Vigabatrin REMS Program Privacy Policy

Effective Date: 19 May 2017

Descriptive
The term “VPMG” or “us” or “we” refers to the Vigabatrin Product Manufacturers’ Group or its agents, affiliates, and authorized representatives, the owner of the Vigabatrin REMS Program website (www.vigabatrinREMS.com). The term “you” refers to the user or viewer of our website.

Under the Vigabatrin REMS Program or “Program,” only prescribers and pharmacies, certified in the Program are able to prescribe and dispense vigabatrin medicines. Wholesalers/distributors contracted with vigabatrin REMS Sponsors are able to distribute vigabatrin medicines. The website is targeted for their use, access to REMS materials, and enrollment in the Program. Only patients enrolled in the Program by their prescriber are able to receive vigabatrin medicines. Patients may visit the website but will not be entering information into the website. In order to meet the requirements of the Program, the Program must obtain certain Personal Information from you. VPMG and its authorized representatives are committed to protecting your Personal Information.

Please read the following to learn more about our Privacy Policy regarding Personal Information that is collected, used, and shared by the Program and how that information is protected.

What This Privacy Policy Covers

- This Privacy Policy covers how the Program treats personally identifiable information that the Program collects and receives through the Program website, including patients’ health information and the personally identifiable information of patients, prescribers, or Authorized Representatives designated by pharmacies that enroll in the Program.
  - The term “Personal Information” means any information which can be used to identify a person including by way of example, but not limitation, name, date of birth, mailing address, social media and other third party platform account identifiers, home phone number, mobile phone number, e-mail address, credit card information, and/or Social Security number.
  - The term “Health Information” means any information, in any form, related to the past, present, or future health or medical status, condition, or treatment of a person, including, by way of example, but not limitation, names of doctors, health conditions, medicines, and/or prescription information and history.
- The Program provides links to a third-party website AssureSign.com within the Program website. However, the Program exercises no authority over this
linked destination site, which maintains independent privacy and data collection policies and procedures. The Program assumes no responsibility or liability for the independent privacy practices of this destination site. Similarly, the Program cannot take responsibility for the content of this destination site. These destination links are provided only for your convenience, and as such, you access them at your own risk.

**Your Consent**

By using the Program website, you agree to the terms of this Privacy Policy. Whenever you submit Personal Information to us through the Program website, you consent to the collection, use, disclosure, storage, and deletion of that information in accordance with this Privacy Policy, including agreeing that we may contact you through a variety of means such as email, postal mail, phone, or fax. By submitting information to the Program, you are consenting to the Program using and sharing this information for any purpose consistent with the goals of the Program and to effectuate operation and administration of the Program.

**Information Collection and General Use**

- The Program collects Personal Information when you voluntarily choose to contact us with comments or inquiries through the website or choose to use certain areas of the website, including: enrolling in the Program, and visiting [www.vigabatrinREMS.com](http://www.vigabatrinREMS.com).

  - When you enroll in the Program as a Prescriber, we ask for information such as your name, address, phone and fax numbers, email address, NPI number, specialty, degree, and institution name. Once you certify with the Program and sign into our website, you are not anonymous to us. You will be assigned a Prescriber ID number.

  - When you certify in the Program as an Authorized Representative of a Pharmacy, we ask for information such as your name, phone and fax numbers, email address, pharmacy name and address, pharmacy type (inpatient or outpatient), and NPI and NCPDP numbers. Once you provide the information to the Program and sign into our website, you are not anonymous to us. The pharmacy will be assigned a Pharmacy ID number.

  - When a Prescriber enrolls a patient in the Program, we will ask for patient Personal Information such as the patient’s name, e-mail address, address, phone number, and birth date. The patient will be assigned a Patient ID number. Patient written authorization is not required for the Vigabatrin REMS Program to receive this information because this is a FDA mandated program (per 45 CFR 164.512 (b)(1)(iii)).

  - Prior to each dispensing of vigabatrin, the Authorized Representative of a Pharmacy must verify that the Prescriber is certified and that the patient is enrolled in the Vigabatrin REMS Program, and must document all enrolled Prescriber and Patient ID numbers in addition to the authorization code.

- The Program also collects information about your transactions within the Program. Certain visitors to the Program’s website interact with the site in ways that require the Program to collect Personal Information and other
information. The amount and type of information that the Program gathers depends on the nature of the interaction. Those who engage in transactions with the Program—for example, by enrolling patients or conducting Program enrollment verification—are asked to provide additional information, including as necessary the Personal Information required to process those transactions. In each case, the Program collects such information only insofar as is necessary or appropriate to fulfill the purpose of the visitor's interaction with the Program. The Program does not disclose Personal Information other than as described in this Privacy Policy, or otherwise not permitted under law. Visitors to the Program website can always refuse to supply Personal Information, with the caveat that it may prevent them from engaging in certain website-related activities.

- When you visit the Site, and during your interactions with the Site, we may collect Non-Personal Information from you. “Non-Personal Information” means a data element or collection of data elements that by itself cannot ordinarily be associated with a specific individual. Non-Personal Information includes by way of example but not limitation, the Internet browser or computer operating system you are using, your navigation of the Site including the pages of the Site that you access, the amount of time spent on various portions of the Site, the length and dates of your visits to the Site, and certain Site data captured through your interactions with the Site and other sites. Non-Personal Information may include information provided by you through the Site or otherwise (e.g., through a third-party site) that is not Personal Information or Health Information. Certain Non-Personal Information may be collected on an aggregated, anonymous basis through web server logs, cookies, ad servers, tracking pixels, web beacons, and similar Internet tracking devices (collectively “Tracking Mechanisms”). Web servers automatically collect Non-Personal Information, with your IP address, when you request pages of the Site or other sites. Based on certain interactions with the Site, third-party sites, mailings, other communications with us, and/or our system configurations, certain Non-Personal Information may be associated with your Personal Information such that your Non-Personal Information is identifiable with you.
  - You may be able to opt-out of certain third-party associations by following third party customization and/or opt-out options. Google®, Twitter®, and LinkedIn® may provide customization and/or opt-out of certain Tracking Mechanisms through their respective sites. For example, Google’s Ads Settings, DoubleClick opt-out page, Twitter’s promoted content settings, LinkedIn account settings, and Network Advertising Initiative opt-out page may limit the collection and usage of certain third-party Tracking Mechanisms.
  - The collected Non-Personal Information may be used by us and our affiliated companies for a variety of analytic and developmental purposes including to improve and enhance the Site and our products and services, to create new products and services, to customize your experience on the Site and other sites that you visit on the Internet, to
identify and/or offer products, services and website functionality that may be of interest to you, and other legitimate business purposes.

- We may use different kinds of cookies including session ID cookies and persistent cookies. Session ID cookies are used to personalize your user experience, to determine ways to improve the Site, Site content, and the services offered through the Site. These cookies are deleted from your hard drive when you close your browser session. Persistent cookies are used to collect non-personally identifiable information such as Internet Protocol (IP) addresses, browser type, Internet Service Provider (ISP), referring/exit pages, platform type, date/time stamp and number of clicks.

- You may set your browser to accept cookies, warn you when a cookie is sent, or turn off all cookies (except Flash cookies). Check your web browser’s help menu or your mobile device settings to find out how. Some mobile devices store cookies not only in areas connected to the web browsers but also in an app-specific area, so you may have to check your app settings options to determine how to manage or delete cookies stored in these other areas. If you do not accept cookies, some features, services, or activities available through the Site may not function correctly and you may be unable to access certain content.

- We may embed tracking pixels within various pages of the Site to enable use of site analytics. The site analytics enable us to determine the usage frequency of various areas of the Site and identify areas of the Site for enhancement. While you are visiting and after you leave the Site, we may use web beacons to notify you of areas of the Site and other aspects of our organization and its affiliated companies in which you may be interested. Certain tracking pixels and web beacons may be cleared or reset through configuration of your web browser such as by clearing your cache. We may use ad servers to provide you with offers of possible interest.

- We use your IP address so that we can send data (such as the pages you request) to you and collect Non-Personal Information during the process. We aggregate this Non-Personal Information with similar Non-Personal Information collected from other users to track overall visitor traffic patterns and help us understand Site usage and preferred and most frequently used pages, products and services, to provide you with better service, to improve Site use and functionality, and to provide you with information on other products and services that may be of interest to you.

- We may analyze Non-Personal Information in the aggregate to study outcomes, costs, and provider profiles, and to suggest benefit designs for employers or health plans. These studies may generate Aggregate Data (described below) which we may utilize for a variety of purposes.
  - We may perform statistical analyses of the traffic patterns, Site usage, and behaviors associated with the Site. We may use
these analyses to generate Aggregate Data from the original Non-Personal Information. We may combine, separate, aggregate, or otherwise parse and process Non-Personal Information. The parsing and processing of such information may generate Aggregate Data. “Aggregate Data” is summary level data, such as the number of web visitors in a specific geographic area. Aggregate Data does not contain information that can be used to identify or contact you, such as your name, address, telephone number or e-mail address, and does not reflect the original form of the Non-Personal Information collected from you.

- The Program uses your Personal Information to fulfill your requests for information; to verify your enrollment and/or certification in the Program; to assess compliance with the Program; and to contact you on Program-related matters. We use aggregated (non-personally identifiable) information to help us understand trends, website performance, and patient needs. For example, we may analyze the gender or age of visitors to the Program website, and we may use that analysis of aggregated data internally or share aggregated data with others such as companies that sponsor and/or support the Program (i.e., a VPMG company and their trusted partners) and the U.S. Food and Drug Administration (FDA). Any third party that receives aggregated data will agree not to attempt to re-identify the persons to whom it belongs.
- This website does not track users over time and across the third-party website to provide targeted advertising, and therefore does not respond to Do Not Track (DNT) signals. However, some third-party sites do keep track of your browsing activities when they serve you content, which enables them to tailor what they present to you. If you are visiting such sites and do not want to be tracked, please adjust your web browser settings so third parties know you do not want to be tracked.

Information Sharing and Disclosure

- The Program does not sell Personal Information to third parties. We may share your Personal Information with VPMG and selected service providers or consultants acting on our behalf in connection with the Program, or under the below circumstances. These third parties will be required to protect your Personal Information in a manner consistent with this Privacy Policy.
  — We respond to subpoenas, court orders, or legal process, requests for cooperation from law enforcement or other government agencies, to enforce the terms and conditions associated with the Site including this Privacy Policy and the Terms of Use. In such cases, we may raise or waive any legal objection or right available to us.
  — When we believe disclosure is appropriate in connection with efforts to investigate, prevent, or take other action regarding illegal activities, suspected fraud, situations involving potential threats to the physical safety of any person, violations of the Program’s Terms of Use, or as otherwise required by law.
— We may transfer information about you if the Program, a VPMG company, or a business(es) that supports the Program is acquired by or merged with another company and you hereby consent to such transfer.

- The Program does not sell Non-Personal Information to other companies or organizations; however, we may disclose Non-Personal Information as follows:
  — We may share Non-Personal Information with our affiliated companies, third parties who provide services to us, and other parties that you have authorized.
  — We may disclose Aggregate Data to other companies or organizations for any legitimate business purpose.
  — We may disclose products and services developed using the Non-Personal Information, including products and services that disclose anonymous and/or deidentified Site data for any legitimate business purpose.

Analytics
We may use certain in-house or third-party functionality to analyze your communications with us and interactions with the Site. The analysis enables us to monitor the services that we provide so that we can improve the services provided to you. These third parties will be required to protect any Personal Information in a manner consistent with this Privacy Policy. Other analytics capabilities are reflected in the description of Non-Personal Information.

Third Party Usage
We may use third parties to: (a) operate and maintain the server(s) on which the Site operates, (b) provide Tracking Mechanism(s) that we embed in or use with the Site, (c) provide advertisements and other information to you about the Site, products, and services through a third-party site based on a prior visit to the Site, (d) analyze communication with us and interactions with the Site, (e) de-identify data, and (f) collect Non-Personal Information from you (e.g., on your interactions and/or experience with the Site and/or us). The third party may then share the Personal Information, Non-Personal Information, Aggregate Data, and/or other data with us.

Information From Children
The Program is not intended for any user under the age of 13 and we do not knowingly collect Personal Information from children under the age of 13. We request that children under the age of 13 not submit any Personal Information through this website.

Notices and Bulletins
Periodically, we may need to communicate with you regarding the Program and will use Personal Information to send such communications.

Confidentiality and Security
- We take commercially reasonable steps, including appropriate physical, electronic, and administrative safeguards, to protect Personal Information from loss, misuse, and unauthorized access, disclosure, alteration, or
destruction. However, no internet transmission is ever fully secure or error-free. Please keep this in mind when disclosing Personal Information to us or to any other party via the internet.

- We limit access to Personal Information to employees, contractors, and agents who we believe reasonably need to come into contact with that information to in order to do their jobs and to operate the Program.

**Information Retention**

- The Program retains information collected through the Program website for as long as it is necessary to comply with applicable laws, regulations and court orders.
- For ease of use, the Program website temporarily stores some user provided information, such as username and password, until the browser is closed.
- Information transmitted to your facility through the Program website may be stored according to your facility’s privacy policies and procedures. Your facility, not the Program, determines how long that information is retained.

**Visiting Our Website From Outside the United States**

The use and content of our website is intended for U.S. residents only. This Privacy Policy is intended to apply to collection of information from residents of the United States. If you are not a resident of the United States, please be aware that your information may be transferred to, stored, and processed in the United States.

**Changes to This Privacy Policy**

The Program may use Personal Information, Health Information, and Non-Personal Information collected from you pursuant to the Site only within the scope of use described in this Privacy Policy. However, we reserve the right, from time to time in our sole and absolute discretion, to change, to modify, or to add terms or remove terms from this Privacy Policy. Changes to this Privacy Policy will be reflected when we post a new version number and updated revision date. The version number includes a major number, a decimal point, and a minor number. A change to the major number reflects a significant change to the policy, while a change to the minor number reflects a less significant change to the policy. Examples of significant changes include additional provisions that reflect new Site functionality, significant modifications to existing provisions, and more significant changes to Site functionality that cause provisions to be modified, added, or removed. Examples of less significant changes include additional provisions that clarify current Site functionality, minor modifications to existing provisions, and less significant changes to Site functionality that cause provisions to be modified, added, or removed.

We will provide an advance notice of a major change prior to your access of any portion of the Site for which registration is required. For example, we may (i) require that you reaccept the updated version of the web policies, (ii) send an electronic notification advising of the update to the web policies, (iii) include a notice on the Site viewable without login advising of the update to the web policies, and/or (iv) advise of the
updated web policies during a phone call. We do not ordinarily provide advance notice of a minor change.

We recommend that you check the version number and revision date prior to using the Site, and that you review this Privacy Policy on a frequent basis. Your continued use of the Site and/or utilization of any Site benefits after this Privacy Policy has been updated (and after advance notice for a major change) indicates your agreement and acceptance of the updated version of the Privacy Policy.

If you have questions regarding this Privacy Policy, please contact the Vigabatrin REMS Program at 1-866-244-8175.

This site contains medical information that is intended for residents of the United States only and is not meant to substitute for the advice provided by a medical professional. Always consult a physician if you have health concerns. Use and access of this site are subject to the terms and conditions as set out in our Privacy Policy and Terms of Use.

Linking
Our Site may contain hyperlinks allowing our users to connect to other websites owned by us and our affiliated companies and websites owned by our third-party vendors, distributors, and providers ("Linked Sites"). You may also access our Site through a hyperlink embedded in a Linked Site. We provide hyperlinks to the Linked Sites to enable you to conveniently access websites that may be of interest to you. Please note that once you click on a hyperlink that transfers you from our Site to a Linked Site, you have left our Site, and this Privacy Policy will immediately cease to apply to any subsequent activity on the Linked Site. We are under no obligation to notify you when you have left our Site and have accessed a Linked Site. Use of any Linked Site will be governed by the privacy policy, terms of use, and/or other policies (if any) on the Linked Site. You may, at your option, participate in surveys or provide other information to our affiliates that control a Linked Site, and that information may be shared with us or with others subject to the privacy policy terms set forth on that Linked Site. Certain Non-Personal Information that you choose to provide through a Linked Site (such as comments) that is subsequently provided to us by the Linked Site provider in connection with a service engagement may be identifiable to us as your Personal Information.