



Monitoring Safety

Process for reporting, collecting and analysing safety data

Our risk management procedure ensures that we comply with applicable regulations for informing regulatory authorities, healthcare professionals and patients about the safety profile of our medicines. We follow strict regulatory requirements and guidelines. For example, we report all serious or unexpected safety events to regulatory authorities. We also send in periodic reports examining all adverse events reported over a set time period.

We are required to notify health authorities of all adverse events brought to our attention. Many national health authorities require us to report serious adverse events within a short limited time period. The US Food and Drug Administration, for example, requires us to report any serious, unexpected adverse event within 15 days. This 15-day period begins as soon as any Roche employee receives information about an adverse event.

All Roche employees receive training on drug safety to help them identify and report adverse events. This is particularly important for our sales representatives. The Drug Safety Department is responsible for collecting information about adverse events and reporting them to health authorities.

If an adverse event is found to be related to a drug, amendments of the SmPC and the patient information may need to be made. The Roche Drug Safety Committee (DSC), reviews drug safety information on a regular basis and decides on the best course of action. This may be a letter to healthcare professionals informing them of the change and recommendations for prescribing, a formal change to our SmPC and patient information or a programme to monitor and educate patients using the product.

We undergo regular inspections from competent regulatory authorities to ensure that we have all processes in place to identify potential safety changes and manage them appropriately.