



## Managing Risks

# Risk Assessment and Risk Minimisation

Almost all medicines have some side effects which occur in some patients. To optimise medication safety, the benefits of taking a particular medicine must outweigh the risks of side effects. Each new Roche medicine is subject to a detailed benefit-risk analysis using our safety risk management processes.

This safety risk management process focuses on the assessment and minimisation of risk. It begins in the earliest phases of the medicine's development and continues throughout the entire lifecycle of the product. The process is conducted according to Roche's Standard Operating Procedures.

We prepare risk management plans that we submit to health authorities in compliance with international guidelines. In preparing these plans we ask a wide range of questions to effectively manage the possible risks related to using our medicines.

These include:

- What do we know about the medicine, what are its known and potential risks?
- What don't we know and how do we want to get information to learn more about the safety of the medicine?
- Which patients should be prescribed the medicine?
- Which patients should not be prescribed the medicine?
- What should people avoid when taking the medicine (for example other medicines, certain foods, alcohol etc)?
- How do we plan to protect patients from risks or plan to manage the risks to keep them within acceptable level?
- How do we plan to communicate risks to healthcare professionals and patients?

The answers to these questions help us to determine the way we approach managing the risks. Some risks can be effectively managed by including a precaution or warning statement in the SmPC and the patient information while others require an additional risk minimisation plan that describes additional precautions to be taken to reduce the risk. This could include additional specific information sent through letters to healthcare professionals, or brochures for patients. Sometimes there may be a recommendation for certain regular medical tests to be carried out while the



patient is taking the medicine so that an adverse effect is recognised early, avoided or lessened in its effect.

Our risk management plans are regularly reviewed and updated when new safety information is made available. We collect information on the safety of our drugs on an [ongoing basis](#).