REGENERON
SCIENCE TO MEDICINE®

POLICY NAME:

114 Adverse Effects & Medical Safety Information

Effective Date: 03/11/08
Revised Date: 09/06/16
Contact:

PURPOSE

Regeneron Pharmaceuticals, Inc. is committed to conducting business in accordance with applicable rules and regulations to ensure regulatory compliance. The purpose of this Policy is to set forth the obligations of Regeneron employees and agents to report any adverse event (AE) or potential AE associated with a Regeneron product within 24 hours of first becoming aware of it. Regeneron's agents include contractors, temporary employees, consultants, and vendors with AE reporting obligations specified in their contract(s) or agreement(s). This Policy applies to marketed products manufactured, marketed, co-marketed and/or sponsored by Regeneron or for which Regeneron is the authorized licensee. Safety information on Regeneron's investigational products should be reported in accordance with study-specific reporting procedure.

SCOPE

This policy applies to all employees of Regeneron.

POLICY

An AE, as the term is used in this Policy, shall be defined broadly and includes any unintended experience associated with the use of a Regeneron product in humans whether or not the event is considered product related. This includes any unanticipated exposures to the Regeneron product, with or without any associated adverse outcome, such as use during pregnancy or breastfeeding, overdose, misuse, abuse, or inappropriate drug administration.

All AEs and potential AEs must be reported to the Regeneron Call Center at **1-844-REGN-MID (1-844-734-6643)** or emailed to MEDICAL.INFORMATION@REGENERON.COM, within 24 hours of awareness. The Regeneron Call Center is responsible for communicating with Regeneron Pharmacovigilance and Risk Management (PVRM). PVRM and its designated vendors have the responsibility to assess whether a reported event constitutes an AE under applicable regulations and determine the need to submit them to regulatory agencies.

The following are examples of AEs and potential AEs that should be reported to Regeneron Call Center within 24 hours:

- Any AEs or potential AEs associated with the approved use of the Regeneron product;
- Any AEs or potential AEs associated with off-label or unapproved use of the Regeneron product;
- Any AEs or potential AEs associated with use in children;

- Use during pregnancy or breastfeeding with or without adverse outcome (such as congenital anomaly/birth defect);
- Lack of effect or failure of expected pharmacological action (the product is not working);
- Medication errors;
- Drug overdose, accidental or intentional, including a healthcare provider prescribing of off label doses;
- Drug misuse or abuse;
- Signs or symptoms of drug withdrawal;
- Product quality or product defect complaints, including broken pills, bad odor, container closure issue, damaged or empty vial, improper labeling on the vial or packing carton, etc.;
- Any other issues or difficulties relating to Regeneron's product, such as difficulty administering an injection;
- Any unexpected outcome event or occurrence during the use of a Regeneron product, even if perceived as positive (e.g., desired hair growth, or blood pressure drug lowering cholesterol).

While complete details may not be obtainable, an employee/agent should attempt to gather as much information as possible, including:

- Name of the Regeneron product with information on how the product was used (indication, dosage, duration of use, etc.);
- Description of the AE or potential AE, using as many of the actual words in the original communication as can be recalled;
- Reporter Information, including contact details (name, mailing address, telephone number, etc.). The reporter may be a patient, another consumer, a healthcare professional, or anyone else with knowledge of the AE;
- Patient information, including age, patient identifier (e.g., patient initials or other description),, gender, medical history, and contact information;
- Date the Regeneron employee or agent became aware of the AE or potential AE;
- When available, the lot number of the Regeneron product used.

The duty to report an AE arises regardless of where, when or how the information was brought to the attention of the Regeneron employee or agent. Examples include information:

- Learned during a presentation in the office or during a meeting with a vendor, healthcare professional, or customer;
- Learned from friends, neighbors, acquaintances, competitors;

- Learned at work or in non-work situations;
- Communicated in person or remotely (e.g., electronically).

There is no penalty for reporting information that is determined not to be an AE. If there's any doubt about whether an event is or is not an AE, it should be reported to the Regeneron Call Center.

Timely reporting is essential for Regeneron to be in compliance with regulatory reporting requirements to such agencies as the FDA. Failure to report an AE by an employee or agent could lead to disciplinary or legal action up to and including termination of employment, contract, services, assignment or any other remedy as may be appropriate under the circumstances.

FURTHER INFORMATION

For any questions or clarification of reporting responsibilities as a Regeneron employee or agent, contact Regeneron PVRM at MEDICAL.SAFETY@REGENERON.COM