



## **Roche Directive**

### **Collaborating with Patient Groups and Patients**

## 1. Introduction

In the past the pharma and diagnostics industry (“the industry”) made decisions on behalf of patients in the development and product lifecycles of its medicines and diagnostics. However, the healthcare environment has rapidly changed in the last years and patients are more and more involved in their healthcare decision making and choices. As a consequence of this change patient centricity has become a very important topic for the industry. Today, as a matter of daily practice the industry collaborates with patients in different areas ranging from clinical trial design and endpoints, drug development and market access. This change has created meaningful value for patients, the industry, the healthcare system and society as a whole.

Roche’s objective is to create value for patient groups and patients.

We have further explained our sustainable and value based collaboration with patients in our ***Roche Position Paper on Collaborating with Patient Groups and Patients***<sup>1</sup>.

Any collaboration with patient groups and patients must comply with all applicable laws, regulations, industry codes, the Roche Group Code of Conduct and all Roche policies and directives.

## 2. Definitions and Scope

We understand that patient groups and patients are defined broadly to include patient organisations, patient groups, patient associations, patient advocacy groups, patient communities, expert patients, online patient communities, family members, caregivers and individual patients (hereinafter referred to as “Patients”). The term “diagnostics” includes medical devices and services offered by Roche Diagnostics and Roche Diabetes Care (“Dia/DC”).

This Directive applies to the Roche Group (Pharma, Dia/DC and Group Functions). In addition, any third party (e.g. an agency) working with Patients on behalf of Roche are responsible for applying this Directive.

This Directive does not apply to Patient Access Programs as specified in the Key Group Guiding Compliance Principles and Definitions for the Set-up, Approval, Verification and Reporting of Patient Access Programs<sup>2</sup>.

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<sup>1</sup> Refer to [https://www.roche.com/sustainability/approach/positions\\_policies\\_downloads.htm](https://www.roche.com/sustainability/approach/positions_policies_downloads.htm)

<sup>2</sup> Refer to the Key Group Guiding Compliance Principles and Definitions for the Set-up, Approval, Verification and Reporting of Patient Access Programs.

### **3. Purpose of Collaborating with Patients**

We recognise the unique experience, expertise and perspectives of Patients. We believe that incorporating the Patient perspective can help us to develop better medicines and diagnostics, for example by including the Patient input in our clinical trial design to ensure meaningful clinical trial endpoints. In this context we also recognise the importance of enabling access to information on clinical trials and clinical trial summaries. Patients are critical in helping Roche to gain a greater understanding of what it is like to live with a disease, the challenges facing Patients and the role that medicines and diagnostics play in the management of a disease. In addition, discussing healthcare related topics like access and value of our innovative medicines as well as diagnostics and new approaches in health systems like personalised healthcare (PHC), is an important common ground for collaborating with Patients.

The purpose of our partnerships with Patients is to advance science and help Patients access medicines and diagnostics that meet their needs. This is also reflected in our purpose statement “*Doing now what patients need next*”.

### **4. Roche’s Commitment**

We are committed to meet patients’ needs for high-quality medicines and diagnostics. As an essential part of this commitment, we collaborate closely with patient groups and patients and we enter in a dialogue with them on research and scientific developments. This means that Patients are involved throughout the entire lifecycle of our medicines and diagnostics. We are further committed to collaborate with Patients to develop sustainable partnerships to ultimately have a positive impact on society.

All partnerships with patient groups and patients must reflect the principles and standards of integrity, independence, respect, equity, transparency and mutual benefit.

### **5. Principles and Standards for our Collaboration with Patients**

#### **5.1 Integrity**

- a. Our collaboration with Patients should always maintain high standards of integrity. It is the responsibility of every Roche employee to act with integrity when collaborating with Patients. It is both the reality and perception of our behaviour in collaborating with Patients that matters.
- b. Our collaboration with Patients must be legitimate and must not seek to gain competitor and/or other confidential information from Patients. When we engage Patients for certain services (e.g. advisory boards) it must never be to induce or encourage use of Roche medicines or diagnostics.

## **5.2 *Independence***

- a. Maintenance of independence is paramount to our collaboration with Patients. The Patients' independence should not be compromised or perceived as being compromised because of collaborating with Roche.
- b. Patients must not be asked to endorse and/or to promote a specific Roche medicine or service.

## **5.3 *Respect and Equity***

- a. Mutual respect and equity are important aspects in our partnerships with Patients. Roche and Patients must understand and respect each other's values, objectives, priorities and ways of working.
- b. We must respect the relationship between Patients and their healthcare professionals and other relevant stakeholders.
- c. The personal data/information (data privacy) of Patients must always be respected and handled in accordance with applicable data privacy laws<sup>3</sup>. Appropriate handling of data privacy will result in trust of all stakeholders – this is key to Roche's PHC strategy.

## **5.4 *Transparency***

- a. Roche is open about its partnerships with Patients and expects the Patients to be similarly transparent.
- b. Roche annually discloses financial support, significant non-financial support and contracted services with Patient Organisations<sup>4</sup>.

## **5.5 *Mutual benefit***

The collaboration between Roche and Patients must be mutually beneficial to both parties. The value of the collaboration between Roche and Patients should always be clear.

## **6. *Support to Patients***

All support to Patients should be based on and reflect a sustainable partnership. A written agreement between the Patient and Roche must be in place whenever Roche is to provide financial support, and/or significant non-financial indirect support, and/or when Roche will enter into a partnership with the Patient but no support is provided.

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<sup>3</sup> Refer to the Roche Directive on the Protection of Personal Data

<sup>4</sup> Refer to <https://www.roche.com/sustainability/patientorganisations/patient-groups-list.htm>

Any financial support provided to Patients must adhere to the provisions of the Directive on the Provision of Support (Grants/Donations and Sponsorships) to Healthcare Organizations and other Healthcare-Related Entities for the Pharmaceuticals Division and the DS62 Interactions HCPs and HCOs, Annex 1: Grants and Sponsorships to Healthcare-Related Entities (Dia/DC). Financial contributions in the form of grants, donations and sponsorships to patient organisations must be reported in the Roche Group sustainability reporting tool (GAIA)<sup>5</sup>.

## **7. Services provided by Patients**

In our collaboration with Patients Roche may require services from Patients such as consultancy, speaker services and participation at advisory board meetings.

In such cases, Roche should have a written agreement with Patients which fulfils the following criteria:

- a. clear identification and documentation of the legitimate business need for the services in advance of requesting the services and entering into the arrangements;
- b. direct relation between the criteria for selecting services, the identified need and the selected expert;
- c. no inducement to recommend a Roche particular medicinal product or service;
- d. data privacy and transparency; and
- e. reasonable compensation for the services (fair market value), travel and/or a disturbance fee if allowed by local law, regulation and industry code.

The divisions, with the support of the Group Healthcare Compliance Council (“HCC”), will provide further guidance for the determination of a fair market value (FMV) for Patients to be applied locally.

When Roche partners with an individual patient from a particular Patient Organization/ Group the agreement should be signed by the Patient Organization/Group.

Fees paid for contracted services from patient organisations must be reported in the Roche Group sustainability reporting tool (GAIA)<sup>5</sup>.

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<sup>5</sup> Refer to GAIA and the Sustainability Reporting Guidance Economic Performance

## **8. Sharing of Information with Patients**

Any shared information about Roche medicines and diagnostics must be neutral in tone, clear, accurate, balanced and fair. It must allow the Patients to form their own interpretation and opinion. It must not raise unfounded hopes of successful treatment outcomes or be misleading with respect to safety of the product.

Except where it is allowed by local law any form of promotion of Roche medicines to Patients is prohibited. In addition, subject to local laws which allow such practices (e.g. in the US), statements must not be made for the purpose of encouraging patients to ask their healthcare professional to prescribe a specific prescription-only medicine or seek specific services.

Each division, with the support of the HCC, will provide further guidance by elaborating a standard for sharing of information about Roche medicines and diagnostics with Patients.

## **9. Implementation**

- a. Roche line management, with the support of legal and compliance functions, is accountable for the implementation and enforcement of this Directive.
- b. In the case of a global team collaborating with Patients, the responsible local function in the country affiliate where the Patient is based must first approve in writing the proposed partnership before the global team may proceed. For example, a Patient that is domiciled in Italy must have the Roche Italian affiliate's consent in accordance with its applicable internal processes, before the relevant global team can partner with the Patient.
- c. Roche will regularly assess the terms and conditions that determine appropriate behaviour in collaborations with Patients and if necessary, amend this Directive accordingly.
- d. Legal Compliance may elaborate and release further guidance and clarifying Q&As on the interpretation of the letter and the spirit of this Directive. This includes benchmarking against best practice and changes in the legal or regulatory framework.

## **10. Entry into Force**

This Directive was elaborated by Legal Compliance and adopted by the HCC. It was approved by the Corporate Executive Committee on December 12, 2018 and entered into force on January 1, 2019. It replaces and supersedes the Roche Working with patient groups: Good practice guidelines [Version 3.1 from July 25, 2013].