Behaviour in Business

Directive on Integrity in Business
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Introduction

As a Group that operates around the globe, Roche is committed to observe high ethical standards in all of its business dealings. Integrity, Courage and Passion are our Core Values which determine our business behaviour. In our Corporate Principles¹ we have made a commitment to our stakeholders to maintain high ethical, quality and social standards in all business dealings.

Our Purpose Statement *Doing now what patients need next* requires us to hold patients’ interest in the highest regard. Any breach of integrity could result in a loss of our licence to operate, making us unable to provide an uninterrupted supply of safe products to the patients who need them. Instead of paying high fines, we want to invest our company resources in the research and development of innovative products and services.

The key expectations regarding integrity in business are set forth in the *Roche Group Code of Conduct*. This Directive is designed to further specify and explain integrity-related aspects. Pursuing high ethical standards means not only compliance with applicable laws and regulations, but equally striving to avoid even the perception of any non-compliant behaviour. All these efforts are necessary to provide an adequate corporate defence as required by applicable laws and guidelines.

Furthermore, our commitment to high ethical standards requires us to enact and enforce our integrity standards globally, irrespective of local laws which might be less stringent. We are committed to following the *One Roche Approach* principle, meaning that our integrity standards are equally binding for Group Functions, Pharmaceuticals Division and Diagnostics Division. Finally, we also expect our business partners to comply with our integrity standards in any Roche-related business transactions.

Expecting high ethical standards from our employees requires us to provide adequate help and advice, wherever and whenever needed. Employees who have any doubts about correct business behaviour should address related questions either to Line Management, the local Compliance Officer, the Chief Compliance Officer, available local help and advice resources or the *Roche Group Code of Conduct* Help & Advice Line². Similarly, Roche employees, who believe in good faith that the *Roche Group Code of Conduct* has been violated, are expected to speak up by using the available speak up options³.

Roche has set up a comprehensive compliance management process to ensure the implementation of our high integrity standards. Roche is aware that adhering to these standards might lead to a loss of business in some cases. However, we are sure that doing so provides us with a business advantage. We are convinced that integrity is and will remain the basis of our sustainable and successful business and our Roche culture. Let’s always keep in mind: Each and every Roche employee contributes to this goal, so our behaviour matters!

¹ See p. 9 and 10 of the *Roche Group Code of Conduct*.
² See p. 12 of the *Roche Group Code of Conduct*.
³ See p. 13 of the *Roche Group Code of Conduct*. Employee feedback is also essential for the local Compliance Officer, who can then report any material incidents by means of the *Business Ethics Incidents Reporting* (BEIR). Corruption cases are always considered material.
1 Business Integrity

1.1 Objectives & Topics

With the present Directive on Integrity in Business (hereinafter referred to as Integrity Directive), Roche is pursuing the following objectives:

• further specify and clarify the key expectations regarding integrity in business as set forth in the Roche Group Code of Conduct;
• establish a common understanding on business integrity;
• prevent infringements of business integrity by (i) defining acceptable and unacceptable behaviours and (ii) providing guidance on when and where to seek help and advice;
• provide further links to additional directives and regulations containing guidance on a specific issue.

The Integrity Directive addresses the following topics:

• Bribery & Granting of Advantages;
• Gifts & Entertainment;
• Dealing with Business Partners;
• Conflict of Interest.

1.2 Our Definition of Business Integrity

Business Integrity is defined as both the actual and the perception of ethical behaviour in business that is in line with the Roche Group Code of Conduct and our commitment to run our business in a socially responsible way4.

Business integrity means first and foremost that we adhere to all applicable laws and regulations as well as to the integrity standards as set forth by Roche5. We have to be aware that integrity risks and perceptions need to be constantly assessed and defined according to a solid and pro-active business judgement. Hence, applicable integrity standards need to be adapted as a result of the changing business environment. In order to stay up to date, employees have access to an updated E-Learning, which is dedicated to providing employees with the latest information on integrity issues, including examples and case studies.

4 See Roche Corporate Principle “Commitment to Society” on p. 10 of the Roche Group Code of Conduct.
5 These include the Roche Group Code of Conduct, all Directives, Policies, Guidelines, SOPs adopted by Roche, e.g. the Roche Behaviour in Competition Directive, the Roche Insider Directive and the Roche Good Practice Guidelines on Working with Government Officials and any other legally binding Codes, e.g. IFPMA Code, EFPIA Codes, EUCOMED Code, etc. Guiding key documents are referred to in the Roche Group Code of Conduct and this Directive (see website of Group Legal Department).
2.1 Roche’s Stance: Zero Tolerance

Roche rejects all forms of bribery (public, private, active and passive bribery as defined below) and does not tolerate any other form of corrupt behaviour. Not only do such actions undermine the Group’s integrity and reputation, they are also a criminal offence of both the employee and the company involved – this may lead to severe penalties, including fines for the company and prison time for the employee. Furthermore, companies convicted of corruption can be blacklisted, resulting in an exclusion from public tenders.

2.2 Background

Appropriate ethical behaviour in business dealing is essential to creating and maintaining a healthy, fair and just environment of value and benefit to all. Inappropriate behaviour leads to a corrupt society in which economic and political decisions become twisted, slowing the social progress, hampering economic development and falsifying prices for products and services. A corrupt society is an unequal and unfair society.

For these reasons, international efforts to combat corruption have intensified over the last few decades and led to the OECD’s Convention on Combating Bribery of Foreign Government Officials in International Business Transactions. This Convention requires signatory states to implement laws which adequately address and sanction the bribery of foreign government officials. It also explicitly requires the introduction of liability of legal persons, meaning that sanctions are aimed not just at the individuals who commit bribery, but also at companies involved in corrupt activities. This liability for companies is put into practice through the introduction of a corporate offence of failing to prevent bribery cases. In such a setting, the company is charged with an organisational failure to prevent, detect or respond to a bribe.

However, a company may escape liability if it can prove that it had in place adequate measures to prevent, detect and respond to bribery cases, also known as the corporate defence.

Switzerland, as a signatory state of the OECD Convention, introduced legislation based on the OECD standard in the year 2003. It also opted for a system with a corporate offence and defence, which is described in article 102 of the Swiss Criminal Code. Roche, as a Swiss company, is subject to this legislation and is therefore under a legal obligation to provide a comprehensive compliance programme to prevent, detect and respond to corrupt behaviour. Since the law prohibits not only bribes paid to foreign government officials, but also bribes to...
both government officials and private persons, the compliance programme must cover all kinds of bribery. Remembering that good documentation will also be a key element of the corporate defence, these efforts should also encompass “compliance evidencing” in order to prove the comprehensiveness of our compliance activities.

Other countries have also introduced or amended their anti-bribery legislation, meaning that companies can be liable in multiple jurisdictions for bribes paid anywhere in the world.

2.3 Corruption

Corruption is the abuse of entrusted power for obtaining illegal private gain. Any form of corruption will not be tolerated by Roche and employees found to violate this rule will face disciplinary measures, up to termination of the contract and the initiation of criminal proceedings. Next to bribery (see Chapter 2.4 below), this definition also covers corrupt acts such as embezzlement, fraud, theft and the misuse of company assets.

Fraud is the criminal offence of deliberately deceiving another person in order to unjustly obtain an economic advantage (property or services).

Embezzlement is the fraudulent appropriation by a person for his/her own use of property or money entrusted to him/her but owned by someone else.

Theft means the unauthorised taking of the company’s property with the intention of not returning that property to the company.

Misuse of company assets is a Roche employee’s unauthorised use of Roche’s assets for other reasons than to conduct Roche’s business.

2.4 Bribery

Bribery constitutes a special form of corruption involving at least two persons and is characterised by an exchange of improper advantages. The definitions are as follows:

Active bribery is understood as the promise to give or the giving of any payment, including any improper advantage, whether directly or through intermediaries, to someone holding a public office (public bribery) or to someone in business (private bribery) with the intention and expectation to obtain an undue benefit in return for the bribe.
Passive bribery is understood as the solicitation or acceptance of a payment or any other improper advantage, whether directly or through intermediaries, from someone in return for which the person who has accepted the bribe favours the giver in an undue way.

An advantage can be anything of value, including payments, rebates, meals, gifts, entertainment, travel expenses, grants, sponsorships and charitable contributions. Even immaterial support, such as help getting a job, may qualify. Such an advantage is considered improper if it is illegal or if the recipient has no entitlement to it.

On the other side of the corrupt exchange, the benefit obtained by the bribe-giver is considered undue if the bribe-receiver is abusing his position in order to receive said benefit. In other words, the bribe-receiver is not acting in the interest of the employer, but in his/her own. Typically, the bribe-giver aims to secure an undue benefit in the form of an advantage in business, such as the awarding of a contract or the retention of business.

The offer or demand of an improper advantage in return for an undue benefit is already punishable, even if the other side refuses and no exchange takes place. Advantages given to family members, friends, or any other person chosen by the intended target of the bribe are also prohibited. It should further be noted that even small courtesies can, if abused, be interpreted as bribes.

2.5 Granting of Improper Advantages

The granting of improper advantages is the promise to give or giving of an improper advantage without a specific business decision in mind; in contrast to the bribery definition above, there is no “service in return”. The improper advantage can, therefore, be seen as a “goodwill” payment to increase the sympathies towards the giver. Granting an improper advantage to a government official is a type of corruption and can be a punishable offence.

A government official is anyone who holds a public office, is employed by the state or has political influence. Examples include members of parliament, the armed forces, judges, customs officers, civil servants, politicians, public health officials (including physicians) and all persons employed by a government-owned organisation.

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8 For the conditions under which an advantage is not considered improper and may therefore be provided, please refer to Chapter 2.6 on Permissible Advantages.
9 See Chapter 3 on Gifts & Entertainment.
10 Employees dealing with government officials should also refer to p. 41 of the Roche Group Code of Conduct and the Roche Good Practice Guidelines on Working with Government Officials (see website of Group Legal Department).
Roche prohibits the granting of improper advantages of any kind to government officials, whether from company or private funds. This also applies to indirect contributions, such as payments made through consultants, advisers, suppliers or other third parties.

The granting of improper advantages to private business partners is not in line with Roche's high integrity standards and is therefore also banned.

2.6 **Permissible Advantages**

However, there are situations where the giving of advantages is allowed. Employees may offer or provide advantages to business partners if the following conditions are cumulatively fulfilled:

- it is allowed by the applicable national laws;
- it is in conformity with local custom;
- it is appropriate;
- it is properly entered into the company’s books; and
- it is made in the country where the services are rendered.

Any facilitation payments are forbidden unless such payments can be qualified as permissible advantages.

When assessing whether an advantage is appropriate, we must keep in mind the Roche values and the integrity standards as set forth in the *Roche Group Code of Conduct* and this Directive. We must also be aware that there are additional rules concerning expenditures provided to certain groups and persons. For example, interactions with healthcare professionals (HCPs), healthcare institutions, healthcare providers and patient organisations are subject to more stringent rules. In case of doubt, we should ask our local Line Manager or Compliance Officer, use the available local help and advice resources or contact the *Roche Group Code of Conduct Help & Advice Line*.

It is considered best practice that employees consult with the local Compliance Officer and/or get the risk-based approval before granting any permissible advantages. Risk-based approval processes by Line Management and/or the local Compliance Officer should be locally established.

Properly registering advantages to business partners in the company’s books is also critical. For transparency reasons, various regulations (e.g. the *US Sunshine Act* or the *EFPIA HCP/HCO Disclosure Code*) require Roche to record and publish certain expenditures. It should be noted that such publication usually necessitates that the recipient of the advantage provides his/her informed consent, and the provision of an advantage must therefore be dependent on such written consent.

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11 These include the *IFPMA Code, PhRMA Code, EFPIA HCP Code, EFPIA PO Code, AdvaMed Code and EDMA Code of Ethics*. Also see the *Directive on Interactions with Healthcare Professionals and Healthcare Organisations* and the *Directive on Grants, Sponsorships and Donations*. Further refer to the *Roche Marketing and Sales Compliance Questionnaire* (see website of the Group Legal Department).
2.7 **Dos & Don'ts**

- Do strictly adhere to Roche’s integrity standards. Remember that perceptions matter: even if a payment may be legal, it might be perceived as a bribe and cause reputational harm and/or trigger an investigation by authorities.

- Do ask for help and advice in case of doubt about correct business behaviour.

- Do work with local associations to establish a legal and regulatory environment which prohibits and sanctions any form of corruption.

- You may give an advantage if it is:
  - allowed by the applicable national laws;
  - in conformity with local custom;
  - appropriate;
  - properly registered in the company’s books; and
  - made in the country in which the services are rendered.

- Remember that even individually acceptable advantages may become inappropriate if given frequently.

- Do take note of the *Roche Position Paper on Respecting Human Rights*\(^\text{12}\) and make clear Roche’s stance in dialogues with internal and external stakeholders.

- Do immediately report any suspicious behaviour you encounter using the speak up options\(^\text{13}\) available.

- Do not practice, tolerate or in any form support any corrupt business behaviour.

- Do not promise or give improper advantages to business partners.

- Do not demand or accept improper advantages from business partners.

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12 The *Roche Position Paper on Respecting Human Rights* is available at [http://www.roche.com](http://www.roche.com)

13 See p. 4 of this Directive and p. 13 of the *Roche Group Code of Conduct*. 
3.1 **Perceptions Matter**

Even when gifts or entertainment are exchanged out of the purest motives of personal or professional friendship, they can be misunderstood. For example, a gift provided to a Roche employee can appear to be an attempt to influence this person to direct Roche business to a particular business partner. Similarly, entertainment provided to business partners by Roche employees could create the impression of corruption.

To avoid both the reality and the perception of improper relations with existing or potential business partners, both public and private, as well as to maintain our personal and our company’s integrity and independence, Roche has strict rules on the provision or acceptance of gifts and entertainment. Such expenditures, which include costs for travel, accommodation, meals and recreational activities, are subject to the principles set out below. It should be noted that local Roche companies may have even stricter rules, up to and including a complete ban on gifts and/or entertainment.

3.2 **Giving Gifts & Entertainment**

Gifts or entertainment may be given to business partners only where appropriate and where there is no risk of creating the perception of influencing the recipient in his/her decision. Gifts must be of minimal value and entertainment must not go beyond what is reasonable. Expenditures for lavish or inappropriate gifts or entertainment may constitute acts of bribery and are strictly prohibited. Employees should also keep in mind the rules concerning the granting of permissible advantages set out in Chapter 2.6 above.

3.3 **Receiving Gifts & Entertainment**

Roche employees are prohibited from demanding or soliciting gifts or entertainment of any kind, both from existing and potential business partners. This includes not only merchandise but advantages of all kinds.

Unsolicited gifts or entertainment may be accepted provided they do not go beyond common courtesy and are an accepted local business practice. The value and frequency must not raise any question of an obligation on the part of the recipient. The offer of any advantage that does not meet these conditions must be rejected.

Examples of acceptable gifts are promotional items and small courtesies such as flowers or gift baskets, provided they are inexpensive, given infrequently and at appropriate times. However, the acceptance of cash or cash-equivalent items (e.g. vouchers) is prohibited.
Offers of entertainment may only be accepted if they arise out of the normal course of business, cannot be seen as lavish and take place in settings that are appropriate. They should not be extended to family members or friends or any other person unrelated to the business.

If in doubt as to the appropriateness of accepting an unsolicited advantage, we must contact our Line Manager and act according to his/her decision.

3.4 **Dos & Don’ts**

- **You may accept gifts or entertainment if they**
  - are unsolicited;
  - do not go beyond common courtesy;
  - are an accepted local business practice; and
  - do not raise any question of an obligation on your part.
- **Remember that even small gifts or reasonable entertainment may become inappropriate if provided frequently.**
- **Do seek help and advice if you are unsure about giving or receiving gifts or entertainment.**

- **Do not solicit gifts, entertainment or other personal advantages from any existing or potential business partner.**
- **Do not provide or accept any gift or expense which you would not want to have reported in a newspaper.
4.1 **Principles**

All transactions by Roche with business partners are made on the basis of quality, service, competitive price, suitability and sustainability. Roche seeks to establish mutually beneficial, long-term relationships with its business partners based on these principles.

Employees who deal with public and/or private business partners must adhere to the applicable Roche standards\(^\text{14}\) as well as all other relevant laws and regulations. We must conduct adequate due diligence of business partners and observe certain principles concerning their contracts and remuneration.

4.2 **Due Diligence**

Modern anti-bribery laws make companies responsible for all persons and firms acting on their behalf\(^\text{15}\). This means that Roche may be responsible for actions taken by its business partners. An effective due diligence is therefore essential. Due diligence can be understood as the careful selection, instruction and monitoring of business partners using a risk-based approach. Business partners are expected to follow similarly strict rules concerning business integrity as Roche itself.

Due diligence should commence even before contract negotiations begin; a careful selection of a potential business partner should seek to establish its integrity, quality, suitability and credibility\(^\text{16}\). Integrity-related issues can be covered using the help of the *Anti-Corruption Compliance Questionnaire for Roche Business Partners*\(^\text{17}\). Once a business partner has been selected and negotiations begin, an adequate integrity clause must be included in any agreement\(^\text{18}\).

After signing of the contract and adequate instruction concerning integrity and other duties, the due diligence of business partners takes on the form of monitoring to ensure compliance with the rules set out in the agreement. The intensity of monitoring efforts should follow a risk-based approach. Any violation of Roche integrity standards must be reported to the local Compliance Officer or Chief Compliance Officer and swiftly and consequently dealt with. Employees should also remember to adequately evidence their compliance efforts.

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14 For example the *Procurement Code of Conduct* or the *Roche Good Practice Guidelines on Working with Government Officials* (see website of the Group Legal Department).

15 A distinction needs to be made between business partners which act in the name and on the account of Roche (e.g. agents) and those acting in their own name and own account (e.g. distributors). For the actions of the first group, Roche will be held accountable as if Roche employees had acted. Whether the actions of the second group are attributable to Roche must be assessed case by case, based on the circumstances and applicable law. It will depend on how far Roche is able to instruct and monitor the business partner.

16 For contracts with HCPs, also see the *Guiding Principles Regarding the Due Diligence of Healthcare Professionals prior to their engagement*.

17 The Questionnaire can be found on the website of the Group Legal Department.

18 Other important non-integrity documents (e.g. concerning Health & Safety) should of course also be included.
4.3 Contracts & Remuneration

When services are provided to Roche or on behalf of Roche by business partners such as consultants, advisers, agents or specialists, the following principles apply:

- each agreement must be in compliance with both the legislation of the country to which it applies and Roche integrity standards;
- where applicable, the agreements should include adherence to the Roche Supplier Code of Conduct\(^\text{19}\) as one of the obligations of the business partner;
- all agreements must clearly define the respective roles and responsibilities of the business partner and Roche, as well as the basis for the remuneration;
- the remuneration of the business partner should be in line with the fair market value\(^\text{20}\) of the services provided. In all cases, the business owner must be able to explain and justify the amount provided;
- payments must be in compliance with local legislation and Roche integrity standards and shall be made in the country in which the contracted services are rendered. All corresponding payments must be properly entered into the company’s books and available databases;
- applicable fiscal regulations of the respective countries must be taken into account;
- all agreements must be reviewed at regular intervals to ensure that they remain current and appropriate for the activities in the country to which they relate;
- in case of a compliance issue with a business partner, immediate remedial action must be demanded from said business partner. In serious cases, the agreement must be terminated\(^\text{21}\).

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19 This document is available on the website of the Group Legal Department.
20 Concerning the remuneration of HCPs, the document *Guiding Principles of Fair Market Value Determination for Services of Healthcare Professionals* contains additional information.
21 Be aware that any termination of an agreement due to unethical behaviour of the business partner must be reported to the Chief Compliance Officer by the local Compliance Officer under the *Business Ethics Incident Reporting Regulation*. 
4.4 Dos & Don’ts

- Do check your business partners and recheck them regularly.
- Do make sure costs are commensurate with the agreed performance.
- Do demand an invoice.
- Do make sure that contracts with business partners include an adequate integrity clause.
- Do demand an immediate correction or terminate the agreement if you become aware of a compliance issue with a business partner.

- Do not make any payments or remunerations to business partners that violate local legislation.
- Do not over-invoice.
- Do not open or commission a bank account for your business partner.
- Do not make any informal payments.
Conflict of Interest

5.1 Principles

Employees of Roche should avoid situations where their personal interest could conflict with, or even appear to conflict with, the interests of Roche. A conflict of interest exists when an employee’s personal interests are inconsistent with those of Roche and create conflicting loyalties\(^{22}\). Such conflicting loyalties could cause an employee to give preference to personal interests in situations where responsibilities to Roche should come first.

Typical examples where conflicts of interest may arise are when an employee can influence Roche decisions on:

- job applications by friends or relatives;
- dealings with business partners employing or (part-)owned by the employee, friends or relatives;
- any other issue about which the employee has a strong personal or commercial interest, which may bias him/her unduly.

However, a conflict of interest also exists where outside activities take up too much of an employee’s time or resources and this negatively influences his/her work performance.

If a conflict arises between our private interests and those of Roche, we should immediately inform our Line Manager so that an appropriate solution can be found. If the Line Manager changes, we must inform him/her of any conflicts of interest as well. This is another area where perception matters: if even the hint of a conflict of interest appears, any decision (even if it is the right one for Roche) may be subject to scrutiny. It is therefore prudent to disclose potential conflicts of interest early on.

Conflicts of interest may also arise from board memberships with non-Roche organisations. Employees wanting to be active for an external organisation next to their work at Roche should read and follow the Roche Directive on Employees Holding Board Memberships\(^{23}\) and get approval for their external activity if required.

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\(^{22}\) See also p. 19 of the Roche Group Code of Conduct.

\(^{23}\) The Directive as well as more information on the issue and the Self-Declaration Questionnaire can be found on the website of the Group Legal Department.
5.2 **Dos & Don'ts**

- Do avoid situations where your personal interest conflicts with the interests of Roche.
- Do inform your Line Manager immediately if a conflict of interest arises.
- Keep in mind that a change in Line Management will require you to inform the new Manager about all your (potential) conflicts of interest.
- Do make sure you have your Line Manager’s written approval if he/she allows you to continue working on a project despite a potential conflict of interest (compliance evidence).

- Do not hide a conflict of interest situation. Disclosing such a situation will not lead to disciplinary measures, while a failure to do so may.
- Do not accept a board membership at an external organisation without prior clarification of the issue and, if required, Roche approval.
Implementation

All individual Roche companies are responsible for enforcing this *Integrity Directive*.

All Roche employees concerned must be informed accordingly.

Entry into Force

This amended *Integrity Directive* was reviewed and approved by the Healthcare Compliance Council on September 19, 2013. It was adopted by the Corporate Executive Committee on November 11, 2013 and entered into force the same day.