 / Whether the reporter is willing to participate in follow-ups

报告者对该事件的严重性判断/ The reporter's judgment on the seriousness of the event
报告者信息/ Reporter's information

我们将严格遵守适用的个人信息存储和跨境传输的法律法规，并采取和督促接收您个人信息的第三方采取适当的组织和安全管理措施，保护您的个人信息安全。

We will strictly comply with applicable laws and regulations regarding the storage and cross-border transfer of personal information, and will take, and urge the third parties receiving your personal information to take, appropriate organizational and security management measures to protect the security of your personal information.

如果您有任何疑问，或有意依据法律法规行使个人信息权利（包括但不限于查阅权、修改权、删除权等），您可以联系 privacy@menariniapac.com 进行咨询。

If you have any questions or intend to exercise your personal information rights (including but not limited to the right of access, rectification, deletion, etc.) in accordance with laws and regulations, you may contact privacy@menariniapac.com for consultation.

您已阅读并知悉，如您通过热线电话向我们提供您的个人信息，即表明您授权我们按照本授权书中告知的内容，将您的个人信息传输至中国境外。

You have read and acknowledged that by providing your personal information to us via the hotline, you hereby authorize us to transfer your personal information outside the territory of the People's Republic of China in accordance with the contents notified in this Authorization Letter.