Global Patient Safety

SK Life Science serves patients by monitoring the benefit-risk profile of SK Life Science products through the practice of Pharmacovigilance. Pharmacovigilance is defined by the World Health Organization as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem.”

In compliance with the applicable worldwide regulations, SK Life Science is committed to collect, review, and evaluate information regarding adverse events experienced by clinical trial subjects who receive our investigational drugs and by patients taking our approved products. This information helps us better understand, assess, and communicate the safety profile of SK Life Science products and allows us to deliver safer products to patients.

We collect and analyze safety data throughout a product’s life cycle. Product safety is rigorously evaluated during the development process through clinical trials. Not all adverse events associated with the use of a medicinal product are observed in clinical trials. It is therefore important for us to continue to collect adverse events associated with the use of our products even when the product has been approved for use on the market. Once the product receives marketing approval from health authorities, safety data collection continues through multiple channels: additional clinical studies, reports by patients and health care professionals, registries, scientific literature, and external database reviews.

Adverse Event Reporting

All medicines have potential side effects as well as benefits. We routinely monitor the safety of all our products. This includes review of safety data from clinical studies and review of side effects. By monitoring safety information on our products, we can take due and appropriate actions to safeguard patient safety.
Our primary goal is to create safe, effective products for everyone. If you experience an adverse event from one of our drugs, tell your healthcare provider and then report it to us. This helps us track the safety of our medicines accurately.

What is an Adverse Event?

Any adverse event associated with the use of a drug or biological product in humans, whether or not considered product-related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

Why Report Adverse Events

Reporting adverse events is important for numerous reasons. They help keep SK Life Science compliant with regulatory requirements, allow SK Life Science to monitor drug safety and rapidly identify if there are changes in reported events as identified in the package inserts, and allow SK Life Science to collect and monitor information on the safety of its products and ensure prompt identification of changes in the product benefit-risk profile.

How to Report Adverse Events

To report adverse events, please contact the SK Life Science Medical Information Call Center via the following number: 1-866-657-5574. You can also email Medicalinfo@SKLSI.com.

Patients should always ask their healthcare provider for medical advice about adverse events.
If you are participating in a clinical trial, please report the adverse event to your coordinating study site.