

## **Risk factors**

## Principal risks and uncertainties

All stakeholders of Roche, including investors, employees, healthcare professionals or patients, share a number of risks through their engagement with Roche or its products. They should carefully consider such risks, whether they are intrinsic to science, industry, the company, nature or otherwise related to the engagement.

Listed below are the principal risks and uncertainties Roche considers to be of importance to our business. If these risks occur, they may have a significant effect on our revenues, profit, financial condition and/or reputation. They are not listed in any particular order of priority.

| Business<br>Environment | Pressure from competitor and substitution products (generics/biosimilars)  |
|-------------------------|--|
|                         | Healthcare reforms, pricing, reimbursement and cost-containment measures from governments and payers   |
|                         | Illegal trade of Roche products (e.g. theft, diversion and counterfeiting) which may impact patients' health                                 |
|                         | Loss or expiration of our patents and the limitation or circumvention of our intellectual proprietary protection in certain countries        |
|                         | Volatility of shares or non-voting equity securities ("Genusscheine")  |
|                         | Globalisation of the Group's business  |
|                         | Public pressure on the industry, Roche or its technology   |
| Operations              | Reliance on third-party relationships and outsourcing arrangements (research, development, manufacturing, distribution, sales and marketing) |
|                         | Manufacturing and supply chain difficulties  |
|                         | Risks in alliances and acquisitions  |
|                         | Risks in emerging markets  |
|                         | Financial risks (e.g. foreign exchange risk, interest rate risk, market risk, credit risk or liquidity risk)                                 |
|                         | Inability to attract, engage and retain qualified personnel  |
|                         | Risks related to social responsibility and sustainability  |

| People and<br>Environment                       | Man-made and natural disasters (e.g. explosions, earthquakes or flooding)   |
|---|---|
| Information and<br>Communications<br>Technology | Handling and remediating of hazardous materials and waste  Disruptions of Information and Communications Technology systems or networks |
|   | Breaches of data security   |
|   | Risks related to social media and mobile technologies   |
| Compliance                                      | Exposure to litigation (e.g. product liability, patent infringement or antitrust) and/or government investigations                      |
|   | Changes in laws (e.g. tax, environment, data privacy laws) or regulatory requirements   |
|   | Marketing and sales: Failure to comply with laws, rules and regulations   |
| Products and<br>Services                        | R&D may not succeed in developing clinically differentiated healthcare solutions which meet patients' needs                             |
|   | Delay in product launch   |
|   | Unexpected safety or efficacy concerns which could impact patients' health  |

## **Risk Treatment**

Roche is committed to applying best effort and diligence in managing risks to the benefit of its stakeholders and avoiding any detriment to an extent that is reasonably possible. To effectively manage risk a systematic and structured Group Risk Management Process is operated. This process clearly addresses uncertainty in defined metrics and terms so that all stakeholders understand the variables for analysis. In this process the assessment of above-mentioned risks is followed by Risk Treatment. The objective of Risk Treatment is to implement necessary responses to achieve the target risk level (by reducing or modifying negative impact, or likelihood of an adverse occurrence). These responses are to establish Controls, Actions and Fallback plans for mitigating the risk.